[ORAL ARGUMENT NOT SCHEDULED]

No. 19-5222

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

MERCK & CO., INC., et al.,

Plaintiffs-Appellees,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia

BRIEF *AMICUS CURIAE* OF GOLDWATER INSTITUTE IN SUPPORT OF PLAINTIFFS-APPELLEES AND IN SUPPORT OF AFFIRMANCE

TIMOTHY SANDEFUR
D.C. Circuit Bar No. 53421
JONATHAN RICHES
D.C. Circuit Bar No. 55724
Scharf-Norton Center for Constitutional Litigation
at the GOLDWATER INSTITUTE
500 E. Coronado Rd.
Phoenix, AZ 85004
(602) 462-5000
litigation@goldwaterinstitute.org

Certificate as to Parties, Rulings, and Related Cases

Pursuant to D.C. Cir. R. 28(a)(1), *Amicus* certifies the following:

Parties and A*mici:* Except for *Amicus* Goldwater Institute, all parties appearing before the district court and in this Court are as listed in the Brief for Appellant.

Rulings Under Review: Appellants seek review of the July 8, 2019 opinion and order of the United States District Court for the District of Columbia. *See Merck & Co., Inc. v. U.S. Dep't of Health & Human Servs.*, 385 F. Supp. 3d 81 (D.D.C. 2019). References to the rulings at issue appear in the Brief for Appellant.

Related Cases: This case has not previously come before this Court or any other court. Counsel for *Amicus* is not aware of any other related cases pending before this Court or any other court within the meaning of D.C. Cir. R. 28(a)(1)(C).

Corporate Disclosure Statement

Pursuant to Rule 29(a)(4), *Amicus Curiae* Goldwater Institute, a nonprofit corporation organized under the laws of Arizona, hereby states that it has no parent companies, subsidiaries, or affiliates that have issued shares to the public.

Statement Regarding Consent to File and Separate Briefing

Per Fed. R. App. P. 29 and D.C. Cir. R. 29, the Goldwater Institute respectfully files this brief *amicus curiae* with the consent of all parties.

The Institute certifies that a separate brief is necessary because it highlights the first amendment implications of the Rule at issue in this case—which forces companies to state untrue things about their products, and therefore exceeds the limits of the *Zauderer* Doctrine.

No party's counsel authored the brief in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting the brief. No person other than the *Amicus*, its members, and counsel, contributed money that was intended to fund preparing or submitting this brief.

Table of Contents

Table of Authorities

Cases

Other Authorities

Regulations

Glossary

AAC	Actual Acquisition Cost
AMP	Average Manufacturing Price
AWP	Average Wholesale Price
FDA	Federal Drug Administration
GI	Goldwater Institute
PBM	Pharmacy Benefit Managers
U&C	Usual & Customary
WAC	Wholesale Acquisition Cost

Identity and Interest of *Amicus* and Source of Authority to File

The Goldwater Institute ("GI") was established 30 years ago as a nonpartisan public policy and research foundation devoted to advancing the principles of limited government, individual freedom, and constitutional protections through litigation, research, policy briefings and advocacy. Through its Scharf-Norton Center for Constitutional Litigation, GI litigates and files *amicus* briefs when its or its clients' objectives are directly implicated. GI has appeared in this Court representing parties or as *amicus curiae* defending freedom of speech, economic liberty, and other important principles. *See, e.g.*, *Libertarian Nat'l Comm., Inc. v. FEC*, 924 F.3d 533 (D.C. Cir. 2019); *Flytenow, Inc. v. FAA*, 808 F.3d 882 (D.C. Cir. 2015).

