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VIA WWW.REGULATIONS.GOV
AND U.S. MAIL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4187-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: ***42 C.F.R. Part 403***
Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency
CMS-4187-P, RIN No. 0938-AT87

Dear Sir or Madam:

The Advertising Coalition hereby comments on the proposed requirement that direct-to-consumer ("DTC") television advertisements of prescription drugs and biological products payable under Medicare or Medicaid must include the product's "Wholesale Acquisition Cost" in the ad. The Centers for Medicare and Medicaid ("CMS") proposed the regulation to minimize expenditures borne by Medicare and Medicaid for prescription drugs and biological products.[1]

Although concern over the prices of prescription drugs paid by Medicare and Medicaid may be legitimate, the proposal in the Notice will neither accomplish its stated objective of lowering prices nor satisfy statutory and constitutional requirements. Because the disclosures as proposed would actually mislead consumers, the proposal would be more likely to produce adverse health consequences. As explained below, the proposed regulation is a form of compelled speech prohibited by the First Amendment, and exceeds HHS's statutory authority. The proposal for mandatory price disclosures in television advertising fails under any level of

[1] *Regulation to Require Drug Pricing Transparency*, CMS-4187-P, RIN No. 0938-AT87, 83 Fed. Reg. 52789 (2018) (the "Notice"). The Notice and its proposed regulation equally encompass prescription drugs and biological products. In the interests of simplicity, these comments will refer to both as "prescription drugs."

scrutiny that the Supreme Court has established for regulations governing commercial speech. Additionally, the proposed disclosures cannot be justified under precedents governing content regulation on the television medium.

The Advertising Coalition ("TAC") includes national trade associations whose members are advertisers, advertising agencies, broadcast companies, cable operators and program networks, social networks, search engines, digital publishers, and newspaper and magazine publishers.[2] It thus represents the single broadest constituency of advertisers, advertising agencies, and media-related and online companies in this country engaged in protecting the free flow of advertising content. Consequently, TAC is vitally interested in any regulation that will affect the rights of advertisers to control their message, in any medium, and in advocating clear and coherent legal standards for advertising, including the constitutional protection it receives. Although the particular disclosure requirement proposed in the Notice involves televised DTC ads for prescription drugs, TAC's concerns involve our nation's commitment to the First Amendment and, particularly, the commercial speech doctrine.

The CMS Proposal

CMS proposes to require for every DTC ad on television for every prescription drug for which payment is available through Medicare or Medicaid an on-screen textual disclosure of the "list price," defined as the "Wholesale Acquisition Cost" ("WAC"), which must be updated monthly.[3] The term "television" is defined in the proposal to include broadcasting, cable, streaming video, and satellite communication. Notice, 83 Fed. Reg. at 52790; *see also id.* at 52799 (text of proposed new 42 C.F.R. Part 403). The proposed rule prescribes specific language for the disclosure, including a qualifier stating that "If you have health insurance that covers drugs, your cost may be different." *Id.* at 52799 (proposed § 403.1202). The rule is to be

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[2] TAC member associations include the American Advertising Federation, 4As – American Association of Advertising Agencies, Association of National Advertisers, Interactive Advertising Bureau, MPA – The Association of Magazine Media, National Association of Broadcasters, NCTA – The Internet & Television Association, National Newspaper Association, and News Media Alliance.

[3] The "Wholesale Acquisition Cost" that must be disclosed is the manufacturer's price for U.S. wholesalers or direct purchasers (not including prompt pay or other discounts, rebates or reductions), for the most recent month for which the information is available, as reported in wholesale price guides or other publications of pricing data. *Id.* at 52799 (proposed § 403.1201(d)). Ads for covered products that have a list price lower than $35 per month for a 30-day supply or typical course of treatment are exempt. *Id.* (proposed § 403.1200(b)).

enforced through the threat of private actions under the Lanham Act for false or misleading advertising. *Id.* at 52794.

The stated purpose of the rule is "to reduce the price to consumers of prescription drugs and biological products." Notice, 83 Fed. Reg. at 52789. The price disclosure is predicated on the assumptions that markets operate more efficiently when consumers have more information, and that they "price shop when looking to purchase a new car, a new house, or even a coffee maker." *Id.* At the same time, the Notice acknowledges that the market for prescription drugs is different, and that "[t]hird-party payment, a dominant feature of health care markets, is not a prominent feature of other markets and causes distortions," such as disrupting the incentives that prices provide. The Notice notes that the system relies substantially on third-party payors, such as Pharmacy Benefit Managers ("PBMs"), which can negotiate a price lower than the manufacturer's list price, depending on the specific features of a given insurance plan. Under this system, according to the Notice, "[a] PBM could have ten different clients with ten different benefit designs and it would be possible that an employee from each client could get the exact same product and all ten could pay a different price." *Id.* at 52790. Notwithstanding these unique market-defining characteristics, the Notice concludes that requiring disclosure of list prices will have a restraining effect on prices because some consumers are in high-deductible plans or otherwise pay a portion of a drug's list price.

