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

Re: Regulation To Require Drug Pricing Transparency; Request for Comments, Docket No. CMS-4187-P, 83 Fed. Reg. 52,789 (Oct. 18, 2018)

Dear Administrator Verma:

The Medical Information Working Group ("MIWG") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS's") proposed requirement that manufacturers of prescription drugs and biological products state the Wholesale Acquisition Cost ("WAC" or "list price") of the product in direct-to-consumer ("DTC") television advertisements.[1] *See generally* 83 Fed. Reg. 52,789 (Oct. 18, 2018). The MIWG is an informal working group of major manufacturers of prescription medicines and medical devices. The MIWG has submitted comments and Citizen Petitions to the U.S. Food and Drug Administration ("FDA") on a number of subjects concerning the ability of manufacturers to engage in truthful, non-misleading speech about their products, including manufacturer responses to unsolicited requests for information; scientific exchange; communications to payors, formulary committees, and similar entities; and dissemination of third-party clinical practice guidelines.

[1] The MIWG consists of the following companies: Amgen Inc.; Bayer Healthcare Pharmaceuticals, Inc.; Boehringer Ingelheim Pharms., Inc.; Bristol-Myers Squibb Company; Eli Lilly and Company; Genentech, Inc.; GlaxoSmithKline, LLC; Johnson & Johnson; Novartis Pharmaceuticals Corp.; Pfizer Inc.; Samumed, LLC; and Sanofi US.

In these submissions to FDA, the MIWG has consistently espoused the principle that truthful, non-misleading manufacturer speech about therapeutic uses of their products promotes the public health. Here, however, the proposed rule mandates manufacturer speech in circumstances that will inevitably mislead consumers and potentially deter a significant number of them from seeking appropriate treatment, thereby undermining the public health. These adverse public health effects of the proposed rule alone warrant its withdrawal.

MIWG has also consistently asserted that broad restrictions on manufacturers' ability to discuss their products can violate the First Amendment. The proposed rule, if implemented, would violate the First Amendment because it does not directly advance the government's asserted interest in reducing federal expenditures on prescription drugs and is more extensive than necessary to serve that interest. Furthermore, the proposal is beyond the authority of CMS—and indeed, the U.S. Department of Health and Human Services ("HHS") as a whole—to promulgate.

The bases for these conclusions are set forth in the remainder of these comments.

I. MANDATORY DISCLOSURE OF PRESCRIPTION DRUG "LIST" PRICES WILL MISLEAD MANY CONSUMERS, AND THEREBY ADVERSELY IMPACT THE PUBLIC HEALTH.

Disclosing the WAC or "list" price of prescription drugs in DTC television advertisements, where time limitations preclude the provision of important contextual information, will inescapably mislead and confuse consumers. WAC is a construct of the Medicare statute designed to operate as a baseline wholesale cost, not including discounts or rebates.[2] WAC is *not* a suggested retail price for patients, and most patients do not pay the list price for prescription drugs.

[2] *See* 42 U.S.C. § 1395w-3a(c)(6)(B) (defining term).

Indeed, as of 2016, 82% of national expenditures on retail prescription drugs were covered by insurance.[3] The actual amount consumers pay for prescription drugs, therefore, varies widely depending upon their insurance plan: the cost of a drug may be entirely covered by insurance, patients may pay only a small fraction of the WAC, or they may pay an amount that bears little or no relationship to the WAC. Data from the Kaiser Family Foundation indicate, for example, that in 2018, 77% of enrollees in Medicare prescription drug plans, and 99% of enrollees in Medicare Advantage plans, paid a copayment for preferred brand drugs.[4] A copayment is unrelated to the "list" price of the drug, unlike coinsurance, which is based on a percentage of the price of the drug. Similarly, for insurance obtained through the Exchanges, most patients' cost-sharing obligations are based on copayments, not coinsurance.[5] Accordingly, most patients pay an out-of-pocket amount that is unrelated to the list price or WAC. Even when the patient's cost is based on the price of the drug through a coinsurance obligation, the applicable price might not be the WAC and the percentage of the price that is the patient's responsibility is unlikely to be known to the patient. Yet, despite its irrelevance to the vast majority of consumers, the proposed rule requires the disclosure of a prescription drug's WAC in all DTC television advertising.

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[3] *See* Rabah Kamal et al., Kaiser Family Found., *What Are the Recent and Forecasted Trends in Prescription Drug Spending?* (Dec. 10, 2018), https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/?_sf_s=recent+trends#item-medicare-become-major-payer-prescription-drugs_2017.

[4] *See* Juliette Cubanski et al., Kaiser Family Found., *Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing* fig.9 (May 17, 2018), https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/; Juliette Cubanski et al., Kaiser Family Found., *Medicare Part D: A First Look at Prescription Drug Plans in 2019* (Oct. 16, 2018), https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2019/;.

[5] *See* Kaiser Family Found., Slide Presentation on *Prescription Drug Cost Sharing*, at 8, https://www.slideshare.net/KaiserFamilyFoundation/prescription-drug-cost-sharing-55098475?ref=https://www.kff.org/health-costs/issue-brief/patient-cost-sharing-in-marketplace-plans-2016/ (slide titled "Share of Plans by Type of Cost Sharing for Preferred Prescriptions Plans with *Combined* Medical and Prescription Drug Deductible" showing that 24% of platinum plans, 21% of gold plans, 26% of silver plans, and 42% of bronze plans had a coinsurance-based obligation); *id.* at 9 (slide titled "Share of Plans by Type of Cost Sharing for Preferred Prescriptions Plans with *Separate* Medical and Prescription Drug Deductible) (only 4% of platinum plans, 10% of gold plans, 10% of silver plans, and 13% of bronze plans had a coinsurance-based obligation).

CMS recognizes that consumers may be "intimidated and confused by high list prices" and "might believe they are being asked to pay the list price rather than a co-pay or co-insurance." 83 Fed. Reg. at 52,797. In fact, such confusion is more than a mere possibility. There are compelling reasons to believe that a substantial portion of consumers will be confused and misled.