As part of its mission, GI has established its Truth in Medicine project, devoted to promoting the free flow of pharmaceutical information among manufacturers, physicians, payers. GI championed the Right to Try Act (S.204), which protects the right of patients to obtain safe medical treatments that have been approved for safety, but not for open sale, by the Food and Drug Administration ("FDA"). It has also championed the Free Speech in Medicine Act, now law in Arizona and Tennessee. GI scholars have also published important scholarly research and analysis on the importance of free speech in medicine. *See, e.g.*, Naomi Lopez Bauman and Christina Sandefur, *Restoring*

Free Speech in Medicine (Goldwater Institute, 2017);[1] Mark Flatten, *Gagged: Feds Use Criminal Charges, Threats to Silence Drugmakers* (Goldwater Institute, 2019).[2]

GI also filed a comment opposing the regulation at issue in this case, during the notice-and-comment period.

Amicus believes its litigation experience and policy expertise will aid this Court in consideration of this case.

Counsel for all parties have consented to the filing of this brief.

Statutes and Regulations

All applicable statutes and regulations are contained in the briefs of the parties or addenda attached thereto.

Introduction and Summary of Argument

The District Court was right to conclude that the "WAC Disclosure Rule" exceeds the Secretary's authority under the Social Security Act. But in addition to being *ultra vires*, the WAC Disclosure Rule is also unconstitutional under the First Amendment because it forces Merck and other pharmaceutical manufacturers to say things that are not true—and that may be positively misleading.

[1] https://goldwaterinstitute.org/wp-content/uploads/2017/06/Restoring-Free-Speech-in-Medicine-Policy-Paper.pdf
[2] https://goldwaterinstitute.org/wp-content/uploads/2019/02/Gagged-Report-2019-02-26-Flatten.pdf

Federal courts have long held that the government may not compel a private entity to engage in speech—with the "narrow" exception, established in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985), that it may force businesses to provide consumers with "purely factual and uncontroversial information" that is "reasonably related to the State's interest in preventing deception of consumers." *Id.* at 651.

This is a "narrow" exception, *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1217 (D.C. Cir. 2012), *overruled by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014), and the WAC Disclosure Rule does not fit within it. On the contrary, it requires firms to "disclose" information that is not only untrue, but is so far from being true that it is likely to mislead consumers, in potentially dangerous ways.

The Rule seems to contemplate some kind of "manufacturer suggested retail price" for medicines—but there is no such thing. Nor is there, realistically speaking, any such thing as a "wholesale acquisition price" as specified by the Rule—or, more precisely, that term is so vaguely and confusingly defined in the rule as to be essentially meaningless, or worse. The Rule's purported definition of this term—which excludes any discounts that occur prior to sale—even contradicts the legal definition of the same term, which *includes* such discounts. *See Mass. v. Mylan Lab.*, 608 F. Supp. 2d 127, 143 (D. Mass. 2008). And the Department's reliance on the Social Security Act as proof that WAC is a widely

accepted and understood term is insufficient to fit within the narrow *Zauderer* exception.

The Rule is misleading because consumers do not actually pay the "list price" or "wholesale acquisition price" of a medicine. Medicines are subjected to so many discounts, rebates, and other price-altering steps in the progress from manufacturer to consumer that forcing companies to disclose the price at the point of manufacturing is simply not helpful to consumer choice and is highly misleading. Nor is there such a thing as what the Rule calls a "typical 30-day regimen or for a typical course of treatment" for many medicines. And even the starting point price is not—and the Rule does not require it to be—tethered to any *actual* sale price. Instead, the Rule only requires manufacturers to *state* a *list* price—a number that the manufacturer puts in a book—that most likely bears no rational relationship to the actual sale price of that medicine.

In sum, the Rule is likely to make sick people believe they cannot afford a drug when they can, or vice-versa—which is to their detriment. True transparency—the actual conveying of truthful information—would most likely be helpful to consumers. But false transparency—the compulsory disclosure of inaccurate or incomplete information—is the opposite. The Rule therefore exceeds the government's "narrow" authority to control the content of a message by a private entity, *Turner Broadcasting System, Inc. v. FCC*, 512 U.S. 622, 641–42 (1994), and unconstitutionally compels private entities to say things that are neither true nor non-misleading.