Discussion

Any proposed regulation that compels commercial speakers to make disclosures necessarily raises constitutional questions and efficacy issues, as well as the question of whether CMS even has statutory authority to adopt the proposed regulations. The proposal also raises the question whether the First Amendment permits special regulation of the "television" medium (as defined in the Notice), and whether traditional justifications for differential regulation remain valid. These comments address each of these questions, as set forth below.

1. ***The Proposed Prescription Drug Price-Disclosure Regulation Would Violate the First Amendment.***

The First Amendment secures "both the right to speak [ ] and ... refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). As the Supreme Court observed, some of its "leading First Amendment precedents have established ... that freedom of speech prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.*, 547 U.S. 47, 61 (2006). This is as true for "corporations as for individuals," *Pacific Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 16 (1986) (pl. op.), and it includes marketers of prescription drugs as much as any other advertiser or company. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 563-66 (2011). The Court has stressed that "speech regulation cannot

unduly impinge on the speaker's ability to propose a commercial transaction and the adult listener's opportunity to obtain information." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 565 (2001). It also recently reaffirmed that "[i]n regulating the communication of prices rather than prices themselves, [the State] regulates speech" and must keep within First Amendment limits. *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1151 (2017).

Just last Term, the Supreme Court reaffirmed how it "has stressed the danger of content-based regulations in the fields of medicine and public health, where information can save lives." *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2374 (2018) (quoting *Sorrell,* at 566) (internal quotation marks omitted). This concern extends to compelled disclosures. *Id.* Although the Notice cites *National Institute of Family & Life Advocates*, it fails to acknowledge that the Court struck down the disclosures at issue in that case, and it contains only the most cursory analysis of the relevant constitutional issues. It also fails to recognize that in *National Institute of Family & Life Advocates*, the Court held that where a disclosure is not "purely factual" and "uncontroversial," the regulation does not just flunk constitutional review under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985), but that *Zauderer* does not apply at all. *See Nat'l Inst. of Family & Life Advocates*, 138 S. Ct. at 2372. As shown below, the proposed disclosures are neither purely factual nor uncontroversial.

The Notice falls far short of justifying the proposed rule as being consistent with applicable First Amendment precedents. This is true regardless of the level of scrutiny that may apply to the proposed disclosure requirements.[4] The proposal falls short of the standards articulated in either *Zauderer* or in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980).

A. The Proposed Rule Fails Scrutiny Under *Zauderer*

The Notice states that the proposed drug price-disclosure mandate is consistent with the First Amendment under the test set forth in *Zauderer*. Notice, 83 Fed. Reg. at 52793. In that case, the Supreme Court held that the government may require certain disclosures in a situation where an advertisement would otherwise be deceptive or misleading. Accordingly, the Notice's assumption that *Zauderer* is the correct test, and that the proposal satisfies it, is mistaken both in

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[4] Because the proposed disclosure requirement is a content-based regulation of commercial speech that targets a particular medium, it is likely that a reviewing court would apply strict scrutiny to assess its validity, or at least heightened scrutiny. *See, e.g., Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2227-28 (2015); *Sorrell*, 564 U.S. at 565 (any attempt to "impose a specific, content-based burden on protected expression," including, specifically, that involved in marketing prescription drugs, is subject to heightened judicial scrutiny).

its premise, and its conclusion. It is far from clear that *Zauderer* sets the right standard for evaluating the proposal's constitutionality, and even if it were, the required disclosures would not satisfy the required review.

First, the Notice advances no interest in preventing misleading advertising for prescription drugs, nor does it suggest that the absence of pricing information makes such ads even potentially misleading,[5] yet the Supreme Court has never applied *Zauderer* outside the context of misleading or deceptive commercial speech. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249 (2010) (*Zauderer* was "directed at *misleading* commercial speech"). In *United States v. United Foods, Inc.*, 533 U.S. 405 (2001), the Court declined to apply *Zauderer* where there was "no suggestion ... the mandatory assessments imposed to require one group of private persons to pay for speech by others are somehow necessary to make [ads] nonmisleading." *Id.* at 416. While some lower courts have held that government interests other than preventing deception may suffice, *see, e.g.*, *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 524 n.16 (D.C. Cir. 2015) (citing cases), the Supreme Court's most recent decision in *National Institute of Family & Life*, is causing courts that currently are applying *Zauderer* more expansively to revisit the issue.[6] For purposes of the present proceeding, CMS should keep in mind that the Supreme Court has never sanctioned the view that the *Zauderer* standard applies beyond preventing potentially misleading or deceptive commercial speech.

Second, the CMS proposal is a poor fit with *Zauderer*'s requirements, even if they may fairly be characterized as establishing a lower level of scrutiny. Assuming that the threshold requirement is met of seeking to prevent misleading commercial speech, a compelled commercial disclosure may be upheld under *Zauderer* only if: (1) the required disclosures convey "purely factual" information; (2) the disclosures are "uncontroversial;" and (3) the disclosures

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[5] CMS states only that "[t]he purpose of this proposed rule is to reduce the price to consumers of prescription drugs." Notice, 83 Fed. Reg. at 52789. *Compare, e.g.*, *Sorrell*, 564 U.S. at 579 ("The State nowhere contends that detailing is false or misleading within the meaning of this Court's First Amendment precedents."). In fact, the Notice proposes disclosures that *themselves* may mislead consumers. *See infra* 6-7, 10, 14-15.

