ORAL ARGUMENT SCHEDULED ON JANUARY 13, 2020

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 THE CATO INSTITUTE IN SUPPORT OF PLAINTIFFS-APPELLEES

ILYA SHAPIRO
CATO INSTITUTE
1000 Massachusetts Avenue, N.W.
Washington, D.C. 20001
(202) 842-0200
ishapiro@cato.org

SEAN MAROTTA
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600
sean.marotta@hoganlovells.com

Counsel for Amicus Curiae

November 19, 2019

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), counsel for *amicus curiae* certifies:

Parties and Amici:

a. Defendants-Appellants' brief lists all parties appearing before the District Court and in this Court. AARP, AARP Foundation, and the Goldwater Institute have appeared as amici before this Court. The National Association of Broadcasters, NCTA - The Internet & Television Association, the Chamber of Commerce of the United States of America, and Washington Legal Foundation have noted their intent to appear as amici before this Court.

b. The Cato Institute is a not-for-profit corporation, exempt from income tax under section 501(c)(3) of the Internal Revenue Code, 26 U.S.C. § 501(c)(3); it has no parent corporation; and no publicly held company has a 10% or greater ownership interest in the Cato Institute.

Rulings Under Review: Defendants-Appellants' brief lists the rulings under review.

Related Cases: Counsel is not aware of any other related cases within the meaning of Circuit Rule 28(a)(1)(C).

/s/ Sean Marotta
Sean Marotta

CERTIFICATION REGARDING SEPARATE BRIEFING

Pursuant to Circuit Rule 29 and Federal Rule of Appellate Procedure 29, counsel certifies that a separate brief is necessary to make clear that the scope of the First Amendment rule the government seeks in this case would extend the *Zauderer* doctrine beyond any of this Court's, or the Supreme Court's, precedents.

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WAC Disclosure Rule	Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency, 84 Fed. Reg. 20,732 (May 10, 2019) (to be codified at 42 C.F.R. § 403.1202)

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Cato Institute, established in 1977, is a nonpartisan public policy research foundation dedicated to advancing the principles of individual liberty, free markets, and limited government.[1] Cato's Robert A. Levy Center for Constitutional Studies helps restore the principles of constitutional government that

[1] All parties have consented to the filing of this brief. No party's counsel authored this brief in whole or in part; no party or party's counsel contributed money intended to fund the brief's preparation or submission; and no person other than *amicus* contributed money intended to fund the brief's preparation or submission.

are the foundation of liberty. Toward those ends, Cato publishes books, studies, and the annual *Cato Supreme Court Review*, and conducts conferences and forums.

Cato believes that the right not to speak is an essential part of the liberty guaranteed by the First Amendment—and that when someone is forced to act as a mouthpiece for a particular government message, that compulsion warrants the most-rigorous First Amendment review. *See generally W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943). When government power treads on free speech rights, whether individual or corporate, it threatens the fundamental First Amendment "principle that each person should decide for himself or herself the ideas and beliefs deserving of expression, consideration, and adherence." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 213 (2013) (internal quotation marks omitted). Cato has filed numerous *amicus* briefs in challenges to compelled-disclosure schemes to explain the First Amendment's limits on the government's ability to require a person to speak. *See, e.g.*, Br. of the Cato Institute as *Amicus Curiae* in Support of Petitioner, *CTIA - Wireless Ass'n v. City of Berkeley*, No. 19-439 (U.S. Nov. 1, 2019); Br. for the Cato Institute as *Amicus Curiae* in Support of Petitioners, *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (No. 16-1140). It does so again here.

SUMMARY OF ARGUMENT

This appeal involves the validity of a regulatory requirement that drug companies include a government-scripted line in their advertisements to consumers. The regulation requires pharmaceutical companies to disclose, in any 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." Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency ("WAC Disclosure Rule"), 84 Fed. Reg. 20,732, 20,758 (May 10, 2019) (to be codified at 42 C.F.R. § 403.1202). The government defends this rule on the ground that it will make consumers marginally less confused about the price they might pay for the advertised drugs. As Plaintiffs have explained, however, that is just not the case. *See* Pls.' Br. at 14–15, 44–49, 53–54.