Argument

I. The Rule's reliance on "Wholesale Acquisition Price" means businesses will be forced to advertise misleading, confusing, and untrue information.

The Rule purports to require drug manufacturers to state in their direct-to-consumer advertisements the "Wholesale Acquisition Cost" ("WAC") for a "typical 30-day regimen or for a typical course of treatment, whichever is most appropriate." 42 C.F.R. § 403.1202 (84 Fed. Reg. 20758). It also defines WAC as "the manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, *not including* prompt pay or other *discounts, rebates or reductions in price*, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data." *Id.* § 403.1201(d) (emphasis added). This wording sounds precise and objective, but the reality is that these terms are essentially meaningless and that there is in reality no such thing as a WAC as the Rule contemplates.

Unlike most consumer products, pharmaceutical products are subject to such a wide array of discounts, special conditions, and other intervening circumstances between manufacture and consumption, that the price consumers pay is virtually never the price at which pharmaceutical manufacturers sell their products. Indeed, there is no single, identifiable price at which a pharmaceutical manufacturer sells its products to all wholesalers.

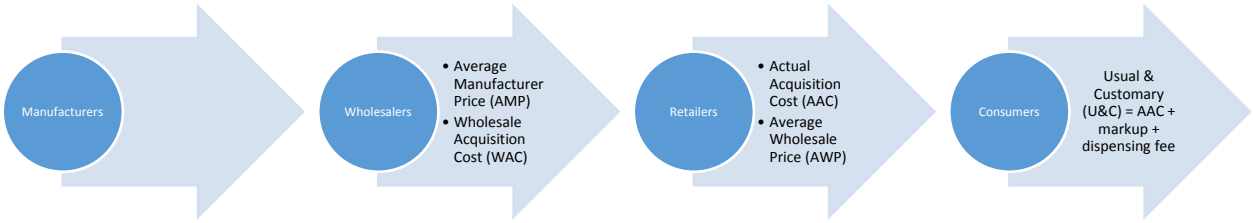
Pharmaceutical products are priced through a multi-step process, which involves many discounts and rebates. A product moves from a manufacturer to a wholesaler, and then either to retailers (pharmacies), hospitals, physicians' offices, or stand-alone clinics, where the consumer purchases that product. (See Figure below.) In some instances, insurers and pharmacy benefit managers ("PBMs") may negotiate the product price further after that. It is only after the product goes through all these stages that the price a consumer pays is established. It is therefore conceivable that every single buyer pays a different price once all applicable discounts and rebates are counted.

Wholesalers pay manufacturers an Average Manufacturing Price ("AMP") or a WAC. Discounts, rebates, etc., are *not* calculated into this price, which means that each wholesaler may pay a different price for the same product. Similarly, retailers, hospitals, physicians' offices, and stand-alone clinics pay an Actual Acquisition Cost ("AAC"), which is typically the WAC plus 10 to 15 percent for branded drugs, or the Average Wholesale Price ("AWP"). And these prices still do not reflect the varying discounts and rebates that are provided to these purchasers. Finally, the consumer pays the Usual & Customary ("U&C") price, which is the AAC + markup + a dispensing fee.

On top of these complicated and multi-layered pricing effects, the price a patient pays can also be affected by the kind of prescription drug insurance coverage the consumer has. In some plans, consumers pay co-pays, whereas a retailer or mail-order pharmacy based on a lower price that was negotiated by a

PBM may not. That means a patient paying cash at a pharmacy will typically pay a different price than a patient who purchases a product through insurance—and, of course, patients covered by different insurance plans will typically pay still different prices.

Figure: Examples of the Prescription Pricing Pipeline



Perhaps things should not be this complicated, but the reality is that they are, and the Rule worsens the confusion because it defines WAC as the "list price," whereas a WAC is typically understood *not* to be the list price, but the price at which a product is *actually sold*—the money-out-of-pocket by the consumer at the time of purchase, including all discounts.