[6] *See, e.g.*, *CTIA-The Wireless Ass'n v. City of Berkeley*, 873 F.3d 774 (9th Cir. 2017), *cert granted, vacated, and remanded*, 138 S. Ct. 2708 (2018), *order for supplemental briefing*, No. 16-15141 (9th Cir. July 5, 2018); *Am. Bev. Ass'n v. City & Cty. of San Fran.*, 880 F.3d 1019 (9th Cir. 2018) (granting rehearing), *order for supplemental briefing*, Nos. 16-16072, 16-16073 (9th Cir. June 27, 2018). *Cf. Cigar Ass'n of Am. v. FDA*, 317 F. Supp. 3d 555, 557-58, 562 (D.D.C. 2018) (granting stay pending appeal of earlier denial of preliminary injunction against new warning labels in wake of *National Institute of Family & Life*).

are not unduly burdensome. 471 U.S. at 651. *See also Milavetz*, 559 U.S. at 249-51. As set forth in the Notice, however, the CMS proposal does not satisfy these requirements.

The proposed disclosures as set forth in the Notice are not "purely factual." CMS admits that due to the role of third-party payors and other intermediaries, the WAC (or "list price") may not be a meaningful price metric for many, if not most, consumers, who never pay that amount. Notice, 83 Fed. Reg. at 52790.[7] The proposed rule itself recognizes this in adding a disclaimer for the list price disclosure that "If you have health insurance that covers drugs, your cost may be different." *Id.* at 52799 (proposed § 403.1202). Disclosures that provide partial information in this way, or have potential to leave misimpressions because of what is left unsaid, are unconstitutional under *Zauderer* because, even if literally true, they are "misleading and, in that sense, untrue." *Am. Beverage Ass'n v. City & Cty. of San Fran.*, 871 F.3d 884, 895-96 (9th Cir. 2017).

Writing in THE NEW ENGLAND JOURNAL OF MEDICINE, Professors Stacie Dusetzina and Michelle Mello examined the CMS proposal, and concluded that "the WAC is not a factually accurate representation of what a drug costs for most patients, and the disclosure omits key information." Citing some of the same factors the Notice identified, the article explained "it is impracticable to state what patients will actually pay because of variation in insurance design and coverage and the fact that rebates and discounts may not be determined when advertisements are made." Stacie B. Dusetzina and Michelle M. Mello, *Disclosing Prescription-Drug Prices in Advertisements – Legal and Public Health Issues*, THE NEW ENGLAND JOURNAL OF MEDICINE, November 14, 2018 ("Dusetzina & Mello") (attached as Ex. 1).

Dusetzina & Mello provided concrete examples showing that disclosing "list prices" as proposed in the Notice would not be "purely factual:"

> [A] widely advertised drug for type 2 diabetes, has a WAC (or list price) of $730 per month. Patients who could benefit from diabetes treatment may assume that they cannot afford it, when in fact insured patients' costs … may be much lower, and cheaper options are available (metformin, for instance, costs $4 per month for patients who pay cash).

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[7] The Notice even acknowledges that with different payors and variations in benefit designs, it is entirely possible different consumers may well get the exact same product and pay different prices. Notice, 83 Fed. Reg. at 52790.

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> 1 month of treatment with [a name brand] anticoagulant ... has a list price of $419, but out-of-pocket prices range from $10 for commercially insured patients using the manufacturer's copayment card to $147 for Medicare beneficiaries in the Part D coverage gap.

Id. As the authors note, the required disclaimer that "your cost may be different" depending on insurance coverage "doesn't communicate that costs to patients are probably much lower than the WAC." *Id.* They conclude: "This fact sets [the CMS proposal] apart from other fee disclosures that have survived legal challenges, such as the basis for calculating attorney fees and the amount of interest charged on loans." *Id.*

The proposed disclosures are not "noncontroversial," as *Zauderer* requires. The stated purpose of the requirement is to "expose" that some drugs are "overly costly." Notice, 83 Fed. Reg. at 15792. In this sense, the list price—and the intimation that it is too high, is hardly uncontroversial. Nor is it uncontroversial to require ads to disclose a "list price" that is very different from what most consumers actually pay because of the unusual nature of this market. Compelled disclosure of what may appear to be an inflated price, or a misleadingly different price from what consumers actually pay, would be the kind of disclosure that is "inflammatory" or suggests something untoward about the product. *Kimberly-Clark Corp. v. District of Columbia*, 286 F. Supp. 3d 128, 140 (D.D.C. 2017) (citing *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216-17 (D.C. Cir. 2012); *Am. Meat Inst. v. USDA*, 760 F.3d 18, 22 (D.C. Cir. 2014)).

Dusetzina & Mello observe there is "[d]isagreement about whether the WAC accurately represents a drug's price." Dusetzina & Mello, *supra*. To the extent drug manufacturers disagree that the WAC is an appropriate and accurate benchmark, that it overstates prices, or that CMS's policy of trying to use it to drive prices down is misguided, it cannot be said to be "noncontroversial." Courts have regularly invalidated disclosure requirements that "promote[] policies or views that are ... expressly contrary to the corporation's views." *Am. Beverage Ass'n*, 871 F.3d at 894. *See also PG&E*, 475 U.S. at 18. This kind of "good faith disagreement" with the import of the disclosure renders it controversial, and thus unconstitutional. *Kimberly-Clark*, 286 F. Supp. 3d at 143 (citing *Am. Meat Inst.*, 760 F.3d at 27).