There is another, equally problematic flaw in the government's case. In contending that the rule passes First Amendment muster, the government offers a remarkably expansive view of *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985). That case accepted compelled government disclosures in the commercial-speech context "to dissipate the possibility of consumer confusion or deception." *Id.* at 651 (internal quotation marks omitted). This Court has expanded that exception, allowing the government to justify compelled disclosures of facts that allowed consumers "to make informed

choices based on characteristics of the products they wished to purchase." *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 24 (D.C. Cir. 2014) (en banc); *see* Pls.' Br. at 52–55 (explaining why *Zauderer* does not save this rule).

But the government would go even farther here. It justifies the WAC Disclosure Rule on the grounds that the disclosure requirement will cause "public scrutiny" that may "prompt[]" pharmaceutical companies to lower their prices. WAC Disclosure Rule, 84 Fed. Reg. at 20,733, 20,737. That these facts may have *some* relevance to consumer decisions cannot change what this is: back-door price regulation. No case allows a government to demand that a company recite facts designed to facilitate certain public-policy aims. This one should not be the first.

ARGUMENT

I. *Zauderer* Does Not Support A Disclosure Requirement Based On Any Government Interest Other Than Informing Consumers In Their Capacity As Consumers.

The government, to its credit, is at least honest about what it wants its rule to achieve. This administration has declared that one of its goals is "to lower drug prices." WAC Disclosure Rule, 84 Fed. Reg. at 20,732. In a section of the rule addressing the "problems that this rule seeks to address," the government states that the rule will "address rising list prices." *Id.* at 20,733 (capitalization altered). How? By "provid[ing] manufacturers with an incentive to reduce their list prices by exposing overly costly drugs to public scrutiny." *Id.* The government hopes

that forced disclosure of a drug's "list price"—a price that, as the Plaintiffs explain (at 6–11), will nearly always exceed the price a consumer pays by orders of magnitude—will expose pharmaceutical companies to public criticism that will, in turn, force them to lower their prices.

That is price control by another name. The government itself described "price transparency" as "a low-risk intervention with the potential to reduce health care costs without directly regulating health care reimbursement systems." WAC Disclosure Rule, 84 Fed. Reg. at 20,735. It expects that by "increasing price transparency and exposing overly costly drugs to public scrutiny" the rule will "incentivize the manufacturers to reduce their list prices." Defs.' Opp. to Mot. for Stay at 31 (D.D.C. June 25, 2019), ECF No. 20. So while the government winks that it is "not regulating how a manufacturer sets its list price," it admits that "[i]f transparency in such pricing" just so happens to "prompt[] a manufacturer to . . . reduce the list price of overly costly drugs," that would be a "*desired* . . . outcome." WAC Disclosure Rule, 84 Fed. Reg. at 20,737 (emphasis added); *see id.* (acknowledging it identified no statutory authority for imposing the disclosure requirement "as a cost-containment measure").

Nothing in *Zauderer*, or this Court's precedents, allows a government to impose a disclosure requirement to achieve a broader regulatory outcome. *Zauderer* held that compelled commercial-speech disclosures are permissible only

if they are "reasonably related to the State's interest in preventing deception of consumers." 471 U.S. at 651 (holding that a disclosure requirement could be imposed "to dissipate the possibility of consumer confusion or deception" (quoting *In re R.M.J.*, 455 U.S. 191, 201 (1982)). This Court has taken a step past *Zauderer*'s holding. In *American Meat Institute*, the Court upheld a country-of-origin disclosure requirement that allowed consumers "to make informed choices based on characteristics of the products they wished to purchase." 760 F.3d at 24. But even this step was limited to disclosure requirements designed to give consumers information relevant to their decision to purchase—or not purchase—a product.