In *Mylan Laboratories*, 608 F. Supp. 2d at 143, the district court noted that WAC is a contentious term, not clearly defined, and then concluded that it "*does not mean a list price*; it means the amount that goods *actually cost*." (emphasis added). The court further found that "[i]f … WAC were understood to mean merely a list price, a price set by manufacturers and listed at the top of invoices but rarely paid by wholesalers"—as the Rule does—then "WAC could

not be used to accurately estimate what pharmacies actually pay for drugs without significant additional information." *Id.* at 143–44 (emphasis added).

The Rule commits just this error, by defining WAC as "the manufacturer's list price … not including … discounts." 42 C.F.R. § 403.1201(d). Thus the Rule disregards the facts that *Mylan Laboratories* found critical: that the WAC is a misleading term if it is employed "without significant additional information" about the discounts, rebates, and other reductions that affect the price that consumers ultimately pay. 608 F. Supp. 2d at 143–44. *See also* Lee H. Rosebush & Lindsay P. Holmes, *Select Issues in Negotiating Drug Pricing and Reimbursement Contracts*, 10 J. Health & Life Sci. L. 59, 66 (2016) ("The accuracy of the WAC is subject to any unknown price reductions, rebates, or discounts that a manufacturer may have offered to a wholesaler or direct purchaser.").

During rulemaking, the Department purported to answer this objection in its lengthy comments on the final rule. 84 Fed. Reg. 20739-20743. In particular, it cited Section 1847A of the Social Security Act (42 U.S.C. § 1395w-3a(b)(4)(B)) as an example of a definition of WAC, which supposedly shows that WAC is "standardized" and "well-defined." 84 Fed. Reg. at 20739. That section of the Social Security Act, however, is a perfect demonstration of why the Supreme Court has referred to the Social Security Act as "'an aggravated assault on the English language, resistant to attempts to understand

it.'" *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 n.14 (1981) (quoting *Friedman v. Berger*, 409 F. Supp. 1225, 1226 (S.D.N.Y.1976)).

It refers the reader to 42 U.S.C. § 1395w-3a(c)(6)(B), which defines the term as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." The Department goes on to say that under the Social Security Act, "the negotiated price" of a pharmaceutical is "typically expressed in network pharmacy contracts as a function of the WAC (e.g., ((WAC x 1.2) – 15% + $2.00))." 84 Fed. Reg. at 20739. But however useful these convoluted formulae may be for defining reimbursement rates by trained experts in specialized government agencies, they do not communicate helpful information to the *layman*—and, just as importantly, they do *not* represent the actual transaction price that a consumer can expect to pay. As the Department acknowledges, the WAC is only a *component* in the formula for defining "the negotiated price" of a pharmaceutical—meaning that it is prior to all negotiations for that drug, and therefore is neither the consumer price nor a reliable indicator of consumer price.

In short, the statutory concept of WAC in this section of the Social Security Act "is *not* based on actual sales data, but rather is a published price. The accuracy of the WAC is *subject to any unknown price reductions*, rebates,

or discounts that a manufacturer may have offered to a wholesaler or direct purchaser." Rosebush *supra*. at 66 (emphasis added).

The WAC is also "not an actual market price." Alex Sugerman-Brozan & James Woolman, *Drug Spending and the Average Wholesale Price: Removing the AWP Albatross from Medicaid's Neck,* 3 Pharmaceutical Law & Industry Report 1, 8 (2005).[3] Instead, it is a *list* price—meaning that it is nothing more than a pre-negotiation price-tag written by the manufacturer, and does not represent any actual purchase or sale. It "is supposed to represent the average price paid by wholesalers" as printed in "the *Blue Book* and other publications," but "[t]hese publications essentially reprint the information the manufacturers have given to them, *with no verification of the accuracy of the data.*" *Id*. at 2. The result is that reimbursements that use the WAC figure "often bear little relation to the cost to providers of acquiring medications, and results in dramatic overpayments." *Id.*