The list price disclosure requirement is unduly burdensome. CMS acknowledges that prescription drug manufacturers tend not to provide pricing information in their advertising, Notice, 83 Fed. Reg. 52970, so the proposed rule necessarily requires "speech that [the] speaker would not otherwise make." *Riley*, 487 U.S. at 795. This would impose a burden that "necessarily alters the content." *Id.* This further burdens the ad with clutter that distracts from

its main message. Obviously, the disclosure cannot "advance[] a government interest," as CMS admits is required, Notice, 83 Fed. Reg. at 52793, unless it is designed to be noticed by viewers, which means the warning *must* distract consumers from the advertising, by design. The fact that advertisers may have an "ability to convey other information of its choosing in the remainder of the advertisement" does not eliminate this burden.[8] Moreover, disclosure of the list price would have to be updated monthly under the rule as proposed, thus adding significantly to the burden.

The addition of textual statements about price (and that "your cost may differ," along with any other explanation the advertiser feels necessary) must also be considered along with the extant requirement for disclosure of the drug's potential side effects, which the government already requires in the audio of ads. 21 C.F.R. § 202.1(e). The cumulative effect of multiple government-compelled disclosures cannot be ignored. *Cf.* Notice, 83 Fed. Reg. at 52793 (claiming the proposed pricing disclosure will not "drown out the speakers own message") (quoting *Nat'l Inst. of Family & Life*). The Notice acknowledged the fact that compelled disclosures can be excessively burdensome, noting that some manufacturers would give up advertising entirely rather than try to comply. Notice, 83 Fed. Reg. at 52798 ("the number of televised DTC ad[s]" may be affected, with "TV drug advertising [] be[ing] reduced").

B. The Proposed Rule Fails Scrutiny Under *Central Hudson*

If the proposed disclosure requirement for DTC prescription drug TV ads cannot satisfy *Zauderer*, it certainly cannot satisfy *Central Hudson*'s more stringent test. *See, e.g., Nat'l Inst. for Family & Life*, 138 S. Ct. at 2376-77. Under *Central Hudson*, regulation of commercial speech is permissible only where: (1) the asserted governmental interest is substantial; (2) the regulation directly advances the asserted interest in a direct and material way; and (3) the regulation is no more extensive than necessary to achieve its purpose. 447 U.S. at 565-66. However, the CMS proposal fails to meet any of these requirements, and CMS thus cannot carry its burden under the First Amendment to justify regulating advertising. *See, e.g., Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 188 (1999).

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[8] Notice, 83 Fed. Reg. at 52793 (citing *Spirit Airlines, Inc. v. Dep't of Transp.*, 687 F.3d 403, 414 (D.C. Cir. 2012)). CMS's reliance on *Spirit Airlines* is misplaced, as the regulation in that case governed *how* prices must be characterized *when* the airline opted to advertise them, and did not compel inclusion of prices in the ads, or the addition of any information the airline was not already conveying in the ad.

***First*, it is not clear the government has a substantial interest in regulating advertising about pharmaceuticals when its goal is to regulate costs under Medicare and Medicaid.**[9] The Supreme Court rejected such a roundabout rationale in *Sorrell v. IMS Health*, 564 U.S. 552. There, Vermont sought to "diminish the likelihood that marketing will lead to prescription decisions not in the best interests of patients or the State," and to serve "public policy goals [of] lowering [] costs," by burdening "[s]peech in aid of pharmaceutical marketing." *Id.* at 557, 576. In response, it adopted a statute that "[o]n its face" was a "content- and speaker-based" regulation of the speech of brand-name companies, that "disfavor[ed] marketing, that is, speech with a particular content." *Id.* at 564. The Court held that, regardless of whether it applied heightened scrutiny or intermediate scrutiny usually applied to commercial speech, the statute was unconstitutional, in significant part, because it burdened pharmaceutical marketers as "disfavored speakers." *Id.* at 571-74. It explained that seeking to change the purchasing behavior of consumers or the pricing behavior of businesses by placing burdens on commercial speech, so as to "tilt the public debate" to achieve the government's ends is not a legitimate government interest. *Id.* at 578.

***Second*, compelling price disclosures in televised DTC prescription-drug ads cannot directly and materially advance CMS's stated interest of Reducing Medicare and Medicaid Expenditures on Prescription Drugs.** The Notice offers only speculation for any conclusion that compelled list-price disclosures in televised DTC prescription drug ads will advance these objectives. *See* Dusetzina & Mello, *supra* ("CMS offered no evidence of the likely effects of the proposed drug advertising price disclosure rule, noting only that it 'may' improve consumer decision making").