First, the Federal Trade Commission ("FTC"), which is charged with protecting consumers from deceptive advertising, has concluded that it is inherently misleading to advertise a Manufacturer's Suggested Retail Price ("MSRP") that does not reflect the price actually paid by most consumers. FTC guidance explains that, where "the list price is significantly in excess of the highest price at which substantial sales in the trade area are made, there is a *clear and serious danger* of the consumer being misled." 16 C.F.R. § 233.3(d) (emphasis added). Courts have likewise recognized that "references to manufacturer's list price" are "deceptive" where they are not an accurate representation of the price actually paid. *Giant Food Inc. v. FTC*, 322 F.2d 977, 982 (D.C. Cir. 1963). Because prescription drug "list" prices are "significantly in excess of the highest price at which substantial sales" of such drugs occur, 16 C.F.R. § 233.3(d), mandatory disclosure of prescription drug "list" prices will inevitably have the same deceptive effect as the disclosure of an inaccurately high MSRP.[6]

In fact, the proposed rule's effectiveness depends, in large part, on the expectation that consumers will perceive WAC to be a relevant indicator of cost. CMS states that consumers cannot

[6] *See also* Max Nisen, Opinion, *Trump's Drug-Ad Price Shaming Won't Fix the Problem*, BLOOMBERG (Oct. 15, 2018, 5:07 PM) [hereinafter "Nisen"], https://www.bloomberg.com/opinion/articles/2018-10-15/trump-drug-ad-price-shaming-won-t-fix-problem ("Most consumers won't immediately know that the intimidatingly large numbers in an ad aren't what they would actually have to pay"); Ezekiel Emanuel, Opinion, *The Trump Administration's Latest Plan to Lower Drug Prices is Hollow—and Maybe Counterproductive*, WASH. POST (Oct. 18, 2018), https://www.washingtonpost.com/opinions/the-trump-administrations-latest-plan-to-lower-drug-prices-is-hollow--and-maybe-counterproductive/2018/10/18/f7ea5a16-d30d-11e8-a275-81c671a50422_story.html?utm_term=.326adb72f55f ("[L]ist prices for drugs are misleading and possibly useless. The actual price that Americans pay is almost always much lower. . . . Just putting the list price out there is likely to confuse people about what they will actually pay").

engage in "meaningful price shopping," "because the average consumer has no anchor price, such as an MSRP for automobiles." 83 Fed. Reg. at 52,793. CMS posits that the disclosure of a drug's WAC will address this problem, by "[a]rming a beneficiary with basic price information [that] will provide him or her with an anchor price." *Id; see also id.* at 52,789 (proposed rule will "ensur[e] that beneficiaries are provided with relevant information about the costs of prescription drugs"); *id.* at 52,792 ("[C]onsumers need some idea of the magnitude of the cost of the advertised drug"). Thus, CMS expects consumers to rely on WAC as an "anchor price." FTC guidance makes clear, however, that inducing reliance on an "anchor price" is deceptive and misleading where, as here, the advertised price is not reflective of the actual cost to consumers.

Second, the disclosure of WAC in DTC television advertising will be misleading not only because it does not reflect the actual cost of a prescription drug to most consumers, but also because it is often a misleading basis for the "price shopping" CMS hopes to foster. *See id.* at 52,793. The proposed rule requires the disclosure of the list price "for a typical 30-day regimen or for a typical course of treatment." *Id.* at 52,794. But the list price of a product varies by strength, or dosage, and the recommended dosage (and thus costs) of many drugs depend on a patient's age, weight, or baseline test results. The list price for a typical 30-day regimen will therefore be inaccurate for many patients who could use the drug. Similarly, the "course of treatment" for a particular illness or condition can vary among different types of patients. A "typical-course-of-treatment" price for a drug will thus be inaccurate for the patients whose course of treatment deviates from the norm.

In addition, ancillary costs for different drugs can preclude meaningful "price shopping" based on WAC. As FDA has explained, "lower acquisition cost alone does not necessarily reflect a cost advantage. There are other variables that can affect relative costs among competing therapies. For example, total cost of therapy associated with competing products may vary due to

distinctions in the incidence of adverse events; frequency of physician office visits; days of hospitalization; type and frequency of laboratory tests required; and the need for additional medications."[7]

Third, the inaccuracy of WAC as a basis for price-shopping is exacerbated by the complexities of assessing the ultimate costs and value of competing therapies. Assuming physicians and consumers engage in a discussion about WAC, it is unlikely that such a discussion will consider the true cost of available treatments in light of the variables described above, much less the comparative value of therapeutic options. Such value-oriented considerations are increasingly important and are generally informed by "health care economic information"—*i.e.*, analyses that identify, measure, describe, or compare the economic consequences of using available treatments. As FDA has recognized, however, health care economic information may be difficult to interpret absent specialized "knowledge and expertise."[8] Thus, the expectation that disclosure of WAC will ultimately facilitate selection of cost-effective therapies overstates the importance of WAC and the ability of consumers to understand its relationship to cost and value.

In short, policies and guidance from both the FTC and FDA demonstrate that mandatory disclosure of list prices in the non-contextualized setting of DTC television advertising will inevitably confuse and mislead some consumers. And these harms cannot be mitigated by the proposed disclaimer that, "[i]f you have health insurance that covers drugs, your cost may be different." 83 Fed. Reg. at 52,794. In fact, because the purported effectiveness of the proposed rule

[7] Warning Letter from Janet L. Rose, Director, Division of Drug Marketing, Advertising, and Communications, FDA, to Randall L. Tobias, CEO, Eli Lilly and Company regarding NDA 19-508: Axid (nizatidine) Pulvules (July 19, 1994).