To put it more bluntly, drug companies have in the past printed "phony" prices in their publications, enabling them to charge Medicare and Medicaid an inflated "list price." Charles Silver & David Hyman, *Overcharged: Why Americans Pay Too Much for Health Care* 79 (2018). And the Rule does nothing to address this concern. The Department euphemistically refers to the WAC as "a manufacturer-specified metric," 84 Fed. Reg. at 20744, which is

[3] https://www.communitycatalyst.org/pal-docs/bnaawparticle.pdf

true: it is a number fashioned by the manufacturer at the beginning of a process that is so complicated that the ultimate price is simply not reliably indicated by that initial number.

Medical experts themselves have long complained about the uselessness of WAC as an indicator of price. In *Estimating Drug Costs: How do Manufacturer Net Prices Compare with Other Common US Price References?*, 36 Pharmacoeconomics 1093 (2018),[4] authors T. Joseph Mattingly II, et al., showed that "[t]he discounted price as a percentage of the WAC ranged from 9 to 74%"—an astonishingly wide range that demonstrates the near meaninglessness of the WAC as a predictor of ultimate sale price. As the authors note, "individual discounts for products have a wide variation," which "make[s] a standard discount adjustment across multiple products less acceptable." *Id.*

Mattingly, et al., found that the "true payer costs" for drugs "may be much lower" than what the WAC would indicate, as a result of rebates and discounts that are not factored in under the Rule. *Id.* For example, Humulin, an insulin drug, was discounted *91 percent* from the WAC, and Humalog, another insulin drug, was actually sold at *81 percent* below the WAC. The smallest differential that these authors found was about a third—26 to 30 percent. *Id.* Other research has revealed the same mismatch—concluding that WAC

[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6061401/

overestimates consumer prices to an extraordinary degree. *See* Joseph Levy, et al., *A Transparent and Consistent Approach to Assess US Outpatient Drug Costs for Use in Cost-Effectiveness Analyses*, 21 Value in Health 677 (2018).[5]

Whether or not it is wise to rely on WAC to calculate reimbursement rates is a policy matter. But forcing manufacturers to include it in their ads is a First Amendment matter, and it is plain that WAC is too misleading to fit within the narrow *Zauderer* exception. While it may be difficult to define "purely factual and uncontroversial" for *Zauderer*'s purposes, it is at least clear that the term is confined to matters with regard to which "there is no dispute about factual accuracy." *Kimberly-Clark Corp. v. D.C.*, 286 F. Supp. 3d 128, 140 (D.D.C. 2017).

Here, the only thing about which there can be no realistic dispute is that WAC does *not* represent either the cost of a pharmaceutical, or anything like it. Rather, it is a number declared by the manufacturer without any independent assessments, and prior to any transactions, rebates, and reductions, which bears little or no relationship to—and is absolutely not a reliable predictor of—the actual cost of a medicine.

[5] https://doi.org/10.1016/j.jval.2017.06.013

II. The Rule requires "disclosure" of information that is not purely factual—indeed, is positively misleading.

A. The *Zauderer* rule does not allow the compulsory disclosure of misleading information.

Zauderer allows the government to force businesses to make statements about information if they are purely factual—not if that information is not purely factual. In *CTIA-Wireless Ass'n v. City & County of San Francisco*, 494 Fed. Appx. 752 (9th Cir. 2012), the Court of Appeals found that it was unlawful to force cell phone companies to inform consumers that cell phones were linked with cancer, when in fact they are not. Although the mandate was phrased in a way that did indeed include specifically true statements, the court found that the mandate nevertheless fell outside *Zauderer* because, taken together, the wording was misleading—it "could prove to be interpreted by consumers as expressing San Francisco's opinion that using cell phones is dangerous." *Id.* at 753.