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[9] CMS believes that "unreasonable" Medicare and Medicaid expenditures occur due to the lack of price information in DTC ads for prescription drugs, but the case it builds is highly speculative and weakly supported. The Notice identifies "[m]any incentives in the current system [that] reward higher list prices," 83 Fed. Reg. at 52791, but it does not identify lack of prices in advertising as contributing to that problem. CMS states that "over 40% of beneficiaries … pay the full list price [for prescription drugs] until they meet their deductible." *Id.* at 52790. Another subset "have to pay the full list price" where a plan does not cover a particular drug requested by the patient. This means that upwards of half of all consumers *already* are aware or learn of the "wholesale acquisition cost" that CMS seeks to require advertisers to include in televised DTC prescription drug ads. All of this indicates that CMS's belief that lack of information in the market about prescription drug "list prices" is responsible for unduly burdening Medicare and Medicaid is "conjectural," and cannot serve as a proper government interest for regulating prescription drug advertising.

At a basic level, the supposition that mandatory "list price" disclosures will have the intended effects is counter-intuitive. As CMS concedes, most consumers do not pay list price for prescription drugs, and a significant proportion pay only a percentage of list price. *Id.* at 52790. For these consumers, knowing the "anchor price" of their prescription(s), *id.* at 52793, is unlikely to affect purchasing behavior, because even armed with that knowledge, out-of-pocket cost is the same, leaving no reason to make any change.[10]

The best CMS can say is that the rule will "*potentially* improv[e] awareness" of prescription drug costs, Notice, 83 Fed. Reg. at 52798, and that "[t]riggering conversation[] about a particular drug ... *may* lead to conversations about ... price ..., which in turn *may* cause [] the consumer and the prescriber *to consider* ... alternatives." Notice, 83 Fed. Reg. at 52793 (emphases added). Or that "providing consumers [list] price information *may result* in [] selection of lesser cost alternatives." *Id.* (emphasis added). *See also id.* at 52798 ("this rule *may provide* a moderating price force to counteract ... increases"); *id.* ("This rule *may improve* price transparency ...."); *id.* at 52796 (proposed rule "*may* improve awareness and allow the public to respond, *potentially* increasing the efficiency of prescription drug utilization") (all emphases added). This is the epitome of "speculation or conjecture" that cannot meet the government's burden to show "direct and material" advancement of its interests. *Greater New Orleans*, 527 U.S. at 188.[11]

The analysis in the Notice is also internally inconsistent. CMS seeks to compel disclosure of list prices in televised DTC prescription drug ads because "[p]rice transparency is a necessary element of an efficient market." Notice, 83 Fed. Reg. at 52790. At the same time, it explains that the market for prescription drugs is "distorted" by third-party payors, including in their effects on "incentives that prices provide." *Id.* *See also id.* (citing "market-distorting effects of third-party payors"). The compelled disclosure of prescription drug list prices will not

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[10] Factoring in consumers who already pay list price cannot advance CMS's cause—they already have the information that the proposed regulation would force advertisers to disclose, or gain it upon purchase (because that is what they're charged), so whatever their current purchasing behavior may be, providing them list prices again via compelled commercial disclosures is unlikely to change their behavior.

[11] CMS admits that it "lack[s] data to quantify the[] effects" it hopes to achieve. Notice, 83 Fed. Reg. at 52798.

likely change these incentives, or the impact they have on prices paid by consumers and, ultimately, Medicare and Medicaid.[12]

CMS block-quotes a Congressional Research Service report to assert that "when better price information is available prices for goods sold to consumers fall."[13] But the report goes on to state that "markets in intermediate goods are more complicated," such as when there are third-party payors, and that "settled conclusions have not been reached" on "how price transparency affects [those] markets." Austin & Gravelle, at 47. The CRS Report also states that "special characteristics of the health market make it difficult to directly apply empirical evidence gathered from other markets." *Id.* (Summary).

Additionally, CMS cites a number of reasons for prescription drug price increases, and thus greater burdens on Medicare and Medicaid, that have nothing to do with the product being "overly costly." Notice, 83 Fed. Reg. at 52792, 52793. These include population growth, increases in number of prescriptions per person, and inflation. *Id.* at 52791. Nothing in the disclosure of list prices in televised DTC prescription drug ads will affect these factors. The proposed rule cannot "directly and materially" ameliorate these aspects of the problem that CMS has identified. *Greater New Orleans*, *supra*.

Another way in which CMS hopes that compelling disclosure of list prices in televised DTC prescription drug ads is to force manufacturers to include a price that seems "overly costly," with hopes that rather than doing so, they will reduce list prices. Notice, 83 Fed. Reg. at 52793. Putting aside that forcing an advertiser to tar itself with government-compelled disclosures in order to force it to change behavior is never a legitimate interest for regulating commercial speech, *see supra* 9, CMS admits that even that may not work. As the Notice reflects, this may instead reduce the amount of DTC prescription drug advertising on television, Notice, 83 Fed. Reg. at 52798, conceivably in favor of advertising online or on social media, on radio, or in

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[12] CMS also ignores the effect that may arise from the extent to which prescription drugs are patentable, which gives manufacturers (lawful) monopoly power, and insulates it from forces in a competitive market that may affect its prices. *See, e.g.*, *FTC v. Boerhinger Ingelheim Pharms., Inc.*, 892 F.3d 1264, 1266 (D.C. Cir. 2018); *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014) ("Congress has enacted patent laws rewarding inventors with a limited monopoly.").