[8] FDA, OMB Control No. 0910-0857, Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers, Guidance for Industry and Review Staff 5 (June 2018), https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf (explaining that established procedures and skills are important to comprehending the impact and limitations of cost-based analysis).

depends on the "anchoring" effect of a drug's WAC—*i.e.*, consumers' belief that the WAC represents an accurate price—the disclaimer would defeat the purpose of the proposed rule if it *did* override the anchoring effect created by the disclosure of WAC. CMS must expect, therefore, that the proposed disclaimer will convey only that consumers might not pay the exact WAC, but that the WAC is nevertheless a reasonable estimate of the amount they will pay.[9]

In light of the time constraints that govern television advertisements, moreover, the misleading impact of disclosing WAC in DTC television advertisements cannot be avoided by including additional information or disclosures. There is no practical way, in the course of a 60- or 75-second consumer-directed television advertisement, to place a drug's "list" price in proper context, given the complexity of prescription drug pricing, the variability of patients' insurance plans, and the various factors discussed above that influence treatment costs among patients. *See also* Nisen, *supra* note 6 ("[I]t would be rather difficult to explain the arcane details of list prices, discounts, and cost-sharing in a few seconds of voice-over in a TV ad").

The effect of such misleading disclosures is clear. Consumers who believe they must pay the list price for a prescription drug (or something close to the list price) "may be deterred from contacting their physicians about drugs or medical conditions," which in turn "could discourage patients from using beneficial medications, reduce access, and potentially increase total cost of care." 83 Fed. Reg. at 52,797–98. Once again, these adverse results are not mere possibilities: perceptions (and misconceptions) about high costs lead consumers to avoid beneficial treatments.

[9] *See also* Stacie B. Dusetzina & Michelle M. Mello, *Disclosing Prescription-Drug Prices in Advertisements—Legal and Public Health Issues*, 379 NEW ENG. J. MED. 2290, 2291 (2018) (proposed disclaimer "doesn't communicate that costs to patients are probably much lower than the WAC"), https://www.nejm.org/doi/pdf/10.1056/NEJMp1814065.

For example, one study found that a majority of consumers with high-deductible plans were unaware that they could obtain preventive care without having to make cost-sharing payments.[10]

These adverse public health effects are unacceptable as a matter of public policy. The goal of limiting federal health care costs should not be pursued by mandating inherently misleading and confusing price disclosures that will discourage the use of beneficial—and in some cases life-saving—medicines and deter patients from obtaining information about potentially helpful treatments.[11] For these reasons alone, the MIWG urges CMS to withdraw the proposed rule.

II. THE PROPOSED RULE WOULD VIOLATE THE FIRST AMENDMENT.

Government regulation of commercial speech also implicates First Amendment rights. The preamble to the proposed rule suggests that it would pass constitutional muster under the deferential standard of review applicable to regulations that compel the disclosure of uncontroversial, truthful information about commercial products. *Id.* at 52,793 (citing *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985)). But, because mandatory disclosure of a prescription drug's WAC will confuse and mislead consumers, the less-demanding *Zauderer* standard does not apply. Instead, the proposed rule is subject, at a minimum, to intermediate scrutiny under *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980), and does not pass muster under this more exacting level of scrutiny.

A. The Proposed Rule Is Not Subject To First Amendment Review Under *Zauderer*.

Under *Zauderer*, a disclosure requirement that governs "only 'commercial advertising' and require[s] the disclosure of 'purely factual and uncontroversial information about the terms under

[10] Rajender Agarwal et al., *High-Deductible Health Plans Reduce Health Care Cost and Utilization, Including Use of Needed Preventive Services*, 36 Health Aff. 1762, 1766 (2017), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2017.0610.

[11] Indeed, as we explain below, Congress shares this view. *See* Section III, *infra*.

which . . . services will be available'" will be upheld if it is not "'unjustified or unduly burdensome.'" *Nat'l Inst. of Family & Life Advocates (NIFLA) v. Becerra*, 138 S. Ct. 2361, 2372 (2018) (omission in original) (*quoting Zauderer*, 471 U.S. at 651); *see also Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 541 (D.C. Cir. 2015); *Safelite Grp., Inc. v. Jepsen*, 764 F.3d 258, 263 (2d Cir. 2014); *Cent. Ill. Light Co. v. Citizens Util. Bd.*, 827 F.2d 1169, 1173 (7th Cir. 1987). As explained above, however, mandatory disclosure of a drug's WAC or "list price" does not describe the "terms under which services will be available." Instead, it overstates that cost for the vast majority of consumers.

Because that overstatement is, for the reasons discussed above, inherently misleading, the disclosure of a drug's WAC is neither "purely factual" nor "uncontroversial." *NIFLA*, 138 S. Ct. at 2372 (quoting *Zauderer*, 471 U.S. at 651). For *Zauderer*'s requirements to be met, the "facts conveyed [must be] directly informative of intrinsic characteristics of the product [the company] is selling." *Am. Meat Inst. v. USDA*, 760 F.3d 18, 27 (D.C. Cir. 2014). Where the company compelled to make the disclosure "disagree[s] with the truth of the facts required to be disclosed," or those facts are "one-sided or incomplete," *Zauderer* does not apply. *Id.*; *see also Kimberly-Clark Corp. v. Dist. of Columbia*, 286 F. Supp. 3d 128, 141 (D.D.C. 2017) ("[A] label is controversial when there is 'disagree[ment] with the truth of the facts required to be disclosed") (internal citations and quotations omitted).

Here, WAC is not "directly informative of" the actual cost of a drug to most consumers. Indeed, because the disclosure will convey an inaccurate "anchoring" price, it is misleading. And, the disclosure is "controversial" because it is so "one-sided, or incomplete" that it will inevitably confuse and mislead many consumers in ways that will discourage the use of potentially beneficial drugs. *Am. Meat Inst.*, 760 F.3d at 27. Accordingly, *Zauderer*'s deferential standard is inapplicable.

Nor is the proposed rule subject to less rigorous scrutiny because, "in the context of broadcast advertisements," the government "may take special steps to help ensure that viewers receive appropriate information." 83 Fed. Reg. at 52,790 (citing *Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 390 (1969)). The "fairness doctrine" at issue in *Red Lion* "require[d] that discussion of public issues be presented on broadcast stations, and that each side of those issues must be given fair coverage." *Red Lion*, 395 U.S. at 369–70. The Supreme Court upheld that requirement because broadcast frequencies are "scarce," and broadcasters granted a license to use a frequency were not entitled "to an unconditional monopoly" that allowed them to "snuff out the free speech of others." *Id*. at 387, 391. This rationale is inapplicable here. Manufacturers cannot monopolize discussion of prescription drug prices, or impede the free speech of others on this topic.