National Association of Manufacturers v. SEC, 800 F.3d 518 (D.C. Cir. 2015), confirms this limitation on *Zauderer*. The government there required companies to investigate and disclose in their securities filings and on their websites whether minerals used in their supply chains were conflict-free. *See id.* at 522–524. This Court held that *Zauderer* reaches only disclosure requirements imposed on voluntary commercial advertising or commercial statements at the point of sale. *See id.*

National Association of Manufacturers recognizes that for a governmental interest to support a disclosure requirement, it must be related to helping the consumer make a commercial decision. "Commercial expression not only serves

the economic interest of the speaker, but also *assists consumers* . . . ." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 561-562 (1980) (emphasis added); *see also Am. Meat Inst.*, 760 F.3d at 26 (understanding *Zauderer* as easing *Central Hudson*'s evidentiary showing when the "goal" of a disclosure requirement is "informing consumers about a particular product trait" but caveating "that the reason for informing consumers" must be "an adequate interest"). The government's interest in *compelling* commercial speech must therefore also at least be related to helping consumers make a decision whether to purchase a good or service. *Cf. United States v. United Foods, Inc.*, 533 U.S. 405, 411 (2001) ("First Amendment values are at serious risk if the government can compel . . . subsidies for speech on the side that it favors . . . ."). Otherwise, *Zauderer* would give the government nearly limitless leeway to hijack an ad or product label to ensure that the public hears things that the government believes will influence public opinion on broader policy issues. *See Nat'l Ass'n of Mfrs.*, 800 F.3d at 530 (recognizing that certain disclosures are "undoubtedly a more effective way for the government to stigmatize and shape behavior than for the government to have to convey its views itself" (internal quotation marks omitted)).

The government's First Amendment defense of its rule therefore asks the Court to vastly expand the kinds of governmental interests that can justify a disclosure requirement under *Zauderer*. True, the government also claims its rule

educates consumers, and thus serves a purpose beyond pressuring pharmaceutical companies into lowering their process. *See* WAC Disclosure Rule, 84 Fed. Reg. at 20,733. But as Plaintiffs (at 14–15, 44–49, 53–54) and *amicus curiae* Goldwater Institute (at 5–12, 15–18) have thoroughly explained, the rule actually misleads consumers about the costs they will pay. The government's flimsy consumer-based rationale is further proof—along with the government's own words—of the rule's true aim. The government's argument therefore comes down to a request for this Court to hold that it can impose a disclosure requirement on a company to achieve a regulatory goal through companies' compelled speech, freeing the government from regulating directly and transparently. The Court should reject that request.

II. Further Erosions Of First Amendment Protections For Commercial Speech Will Threaten Anti-Democratic Results.

Allowing the government to compel commercial disclosures to further the government's substantive regulatory aims would threaten anti-democratic results. *Zauderer*, after all, is a narrow exception to a baseline rule that *disfavors* compelled speech. *See Nat'l Inst. of Family & Life Advocates*, 138 S. Ct. at 2372. The First Amendment protects against both speech prohibitions and compulsions. *See Hurley v. Irish-Am. Gay, Lesbian & Bisexual Group of Bos.*, 515 U.S. 557, 573 (1995) ("[O]ne important manifestation of the principle of free speech is that one who chooses to speak may also decide what not to say." (internal quotation marks

omitted)). And so, compelled speech "invades the sphere of intellect and spirit which it is the purpose of the First Amendment to our Constitution to reserve from all official control" and ordinarily triggers First Amendment strict scrutiny. *Barnette*, 319 U.S. at 642.[2]