[13] Notice, 83 Fed. Reg. at 52790 (quoting D. Andrew Austin & Jane G. Gravelle, "Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Health Sector," CRS Report 46 (July 24, 2007).

newspapers. *See id.* at 52795. In short, the Notice provides nothing to support a conclusion that the proposed rule would directly and materially advance the stated objectives.

***Third*, compelling price disclosures in televised DTC prescription-drug ads bypasses alternatives that are less restrictive than compelled speech.** Under the *Central Hudson* test, if CMS can achieve its objectives without "restrict[ing] speech, or [by] restrict[ing] less speech, [it] *must* do so." *W. States Med. Ctr.*, 535 U.S. at 371 (emphasis added). In this regard, existence of "numerous and obvious less-burdensome alternatives" is certainly relevant "in determining whether the 'fit' between the ends and means is reasonable." *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 n.13 (1993).

To its credit, CMS asks if there are "approaches [that] could support price transparency and informed decision making [for beneficiaries] ... in lieu of the measures proposed in this notice," and identifies several possibilities. Notice, 83 Fed. Reg. at 52795. These include (1) an "enhanced CMS drug pricing dashboard" that provides consumers with more information, (2) a "new payment code for drug pricing counseling," and (3) "intelligent plan selection or use of intelligent assignment." *Id.* CMS also indicates that it has "several information products that provide greater transparency," and asks how they can be improved toward meeting the goals of providing beneficiaries with information about the costs of prescriptions "so they can make informed decisions that minimize not only their out-of-pocket costs but also expenditures borne by Medicare and Medicaid." *Id.* CMS further asks whether its dashboards could be used by a non-government entity to offer price transparency resources. *Id.*

Unmentioned by CMS (but equally viable) is that it could engage in *its own* advertising to educate consumers about the costs of prescription drugs. Clearly CMS knows what those costs are insofar as (a) it pays them through Medicare and Medicaid, and (b) there are reporting requirements for certain information about prescription drugs. *See* Notice, 83 Fed. Reg. at 52791. CMS, or any other arm of the federal government, remains free to communicate via property it owns or ads it takes out itself in media of its choosing, drug-price information, the merit of beneficiaries selecting less costly alternatives, and/or its view of which drugs are "overly costly." *See, e.g.*, *Riley*, 487 U.S. at 800 (noting state could "itself publish ... disclosure[s] it require[d of] professional fundraisers"). Nothing prevents the government from purchasing ad time, even right alongside DTC prescription drug commercials, to present the very information that it is trying to force advertisers to convey.

Industry also has acted to provide consumer information that serves the intended purpose without the need for a mandate, and does so more effectively. Even before the CMS proposal was announced, PhRMA released guidelines on October 2, 2018, for the disclosure of costs for

advertised medicines.[14] Under the Updated DTC Principles, ads would direct patients to websites where companies disclose list prices, but also more useful and meaningful information. This would include "average, estimated, or typical patient out-of-pocket costs." *See* Dusetzina & Mello, *supra*. All current PhRMA members have committed to being signatories to the Updated DTC Principles,[15] and though they officially take effect April 15, 2019, changes to the members' DTC television ads will begin in the coming months. PhRMA also announced that it would partner with consumer, patient, pharmacist, provider and consumer groups to develop a new patient affordability platform that will launch in early 2019 to provide such resources as an enhanced search tool that will include medicine-specific public cost and affordability information, new information on how to access company-specific patient assistance and other cost-sharing support, and resources to help patients navigate their insurance coverage.[16]

Such alternatives illustrate that regulating prescription drug advertisers' speech is more extensive than necessary. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 490-91 (1995). In this regard, it is telling that CMS anticipates that government-compelled price disclosures could drive some DTC prescription drug advertising off television altogether. Notice, 83 Fed. Reg. at 52798. Such an outcome is completely at odds with its assurance that the regulation does not "effectively rule out a mode of communication." *Id.* at 52793 (quoting *Nat'l Inst. for Family & Life*, 138 S. Ct. at 2378) (internal quotation marks and editing omitted). Even for ads that would still run, the disclosure is unduly burdensome in its effect. The mandated price disclosures will add to the clutter the government already requires in DTC prescription drug ads, will battle for attention with other visual elements in the ad, and will have to be displayed for a substantial portion of the ad's runtime. This clearly fails the commercial speech doctrine's tailoring requirements.

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[14] *See* https://www.phrma.org/press-release/phrma-members-take-new-approach-to-dtc-television-advertising (announcing enhancements to PhRMA's DTC principles, "Guiding Principles on Direct-to-Consumer Advertisements About Prescription Medicines," http://phrma-docs.phrma.org/files/dmfile/PhRMA_Guiding_Principles_2018.pdf ("Updated DTC Principles"))).

[15] Signatory companies will certify on an annual basis that they have policies and procedures in place to foster compliance with the Updated Principles.