B. The Proposed Rule Is Subject To—And Does Not Satisfy—Intermediate Scrutiny Under *Central Hudson*.

Because *Zauderer* and *Red Lion* do not apply, the proposed rule must, at a minimum, satisfy *Central Hudson*'s more rigorous intermediate standard of review.[12] Under *Central Hudson*, government regulation of truthful, non-misleading commercial speech is permissible where "the asserted governmental interest is substantial," the regulation "directly advances the governmental interest," and the regulation "is not more extensive than is necessary to serve that interest." 447 U.S. at 566. The purpose of the proposed rule is "to reduce the price to consumers of prescription drugs and biological products," and to "improve the efficient administration of the Medicare and Medicaid programs" by "minimiz[ing]" "unreasonable expenditures borne by Medicare and Medicaid." 83 Fed. Reg. at 52,789. The proposed rule fails the last two prongs of the *Central*

[12] The mandatory disclosure is likely subject to the "heightened judicial scrutiny" applicable to content- and speaker-based regulation of "[s]peech in aid of pharmaceutical marketing." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011). Because any speech that fails *Central Hudson* review also would fail this heightened scrutiny, however, we focus our analysis of the proposed rule under the less demanding of the two standards of review.

Hudson test, however, because it does not directly advance the interest CMS seeks to achieve and is more extensive than necessary to serve that interest.

1. The Proposed Rule Would Not "Directly Advance" The Government's Interest.

To show that a regulation will "directly advance" a substantial interest, the government "may not rest on … speculation or conjecture," but rather has "the burden of demonstrating that the measure it adopted would 'in fact alleviate' the harms it recited 'to a material degree.'" *Nat'l Ass'n of Mfrs.*, 800 F.3d at 527 (*quoting Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993)). The asserted effectiveness of the disclosure requirement, however, rests on speculation. The preamble states that "[a]rming a beneficiary with basic price information" will "[t]rigger[] conversations about a particular drug or biological and its substitutes," which "*may* lead to conversations not only about price, but also efficacy and side effects, which in turn *may* cause both the consumer and the prescriber to consider the cost of various alternatives," which in turn "*may* result in the selection of lesser cost alternatives, all else being equal." 83 Fed. Reg. at 52,793 (emphases added). This speculation about how the disclosure of WAC might affect patient-physician interactions does not satisfy the government's burden "of demonstrating that the measure it adopted would '*in fact* alleviate' the harms it recited 'to a material degree.'" *Nat'l Ass'n of Mfrs.*, 800 F.3d at 527 (emphasis added) (quoting *Edenfield*, 507 U.S. at 771).

The effect that disclosure of WAC will have on consumers independent of their interactions with physicians is also speculative. The preamble states that the disclosure "*may* be informative" to "*some* consumers," 83 Fed. Reg. at 52,792 (emphases added), and thus "*may* improve price transparency for consumers." *Id.* at 52,797 (emphasis added). But the preamble elsewhere acknowledges that disclosing WAC could instead "intimidate[] and confuse[]" consumers, *id.*, and that many factors affect the ultimate price paid for a specific drug product, *id.* at 52,790.

The link between disclosing WAC in DTC television advertisements and reducing costs to Medicare and Medicaid is equally speculative, as it rests on the foregoing speculation that such disclosures will change consumer behavior and/or patient-physician interactions. The preamble also asserts that disclosing WAC will induce manufacturers "to reduce their list prices by exposing overly costly drugs compared to alternatives to public scrutiny," *id.* at 52,793, and by "*potentially* improving awareness and allowing the general public to signal in some cases that prescription drug prices have risen beyond their willingness to pay," *id.* at 52,798 (emphasis added); *see id*. ("this rule *may* provide a moderating force to counteract prescription drug increases") (emphasis added). But, as the preamble elsewhere recognizes, the proposed rule could have entirely different effects. Rather than leading manufacturers to reduce list prices, it could lead them to reduce television advertisements. *Id.* And, rather than leading patients to switch to lower-cost alternatives, it could lead them to avoid the best treatment for their condition, "potentially increas[ing] total cost of care." *Id*. These acknowledgements confirm that the effectiveness of the disclosure requirement is speculative. As a consequence, it cannot be shown that the proposed rule will, in fact, "directly advance" that goal to a material degree, as *Central Hudson* requires. 447 U.S. at 564.

2. The Proposed Rule Fails *Central Hudson*'s Final Prong.

The proposed rule also fails to satisfy *Central Hudson*'s final prong, which requires that a speech regulation be no more extensive than necessary to serve the government's interest. *Id.* at 569–70. This prong considers whether there is a reasonable "fit" between the government interest and the regulation. *United States v. Edge Broad. Co.*, 509 U.S. 418, 429 (1993). Ordinarily, in cases of compelled speech, the "fit" requirement is "self-evidently satisfied" when the government's interest is "assuring that consumers receive particular information" and it mandates the disclosure of "'purely factual and uncontroversial information.'" *Am. Meat Institute*, 760 F.3d

at 26 (quoting *Zauderer*, 471 U.S. at 651). For all the reasons discussed in Section I, however, the disclosure of WAC in DTC television advertising will mislead and confuse a substantial number of consumers. And such confusion will frustrate the proposed rule's purpose, by "discourag[ing] patients from using beneficial medications, reduc[ing] access, and potentially increas[ing] total cost of care." 83 Fed. Reg. at 52,797–98. By definition, there is no reasonable fit between the government's interest in reducing prescription drug costs and a rule likely to undermine that goal.

The proposed rule would also "unduly impinge on [manufacturers'] ability to propose a commercial transaction." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 565 (2001). Television advertising is expensive, and the proposed rule will increase that expense by requiring some air time be devoted to disclosing the product's list price and including the associated disclaimer.