Likewise, in *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 965–67 (9th Cir. 2009), the court found it unconstitutional to force video game manufacturers to label their products "18"—intended to suggest that only 18-year-olds could purchase the games. The court had found this age limit to be unconstitutional, so the court said it was also unconstitutional to compel manufacturers to add the label since it "does not convey factual information," and in fact "would arguably now convey a false statement that certain conduct is illegal when it is not." *Id.* at 967.

In *R.J. Reynolds*, *supra*, this Court found that *Zauderer* was not broad enough to entitle the government to force cigarette manufacturers to print hideous photos of the effects of cancer on their products, because although "none of these images are patently false, they certainly do not impart purely factual, accurate, or uncontroversial information to consumers," as contemplated by the *Zauderer* rule. 696 F.3d at 1217. Although the Court later overruled the portion of *R.J. Reynolds* which held that *Zauderer* was limited to correcting consumer deception, *Am. Meat Inst. v. U.S. Dep't of Agric*., 760 F.3d 18 (D.C. Cir. 2014), the Court has never held that *Zauderer* lets the government manipulate consumer choices by forcing manufacturers to convey *inaccurate* data, or data that are *not* "purely factual," "accurate," and "uncontroversial."

The District Court summarized the area of law well in *Cigar Association of America v. U.S. Food & Drug Administration*, 315 F. Supp. 3d 143, 165–66 (D.D.C. 2018), when it explained that "purely factual" means matters about which there can be no reasonable dispute regarding accuracy, and "uncontroversial" means the information is not likely to be misinterpreted by consumers, or to be inflammatory rather than informative. *Id.*.[6]

[6] In *American Beverage Ass'n v. City & County of San Francisco*, 871 F.3d 884 (9th Cir. 2017), the Ninth Circuit explained further that information that is "literally true but misleading," falls outside of *Zauderer* because compelling such disclosure would "create[] the possibility of consumer deception," and "[a] disclosure that may deceive consumers does not further the free flow of accurate information or add to the 'value to consumers of the information [commercial] speech provides.'" *Id*. at 893. The Ninth Circuit later reheard the case en banc and affirmed on a different ground. 916 F.3d 749 (9th Cir. 2019).

The Rule here falls short in virtually every respect. Forcing manufacturers to disclose the WAC exceeds the "purely factual" and "uncontroversial" requirements because it requires the conveyance of information that is not actually true—the price of a drug simply is not the WAC—and which is likely to mislead consumers, because the Rule mandates ignoring the single most important factor in determining the final sale price: the rebates or discounts.

The Department has taken the position that "price disclosure requirements" are lawful under *Zauderer* (84 Fed. Reg. at 20744), and that is no doubt true, but *a WAC is not a price*.

B. The WAC Rule is likely to mislead consumers and harm patients.

The Department contends that because the Rule also forces manufacturers to say "your cost may be different," that the distinction between the truth and the WAC is immaterial. *Id.* But such a disclaimer simply cannot make up for the inadequacy of the WAC as a measure of the actual price a consumer will pay. By that line of argument, the government could compel the statement of a conscious *untruth*, so long as it appends a requirement that the speaker also say "your case may differ."

In response to concerns regarding the misleading nature of the Rule, the Department also cited *Beeman v. Anthem Prescription Management, LLC*, 58 Cal. 4th 329 (2013), a case which upheld, under the California Constitution, a statute that forced pharmacies to conduct a study of the fees charged for

pharmaceutical dispensing services. *Id.* at 336. That statute required that the study "meet reasonable professional standards of the statistical profession," and specified a methodology for the study.[7] *Id.* The Department cites *Beeman* as akin to the mandate here. But it is entirely different. The study required in *Beeman* sought information about *actual* prices—i.e., the cost at which transactions were actually completed. *See id.* at 341. The WAC Rule, by contrast, mandates disclosure not of actual prices or historically-grounded data about transactions, but of numbers that are identified at the beginning of the pricing process and that bear so little relationship to the ultimate price as to be misleading to consumers.