[16] *See* https://www.phrma.org/press-release/phrma-members-take-new-approach-to-dtc-television-advertising,

2. *The Proposed Rule Does Not Receive Lesser Scrutiny By Applying Only to Ads on "Television"*

The Notice misstates the law in suggesting the proposed list-price disclosure for DTC advertising can withstand constitutional scrutiny because it applies only to television commercials. The Notice asserts that, under *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367 (1969), "the Supreme Court historically has recognized that the government may take special steps to [] ensure that viewers receive appropriate information." Notice, 83 Fed. Reg. at 52790 (citing *Red Lion*, 395 U.S. at 394); *see also id.* at 52793 (citing same regarding "First Amendment interest" of "broadcast viewers"). Such statements misread *Red Lion*, assume its continuing validity, and inappropriately seek to extend it to non-broadcast media.

Red Lion has no relevance where CMS proposes to regulate "[a]ny advertisement for any prescription drug … on television," which it defines as "including broadcast, cable, streaming, or satellite." Notice, 83 Fed. Reg. at 52799 (proposed § 403.1202); *id.* at 52790, 52794, 52796. The Supreme Court has made abundantly clear that the special characteristics germane to over-the-air broadcasting that may affect constitutional review of broadcast regulations have no application to cable. *Denver Area Educ. Telecomms. Consortium v. FCC*, 518 U.S. 727, 816 (1996). The same goes for satellite. *See, e.g., Satellite Broad. & Commc'ns Ass'n v. FCC*, 146 F. Supp. 2d 803, 823-24 (E.D. Va.), *aff'd*, 275 F.3d 337 (4th Cir. 2001). As to ads that are "streamed" on "television," the Supreme Court also has made clear that "our cases provide no basis for qualifying the level of First Amendment scrutiny that should be applied to this medium." *Reno v. ACLU*, 521 U.S. 844, 870-71 (1997).

Even as to only over-the-air television broadcasting, time and technological advances have drained the validity from the premises the Supreme Court relied upon a half-century ago in deciding *Red Lion*. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 530 (2009) (Thomas, J., concurring) ("*Red Lion* and *Pacifica* were unconvincing when they [] issued, and the passage of time has only increased doubt regarding their continued validity."). *Red Lion* depended on "differences in the characteristics of [] media" to "justify restrictions in the First Amendment standards applied." *Red Lion*, 395 U.S. at 386. But given technological advancements, it is far less plausible to justify the kind of compulsion and intrusion onto the speech of advertisers who support free over-the-air broadcasting that the present rule proposes.

In this vast media landscape, imposing special speech restrictions on the broadcast medium compared to other media is impossible to justify. *See Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 72-73 (1983) (invalidating restriction on unsolicited contraceptive ads because government could not show policy actually served stated interest). Not only can CMS not rely on the historic constitutional treatment of broadcasting to encroach on DTC prescription drug advertising on cable, satellite, and online, its ability to do so for ads on over-the-air

broadcast television is highly questionable as well. Further, CMS's proposal to have list-price disclosures apply only to DTC prescription drug ads on TV highlights how the rule features the kind of "exemptions and inconsistencies" that mean it "will fail to achieve" CMS's asserted interest. *Coors*, 514 U.S. at 489.

3. *The Proposed Rule Would Fail to Serve Public Health Objectives and Would be Counterproductive*

Forced disclosures of "list prices" using the WAC as the benchmark would be misleading and counterproductive. As the Notice acknowledges, such disclosures would not reflect the prices most consumers pay for prescription drugs, would overstate costs in most cases, and would confuse consumers. For reasons already explained, these factors would undermine any possibility of serving the objective of reducing prices. More significantly, however, a disclosure mandate could have the unfortunate effect of harming public health. Dusetzina & Mello explain that "a potential unintended consequence of price disclosure may be to dissuade patients from seeking care because of the perception that they cannot afford treatment." In the examples they provide, the forced disclosures would post prices that are hundreds of dollars per month higher than what patients actually pay in most cases. Dusetzina & Mello, *supra*. Where this occurs, the disclosure requirement could have the effect of dissuading patients from seeking health care.

The same is true if the proposal would reduce the amount of televised advertising for prescription drugs, as CMS anticipates it might. One of the benefits of prescription drug advertising is that it promotes conversations between doctors and patients that otherwise might not occur. In one study, 62 percent of respondents reported that, after seeing or hearing a DTC prescription drug ad, they sought information about either a condition the advertised drug treats, a prescription they were taking, or a prescription that a family member or friend was taking.[17] Thirty-five percent reported that as a result of seeing or hearing an ad for a prescription medicine they talked with a doctor about a medical condition or illness they had not previously discussed with the physician. *Id.* at 19. Such increased communication has a positive effect on public health. DTC prescription drug ads also helped remind approximately 25 percent of those who saw them to either schedule an appointment with a physician, obtain a preventative vaccine or flu shot, or refill a medicine already prescribed to them. *Id.* at 24. The CMS proposal is likely to discourage such communication, and as a consequence, could undermine public health objectives.

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[17] Princeton Survey Research Assocs. Int'l, *2017 Direct to Consumer Advertising Survey Results*, at 21 (available at http://phrma-docs.phrma.org/download.cfm?objectid=325AA700-6BF9-11E7-929B0050569A4B6C).