At the same time that it increases advertising costs, the proposed rule will undermine the effectiveness of prescription drug television advertising, as the disclosure of WAC will predictably confuse and mislead many consumers in a way that will discourage some from seeking information about the advertised product. Thus, even if mandatory disclosure of WAC will not "'drown[] out'" manufacturers' messages or "'effectively rule[] out'" DTC television advertising as "a mode of communication," 83 Fed. Reg. at 52,793 (quoting *NIFLA*, 138 S. Ct. at 2378), requiring manufacturers to include information that will mislead and confuse some consumers and induce them not to use their products is an undue impingement on manufacturers' ability to engage in truthful, non-misleading commercial speech. DTC television advertising increases use of prescription medicines, *id.* at 52,792, but the government cannot "burden" speech because it is "effective in promoting brand-name drugs." *Sorrell*, 564 U.S. at 578.

These burdens are also likely to harm the public health. DTC television advertisements "can help facilitate more informed discussions between consumers and their health care

providers," 83 Fed. Reg. at 52,792, and "increase[] disease awareness," *id.* at 52,798. By increasing the expense and reducing the effectiveness of such advertising, the proposed rule could lead some manufacturers to reduce television advertising for products, thereby depriving the public of the health-promoting benefits such advertising provides.

There are alternative means of advancing the government's cost-saving interest that would be far less burdensome to protected manufacturer speech, and less harmful to public health. For example, Congress could authorize CMS to publish list price information on a CMS website and to advertise the availability of such information. *Cf. Sorrell*, 564 U.S. at 578 (instead of burdening the speech of others, the government "can express [its] view through its own speech"). Alternatively, Congress could empower CMS to require that advertisements explain where consumers can obtain information about the cost of the advertised medicine, such as an address for a company website that would include the list price and average, estimated or typical patient out-of-pocket costs, or other context about the potential cost of the medicine.[13] Instead of burdening speech that the government believes is contrary to its interest in reducing federal expenditures on health care costs, *see id.* at 577 (rejecting State effort to limit effectiveness of pharmaceutical marketing in order to reduce health care costs), these alternatives would offer those consumers who would like more complete information a way to find it, without confusing other consumers about the costs of prescription medicines advertised on television.

For all of the foregoing reasons, therefore, CMS should withdraw the proposed rule because it would violate the First Amendment.

[13] For purposes of a First Amendment analysis, the relevant inquiry is not whether a government agency currently possesses statutory authority to employ less burdensome means of achieving an otherwise valid governmental interest, but rather whether the government as a whole possesses the power to do so.

III. CMS LACKS STATUTORY AUTHORITY TO COMPEL THE DISCLOSURE OF PRESCRIPTION DRUG "LIST" PRICES IN TELEVISION ADVERTISING.

CMS predicates its authority to require disclosure of WAC in DTC television advertising on two grants of rulemaking power: Sections 1102(a) and 1871 of the Social Security Act. *See* 83 Fed. Reg. at 52,790. CMS states that regulations issued under such grants of rulemaking authority are valid "'so long as [they are] "reasonably related to the purposes of the enabling legislation,"' and do not contradict or undermine that legislation." *Id.* at 52,791 (alteration in original) (quoting *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 369 (1973) (quoting *Thorpe v. Hous. Auth. of City of Durham*, 393 U.S. 268, 280–81 (1969))). The preamble states that this "reasonable relationship" standard is satisfied because the proposed rule "uses means that Congress has generally endorsed—disclosures about drug prices—to advance an end that Congress endorsed—minimizing unreasonable expenditures [in the Medicare and Medicaid programs]—and thus there is a clear nexus between HHS's proposed actions and the Act." *Id.* This reasoning is mistaken.

Both of the Supreme Court decisions cited in the preamble—*Mourning* and *Thorpe*—pre-date *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the seminal decision in which the Supreme Court set forth the two-step framework for determining the validity of an agency's interpretation of statutes it administers. Under *Chevron* step one, a court must apply "the ordinary tools of statutory construction" to "determine 'whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) (quoting *Chevron*, 467 U.S. at 842–43). If Congress lacked a clear intent, then a court will defer to the agency's interpretation if it "is based on a permissible construction of the statute," *Chevron*, 467 U.S. at 843, as determined "in light of its 'language, structure, and purpose.'" *AFL-CIO v. Chao*, 409 F.3d

377, 384 (D.C. Cir. 2005) (quoting *Int'l All. of Theatrical & Stage Emps. v. NLRB*, 334 F.3d 27, 34 n.3 (D.C. Cir. 2003)). As a result of the intervening development of the *Chevron* framework, courts now understand *Mourning* and *Thorpe* "to describe a heightened level of deference that is due the agency's interpretation . . . under *Chevron* step two." *Colo. River Indian Tribes v. Nat'l Indian Gaming Comm'n*, 383 F. Supp. 2d 123, 144 (D.D.C. 2005), *aff'd* 466 F.3d 134 (D.C. Cir. 2006); s*ee also Chamber of Commerce v. NLRB*, 721 F.3d 152, 158 (4th Cir. 2013) ("*Mourning* applies only after a court has determined that Congress" had no clear intent on the question at issue and thus has "delegated interpretative powers to that agency").

Under a *Chevron* step one analysis, Congress has foreclosed HHS from requiring the disclosure of drug prices in DTC television advertising. Even under a *Chevron* step two analysis, moreover, the proposed rule is based on an unreasonable interpretation of the Social Security Act.

A. Congress Has Clearly Denied HHS Authority To Compel The Disclosure Of Drug Pricing Information In Television Advertising.

To determine whether Congress clearly expressed an intent with respect to the precise question at issue, courts use ordinary tools of statutory construction. Thus, in addition to a statute's text, courts must consider "the overall statutory scheme, legislative history, the history of evolving congressional regulation in the area, and . . . other relevant statutes." *Chamber of Commerce*, 721 F.3d at 160 (omission in original) (quoting *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 162 (1998)); s*ee also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (under *Chevron* step one, courts should consider "other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand," and should "be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of" economic and political significance). In addition, courts must consider not only a statute's purposes, but "'the means [Congress] has deemed appropriate, and prescribed, for the pursuit of

those purposes.'" *Colo. River Indian Tribes v. Nat'l Indian Gaming Comm'n*, 466 F.3d 134, 139–40 (D.C. Cir. 2006) (quoting *MCI Telecomms. Corp. v AT&T*, 512 U.S. 218, 231 n.4 (1994)); *see also Vill. of Barrington v. Surface Transp. Bd.*, 636 F.3d 650, 659 (D.C. Cir. 2011) (Congress may "'unambiguously foreclose[] [an] agency's . . . interpretation'" by "prescribing a precise course of conduct other than the one chosen by the agency" (quoting *Catawba Cty. v. EPA*, 571 F.3d 20, 35 (D.C. Cir. 2009))). Application of these principles demonstrates that Congress has intentionally withheld from HHS the authority to compel the disclosure of drug prices in television advertising in order to drive down drug prices and thereby minimize expenses to the Medicare and Medicaid insurance programs.