To support the Rule, the Department relied on a letter to the *Journal of the American Medical Association*—Jace B. Garrett, et al., *Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising*, 179 JAMA Internal Medicine 435 (2019), to show that consumers were more likely to accurately understand their out of pocket costs if given WAC information. 84 Fed. Reg. at 20741. The *JAMA* letter, however, suffers from notable weaknesses. First, it was based on an online survey of frequent survey-takers, not actual patients. Second, the survey takers automatically

[7] The study had to be "computed by reviewing a sample of the pharmacy's usual charges for a random or other representative sample of commonly prescribed drug products, subtracting the average wholesale price of drug ingredients, and averaging the resulting fees by dividing the aggregate of the fees." *Id.* at 336.

assigned participants to the category of uninsured if the participants answered "don't know" to the question of whether they had insurance. This can severely bias the outcome, since there is no way a person can figure out his or her out of pocket cost if the person does not even know what, if any, insurance he or she has. Third, the letter acknowledged that it did not study "clinician responses to price disclosures"—which could easily include a doctor explaining how complex drug prices are in the real world.

Most significantly, however, the *JAMA* letter showed that patients were likely to be *deterred* from asking their physicians about a medicine if they were given a large number as the "price" of the drug. Garrett, et al., *supra* at 436. Given the fact that drugs are regularly discounted by as much as 90 percent from the WAC, *see* Levy, et al., *supra*, this study shows the danger of the misleading mandate imposed by the Rule: patients are likely to not ask their doctors about medicines that could improve or save their lives, if they are given an inaccurate, high number and told—*falsely*—that it is the price. Remarkably enough, the Department concedes this, by saying that this risk "is mitigated when the advertisement includes a caveat that [out of pocket] costs may be less." 84 Fed. Reg. at 20741-42. This is nothing less than an admission by the Department that if it tries to counteract the misleading nature of the information it is forcing pharmaceutical companies to provide, the consumer's dangerous overreaction might be slightly diminished.

None of this is necessary. The pharmaceutical industry has produced more accurate and reliable mechanisms for patients to use when seeking information about the cost of their medicines. The "medical assistance tool," or "MAT," available online at www.mat.org, provides user-friendly information that guides patients seeking data about their medical costs. The information available there is vastly more reliable and helpful than the misleading information compelled by the Rule. This is therefore not a situation such as was contemplated in *Zauderer*, where a "commercial speaker" is seeking "not to divulge accurate information regarding his services." 471 U.S. at 651 n.14.

Conclusion

The WAC Rule not only exceeds the Department's statutory authority, but it also exceeds the narrow exception provided in *Zauderer*, and therefore violates the First Amendment—to the detriment of consumers and patients.

Respectfully submitted,

/s/ Timothy Sandefur
Timothy Sandefur
Jonathan Riches
Scharf–Norton Center for Constitutional Litigation
at the GOLDWATER INSTITUTE
500 East Coronado Road
Phoenix, AZ 85004
Litigation@GoldwaterInstitute.org

Certificate of Compliance

Per Fed. R. App. P. 32(a)(7)(C) and D.C. Cir. R. 32(a), I hereby certify that the foregoing brief complies with the applicable type-volume limitations. This brief was prepared in proportionally spaced serif typeface using Microsoft Word in 14-point. The brief, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and D.C. Cir. R. 32(e)(1), contains 4,184 words. This certification is made in reliance on the word-count function of the word processing system used to prepare the brief.

October 29, 2019

/s/ Timothy Sandefur
Timothy Sandefur

Certificate of Service

I hereby certify that I electronically filed the foregoing with the Clerk of the Court of the United States Court of Appeals for the District of Columbia Circuit on October 29, 2019 using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Timothy Sandefur
Timothy Sandefur