4. *CMS Lacks Statutory Authority to Impose the Price-Disclosure Regulation.*

CMS acknowledges that any regulation it proposes must have a "valid grant of authority from Congress." Notice, 83 Fed. Reg. at 52790 (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000)). It also admits that "Congress has not explicitly provided … authority to compel the disclosure of list prices" in ads, *id.* at 52791, and relies instead on general language in the Social Security Act providing "broad rule-making authority" to adopt regulations "as may be necessary" to implement it. *Id.* at 52790-91 (citing and quoting Social Security Act §§ 1102 & 1871). The Notice suggests that CMS may compel disclosures "so long as they are reasonably related to the [Act's] purposes," *id.* at 52791, and asserts it has the necessary authority to compel disclosures under its mandate to operate Medicare and Medicaid efficiently. *Id.*

Such a generalized grant of statutory authority does not support the specific rule proposed in the Notice. In the case CMS cites for the proposition that "an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress," the Supreme Court stressed that "[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *Brown & Williamson Tobacco Corp.*, 529 U.S. at 161 (citations omitted) (holding that FDA lacked authority to regulate tobacco products, including tobacco labeling, without express grant of statutory authority). *See also MCI Telecoms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 (1994) ("It is highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion—and even more unlikely that it would achieve that through such a subtle device as permission to 'modify' rate-filing requirements."). Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

Reliance on a general grant of authority is *particularly* suspect when an agency proposes to regulate speech. Blanket statutory language that empowers an agency to "perform any and all acts, [and to] make such rules and regulations … not inconsistent with [an enabling] Act, as … necessary in the execution of its functions," does not authorize regulations that "significantly regulate" speech. *Motion Picture Ass'n of Am. v. FCC*, 309 F.3d 796, 802-04 (D.C. Cir. 2002). This is because "such regulations invariably raise First Amendment issues," and require affirmative grants of power from Congress to confirm that it intended the agency to regulate in such a sensitive area. *Id.* at 805-06. The handful of decisions cited in the Notice in support of CMS's legal authority to adopt the rule do not address this problem. *See* Notice, 83 Fed. Reg. at 52790-91. None of those cases had anything to do with regulating speech or the First Amendment, and half of them do not involve HHS or CMS, and mention its authority only in passing. Accordingly, they do not support a statutory basis for the proposed disclosure requirement.

The fact that CMS's proposal raises serious First Amendment concerns is also reason to conclude the agency cannot interpret its enabling statute as authorizing the regulations under the doctrine of constitutional avoidance. *Jones v. United States*, 529 U.S. 848, 857 (2000) ("[W]here a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other … such questions are avoided, [the] duty is to adopt the latter.") (quoting *United States ex rel. Attorney General v. Delaware & Hudson Co.*, 213 U.S. 366, 408 (1909)).[18] And constitutional considerations aside, insofar as CMS cites *other* statutory provisions in which Congress authorized price disclosures, Notice, 83 Fed. Reg. at 52791 (citing Social Security Act §§ 1927(b)(3)(A) and 1860(k)(1)), that, also, should be read as confirming Congress did not authorize *these* price disclosures. *See Am. Library Ass'n v. FCC*, 406 F.3d 689, 700-05 (D.C. Cir. 2005); *MPAA v. FCC*, 309 F.3d at 802-06. Under the maxim *expressio unius est exclusio alterius*, when a statute provides authority for an action, and is silent as to a similar, related action, the law must be interpreted as authorizing only the former and not the latter.[19]

Conclusion

When the government seeks to further its interests in the commercial arena, "regulating speech must be a last – not first – resort." *W. States Med. Ctr.*, 535 U.S. at 373. However, the present rulemaking proposes to burden prescription drug advertising with compelled price disclosures as its first and only option, even though CMS admits the proposed disclosures will not provide useful pricing information for most consumers. Such a proposal cannot satisfy First Amendment review regardless of the level of scrutiny applied. And the attempt to impose such a mandate on a technology-specific basis is fundamentally flawed. For all of the reasons outlined above, the First Amendment and the commercial speech doctrine preclude CMS's proposed rule.

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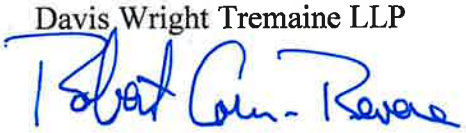
[18] *See also United States v. CIO*, 335 U.S. 106, 120-22 (1948) (construing federal expenditure provision as not prohibiting labor union endorsement of candidate in its weekly periodical, noting that "the gravest doubt would arise … as to [the law's] constitutionality" under the First Amendment, if it were construed otherwise); *United States v. Jin Fuey Moy*, 241 U.S. 394, 401 (1916) (statute must be construed "to avoid not only the conclusion that it is unconstitutional but also grave doubts upon that score"); *Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988).

[19] *E.g.*, *Nextwave Personal Commc'ns, Inc. v. FCC*, 254 F.3d 130, 152-53 (D.C. Cir. 2001), *aff'd*, 537 U.S. 293 (2003). *See also Tenn. Valley Auth. v. Hill*, 437 U.S. 153 (1978); *Original Honey Baked Ham Co. v. Glickman*, 172 F.3d 885, 887 (D.C. Cir. 1999); *Gozlon-Peretz v. United States*, 498 U.S. 395, 404 (1991) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely.").

Very truly yours,

Davis Wright Tremaine LLP



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