1. Congress Has Conferred On FDA Limited Authority To Regulate Consumer-Directed Prescription Drug Advertising.

Section 352(n) of the Federal Food, Drug and Cosmetics Act ("FDCA") provides that a prescription drug is "misbranded" unless the manufacturer or distributor "includes in all advertisements and other descriptive printed matter . . . with respect to that drug a true statement of (1) the established name [of the drug] as defined in paragraph (e), . . . (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e), and (3) such other information in brief summary relating to *side effects, contraindications, and effectiveness* as shall be required in regulations which shall be issued by the Secretary." 21 U.S.C. § 352(n) (emphasis added). This provision also mandates, "in the case of published direct-to-consumer advertisements," that the following statement be printed "in conspicuous text: 'You are encouraged to report negative side effects of prescription drugs to the FDA.'" *Id.*

Thus, Congress itself mandated the disclosure of certain information in prescription drug advertising, and empowered the Secretary to mandate additional disclosures. However, in both instances, Congress conspicuously failed to authorize the disclosure of *pricing information*. That

failure was not inadvertent. In the very same provision, Congress provided that "[n]othing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent *drug price communications* to consumers." *Id.* (emphasis added). Read in its entirety, therefore, this provision makes clear that manufacturers can choose to advertise the prices of their products, but that the Secretary cannot require them to do so.

In fact, that is how FDA itself has read the statute. In 1975, FDA created a qualified exemption in its prescription drug advertisement regulations for "reminder" advertisements and "reminder" labeling intended to provide price information to consumers. When FDA proposed the exemption, some commenters objected that it had "'launched a campaign to legalize the advertising of prescription prices on the grounds that price competition can be a spur to reducing health cost.'" Reminder Labeling and Reminder Advertisements for Prescription Drugs, 40 Fed. Reg. 58,794, 58,794 (Dec. 18, 1975). FDA responded that it was obligated to regulate advertising about prices when manufacturers choose to engage in such advertising, but that it could not mandate price advertising, explaining that, under the FDCA,

> pharmacies *are neither required by the act to publicly disclose prescription drug price information*, nor are they prohibited from posting price lists or otherwise publicly disclosing the prices charged for particular drug prescriptions. These amendments will ensure that the public disclosure of prescription prices, *where the pharmacist elects to post or otherwise advertise prices for prescription drugs*, meets all requirements of the act. *The decision to engage in public disclosure of prescription prices is not for the Food and Drug Administration to make*; these amendments merely constitute a mechanism by which this can be done consistent with the requirements for labeling and advertising under the [FDCA].

Id. (emphases added). The fact that FDA, which is tasked with implementing the FDCA, has previously taken the view that it lacked authority to compel disclosure of prescription drug prices is directly relevant to a Chevron step one analysis of the Secretary's authority over prescription drug advertising. *See Colo. River Indian Tribes*, 383 F. Supp. 2d at 142.

Congress has also empowered the Secretary to require the submission of any television advertisement of a drug for pre-review. 21 U.S.C. § 353c(a). In conducting that review, the Secretary "may make *recommendations*" with respect to "information included in the label of the drug" on changes that are "necessary to protect the consumer good and well-being" or "consistent with prescribing information for the product under review," and "if appropriate and if information exists, on statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific population groups." *Id.* § 353c(b) (emphasis added). The Secretary may not, however, "make or direct changes in any material submitted," except as provided under subsection (e). *Id.* § 353c(c). Subsection (e), in turn, authorizes the Secretary to require a specific disclosure "if the Secretary determines that the advertisement would be false or misleading without a specific disclosure *about a serious risk listed in the labeling of the drug involved*." *Id.* § 353c(e)(1) (emphasis added). Once again, this carefully circumscribed authority to mandate disclosures is limited to clinical risks and does not extend to pricing information.

Together, sections 352(n) and 353c reflect Congress' clear intent to confer a limited authority on the Secretary to compel disclosures in prescription drug advertising in order to promote public health and safety. Congress thus deliberately withheld from the Secretary the broader authority to compel the disclosure of drug prices—particularly for the very different purpose of constraining the costs of prescription medicines. *See Colo. River Indian Tribes*, 466 F.3d at 137–38 (the fact that a statute granted federal agency authority over some aspects of class II gaming, and other provisions "contemplate[d] joint tribal-state regulation" of class III gaming, showed that Congress did not authorize federal regulation of class III gaming); *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 466–68, 473 (2001) (because Clean Air Act elsewhere authorized agency to consider costs, a provision requiring the agency to set ambient air quality

standards "to protect public health" must be understood to foreclose consideration of costs when setting such standards); *see also Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 147 (1985) (noting, in a case not involving agency interpretation of a statute, that "[w]here a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it" (quoting *Transam. Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 19 (1979))); *Great-W. Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 221 (2002) (explaining, in the same context, that courts should "not attempt to adjust the 'carefully crafted and detailed enforcement scheme' embodied in the text that Congress has adopted") (quoting *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 254 (1993)).

2. Congress Has Prescribed Other Means To Control The Costs Of Prescription Drugs Generally, And The Costs Of Such Drugs To The Federal Government In Particular.

The foregoing evidence that the Secretary lacks authority to compel disclosures of prescription drug prices is bolstered by other laws that address prescription drug costs generally—and the costs of such drugs to the federal government in particular—through other mechanisms that are also "carefully crafted and detailed." *Great-W. Life & Annuity*, 534 U.S. at 221.

Congress has addressed the costs of prescription drugs generally by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act. Through that Act, Congress attempted to balance the goal of "mak[ing] available more low cost generic drugs," H.R. Rep. No. 98-857, pt. 1, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48, with the value of patents and exclusivities in incentivizing beneficial pharmaceutical advancement, *see* H.R. Rep. No. 98-857, pt. 2, at 30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2714. Congress has also addressed the costs of biological products through the Biologics Price Competition and Innovation Act of 2009, Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. VII, subtit. A, 124 Stat. 119, 804–821 (2010), which likewise seeks "[t]o balance innovation and price competition." *Amgen*

Inc. v. Sandoz Inc., 794 F.3d 1347, 1351 (Fed. Cir. 2015), *rev'd in part, vacated in part*, 137 S. Ct. 1664 (2017).

Congress has also prescribed numerous, highly detailed methods to control the costs of prescription drugs to the Medicare and Medicaid programs. The Medicaid Rebate Statute provides that companies that wish their outpatient drugs to be eligible for Medicaid coverage must enter into a Medicaid rebate agreement with HHS. 42 U.S.C. § 1396r-8(a)(1). Such an agreement must obligate the manufacturer to pay a quarterly rebate to each State Medicaid program for each of the manufacturer's "Covered Outpatient Drugs." *Id.* § 1396r-8(b)(1). This rebate amount is calculated under a formula that is designed to give each State program the benefit of the manufacturer's "best price" for each of its Covered Outpatient Drugs, and requires manufacturers to report to CMS its "average manufacturer price" and "best price" for each "covered outpatient drug[]," *id.* § 1396r-8(b)(3)(A), to facilitate those calculations. *See id.* § 1396r-8(b)(2)(A), (c)(1)(A).[14]

The Rebate Statute also authorizes other methods to control prescription drug costs, such as establishing prior authorization programs, limiting coverage of certain drugs, and specifying maximum quantities of drugs per prescription and maximum number of refills if "necessary to discourage waste." *Id.* § 1396r-8(d). The statute also requires drug use review programs to assure that prescriptions "are appropriate" and "medically necessary," and to prevent "fraud, abuse, gross overuse, or inappropriate or medically unnecessary care." *Id.* § 1396r-8(g)(1)&(2).

Medicare Part B limits reimbursement payments for physician-administered drugs. *Id.* § 1395w-3a. In general, reimbursement under Medicare Part B for single-sourced drugs is based on the average sales price ("ASP"), which is calculated by including commercial discounts and

[14] Under the Veteran's Health Act, moreover, manufacturers cannot receive Medicaid payments on their products unless they also offer rebates to the Department of Veterans Affairs, the Department of Defense, the Public Health Service, the Indian Health Service, and federally funded community centers. 42 U.S.C. § 1396r-8(a)(5)–(6).

rebates, but excluding certain sales that are also exempt from best price under the Rebate Statute. *Id.* § 1395w-3a(c)(1). Congress also created the WAC construct and authorized WAC-based pricing where the WAC is less than the ASP, *id.* § 1395w-3a(b)(4), although in practice this is highly unlikely to occur.

Relatedly, Congress has adopted measures to limit reimbursements in other federally funded health care programs. For example, under Medicare Part A, which covers hospital inpatient stays, drugs are typically not reimbursed separately, and are instead packaged with all other services provided to the patient during their hospital stay. Specifically, hospitals receive a single lump-sum payment for each hospital stay based on the diagnostic-related group. *Id.* § 1395g. Under Medicare Part D, the voluntary prescription drug benefit, CMS has delegated authority to plan sponsors to negotiate prices with manufacturers. *Id.* § 1395w-111.

In connection with the latter delegation of authority, Congress expressly provided that, "[i]n order to promote competition under this part and in carrying out this part, the Secretary—(1) may *not* interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may *not* require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." *Id.* § 1395w-111(i) (emphases added). These prohibitions underscore that Congress has "prescrib[ed] a precise course of conduct," *Vill. of Barrington,* 636 F.3d at 659, for addressing the costs of prescription drugs to federal insurance programs—a course that does not allow HHS to participate in drug-price negotiations between private parties, much less regulate prescription drug prices outside the federal healthcare programs.

The scope and complexity of the foregoing provisions make clear that Congress has prescribed the precise "means it has deemed appropriate" for constraining the costs of prescription drugs generally, and their costs to various federal programs in particular, *Colo. River Indian*

Tribes, 466 F.3d at 139 (quoting *MCI Telecomms. Corp.*, 512 U.S. at 231 n.4), and that HHS therefore lacks authority to employ other, unspecified methods to achieve either objective. The foregoing provisions, together with the carefully circumscribed authority Congress has conferred on FDA to regulate prescription drug advertising, demonstrate that HHS lacks authority to reduce federal expenditures on prescription drugs by mandating the disclosure of pricing information in television advertisements.

In addition, to the extent public disclosure of prices might lower federal expenditures for prescription drugs, it would do so in a manner at odds with the cost-reducing methods Congress has adopted. As various provisions of the Rebate Statute illustrate, Congress seeks to hold down drug costs by leveraging the government's purchasing power and preventing or discouraging "waste," "abuse, gross overuse, or *inappropriate* or *medically unnecessary* care." 42 U.S.C. §§ 1396r-8(d), 1396r-8(g)(1)–(2) (emphases added). *See also id.* § 1396-1 (purpose of Medicaid is to enable states to furnish "medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of *necessary medical services*") (emphasis added); S. Rep. No. 89-404, at 24 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943, 1965 (Medicare "encourage[s] participating institutions, agencies, and individuals *to make the best of modern medicine more readily available* to the aged") (emphasis added). Thus, Congress does not seek to reduce costs by discouraging *appropriate* and *medically necessary* care. Yet, as discussed *supra*, mandatory disclosures of list prices in DTC television advertising will discourage some from seeking appropriate and medically beneficial use of prescription medications. The fact that the proposed rule would undermine the balance Congress has struck between containing costs and ensuring effective care is yet another factor demonstrating that Congress did not empower the Secretary to adopt such a cost-containment measure.

Finally, given the economic and political significance of prescription drug prices, it is "highly unlikely" that Congress would leave it to the discretion of CMS—a component of HHS that has no expertise in prescription drug advertising—to seek to reduce prescription drug prices using mandatory price disclosures in television advertising. *See Brown & Williamson*, 529 U.S. at 160 ("highly unlikely" that Congress would leave regulation of tobacco, a decision with economic and political significance, to agency discretion) (quoting *MCI Telecomms. Corp.*, 512 U.S. at 231); *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (noting that, because availability of tax credits for insurance purchased through federal health exchanges created under the ACA was an issue of "'economic and political significance,'" if Congress had "wished to assign that question to an agency, it surely would have done so expressly") (quoting *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2444 (2014)).

B. The Proposed Rule Rests On An Unreasonable Interpretation Of The Social Security Act.

The proposed rule is also invalid under *Chevron* step two because it rests on an unreasonable interpretation of the Secretary's authority under the Social Security Act.

First, sections 1102(a) and 1871(a) of the Act are grants of "administrative" authority, not grants of power to promulgate substantive regulations grounded in the general "purposes" of the Social Security Act. Thus, section 1102(a) empowers the Secretary to issue "such rules and regulations, not inconsistent with this chapter, as may be necessary to the *efficient administration of the functions*" with which he is charged under that Act. 42 U.S.C. § 1302(a) (emphasis added). Section 1871 authorizes "such regulations as may be necessary to carry out *the administration of the insurance programs*" under the Health Insurance for Aged and Disabled subchapter of the Act. *Id.* § 1395hh(a)(1) (emphasis added). In *Gonzales v. Oregon*, 546 U.S. 243 (2006), the Court stressed the narrowness of similar language in the Controlled Substances Act, noting that the

Attorney General's authority to promulgate regulations which he "may deem necessary and appropriate for the *efficient execution of his functions* under" was not a delegation of "authority to carry out or effect all provisions of the" Act. *Id.* at 259 (emphasis added). *See also Brookwood Med. Ctr., Inc. v. Califano*, 470 F. Supp. 1247, 1250 (N.D. Ga. 1979) ("Section 1302 is a 'housekeeping statute' authorizing regulations for agency administration," and thus is "clearly insufficient" to sustain a substantive regulation authorizing disclosure of provider-cost reports filed with the agency), *aff'd sub nom. Brookwood Med. Ctr., Inc. v. Harris*, 614 F.2d 1295 (5th Cir. 1980).[15]

Second, even if these provisions authorize substantive rules to effectuate the general purposes of the Social Security Act, those purposes do not include reducing the costs of prescription drugs and biologics to society at large. *Cf.* 83 Fed. Reg. at 52,789 (stating that the purpose of the proposed rule is to "reduce the price to consumers of prescription drugs and biological products"). Instead, the cost-containment provisions of the Social Security Act address a narrower concern—and a different conception of "unreasonable expenditures." As the Rebate Statute illustrates, the costs of prescriptions drugs to federally funded programs are "unreasonable" if they do not reflect the discounts available to the government by virtue of its purchasing power, or if they are the product of "waste," "abuse, gross overuse, or inappropriate or medically unnecessary care." 42 U.S.C. §§ 1396r-8(d), 1396r-8(g)(1)–(2). Accordingly, regulations that minimize the costs of the Medicare and Medicaid programs by enhancing administrative efficiency, by leveraging the government's purchasing power to obtain discounts, and by

[15] Courts have sustained regulations promulgated under section 1102(a) where the Secretary used that authority to implement other substantive provisions of the Act. *See*, *e.g.*, *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 142 F. Supp. 3d 119, 130–31 (D.D.C. 2015) (rejecting *Chevron* step two challenge to regulation, promulgated under § 1102(a), to implement "face-to-face encounter" provision of the ACA). Here, the proposed rule is not designed to implement any of the provisions cited in the preamble; those provisions are cited to illustrate that one purpose of the Medicare and Medicaid programs is to "minimize[] unreasonable expenditures." 83 Fed. Reg. at 52,791.

preventing fraud, abuse and misuse of health care funds are all "reasonably related" to the purpose of the Social Security Act. By contrast, regulations that attempt to reduce the price of products in the marketplace are not reasonably related to the purposes of that Act.

The contrary conclusion proves too much. If the Secretary's mandate to operate the Medicare and Medicaid programs "efficiently" empowers CMS to compel the disclosure of prescription drug prices in DTC television advertisements, then CMS is also empowered to mandate price-transparency advertising for *all other medical services* that the Medicare and Medicaid programs cover. Insurance coverage for physician services, hospital services, and diagnostic tests also causes an "absence of meaningful prices" that mandatory price disclosures in DTC advertising "might" correct, which in turn "might" reduce those costs to consumers at large, and thereby reduce the costs to Medicare and Medicaid. Nor is it obvious why the Secretary's mandate to operate those programs "efficiently" would not also empower CMS to engage in direct price regulation of all health care services and products covered by Medicare and Medicaid. Again, such direct price regulation would have a "clear nexus" to the purpose of "minimiz[ing] unreasonable expenditures" in the Medicare and Medicaid programs.

In short, it is unreasonable to read sections 1102(a) and 1871(a) as empowering HHS to regulate prices and/or advertising with respect to a significant sector of the U.S. economy on the theory that doing so is "reasonably related" to minimizing Medicare and Medicaid costs.

Finally, it is unreasonable to conclude that the Secretary's rulemaking authority to administer the Social Security Act includes the power to regulate prescription drug television advertising, when a different statute regulates such advertising and, as discussed above, does not include the power to mandate the disclosure of drug prices. The Secretary's rulemaking authority under the Social Security Act cannot reasonably be read to exceed the limits of his authority under

the FDCA. That is particularly true where the measures purportedly authorized under the Social Security Act will undermine the balance Congress has struck between containing costs and ensuring effective and medically necessary care in the Medicare and Medicaid programs.

For all of these reasons, even if Congress did not clearly intend to deny the Secretary the authority to reduce prescription drug prices through mandatory price disclosures, the proposed rule still rests on an unreasonable construction of sections 1102(a) and 1871(a), in light of the language, structure, and purposes of the Social Security Act and the FDCA.

IV. CONCLUSION

The MIWG appreciates the opportunity to comment on the important issues raised by the proposed rule. For the reasons set forth above, we believe the proposal should be withdrawn.

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