Since *Zauderer* opened the door to compelled disclosure, governments have eagerly walked through it. Government-compelled "[c]ommercial disclosures have become ubiquitous." Timothy J. Straub, *Fair Warning?: The First Amendment, Compelled Commercial Disclosures, and Cigarette Warning Labels*, 40 Fordham Urb. L.J. 1201, 1224 (2013); *see also* Brian E. Roe et al., *The Economics of Voluntary Versus Mandatory Labels*, 6 Ann. Rev. Resource Econ. 407, 408–409 (2014) ("[P]roduct labeling is an increasingly popular tool of regulators."). "Governments at all levels frequently require the disclosure of potentially relevant information about goods or services offered for sale." Jonathan H. Adler,

[2] Cato has elsewhere explained that the First Amendment does not support granting commercial speech less protection than other forms of speech, as current doctrine does. *See, e.g.*, Br. *Amicus Curiae* of Pacific Legal Found. & Cato Inst. in Support of Respondents, *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011) (No. 10-779). Supreme Court Justices have expressed similar views. *See, e.g.*, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571–572 (2001) (Kennedy, J., joined by Scalia, J., concurring in part and concurring in the judgment); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 518 (1996) (Thomas, J., concurring in part and concurring in the judgment). But, at the very least, the Court should not grant commercial speech even less protection than current doctrine does.

Compelled Commercial Speech and the Consumer "Right to Know," 58 Ariz. L. Rev. 421, 424 (2016).

Take a few examples from the state level. Vermont required that food and dairy manufacturers "warn" consumers about how the manufacturers produced their milk. *See Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996). Vermont also required that processed foods and raw agricultural commodities disclose the use of genetically modified organisms. *Grocery Mfrs. Ass'n v. Sorrell*, 102 F. Supp. 3d 583 (D. Vt. 2015). Illinois required "opinion-based" warnings about video games that the State believed were "sexually explicit." *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006). And California similarly required labels on games that the State deemed "violent." *Brown v. Entm't Merchs. Ass'n*, 564 U.S. 786, 788–789 (2011).

Local governments, too, have eagerly taken to compelled commercial disclosures. New York City forced "chain" restaurants to display a "[s]odium warning" on their menu boards. *Nat'l Rest. Ass'n v N.Y.C. Dep't of Health & Mental Hygiene*, 148 A.D.3d 169, 172 (1st Dep't 2017). San Francisco required advertisers of "sugar-sweetened beverages" to "overwhelm[]" their messages with a large "black box warning" that "convey[ed] San Francisco's disputed policy views." *Am. Beverage Ass'n v. City & Cty. of San Francisco*, 871 F.3d 884, 896–897 (9th Cir. 2017), *vacated and aff'd on narrower grounds* 916 F.3d 749 (9th Cir.

2019) (en banc). San Francisco sought to compel cell-phone retailers to "express . . . San Francisco's opinion that using cell phones is dangerous." *CTIA-Wireless Ass'n v. City & Cty. of San Francisco*, 494 F. App'x 752, 753 (9th Cir. 2012).

And the federal government—as this case shows, and as this Court knows—has seized the opportunity *Zauderer* offers. As discussed, the Securities and Exchange Commission tried to require every company that potentially used "conflict minerals" to investigate and disclose the origin of those minerals on the "company's website and in its reports to the SEC." *Nat'l Ass'n of Mfrs.*, 800 F.3d at 522. The Food & Drug Administration forced tobacco companies to display explicit "color graphics depicting the negative health consequences of smoking." *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1208 (D.C. Cir. 2012) (internal quotation marks omitted), *overruled in part by Am. Meat Inst.*, 760 F.3d 18. The Department of Agriculture has mandated disclosure of country-of-origin information about meat products, *see Am. Meat Inst.*, 760 F.3d 18, and has attempted to extract payments from vegetable growers to support speech concerning the desirability of branded mushrooms, *see United Foods*, 533 U.S. 405. The government has even gone so far as to tell agencies how to best impose disclosure requirements on regulated entities. Memorandum from Cass R. Sunstein, Adm'r, Office of Info. & Regulatory Affairs, to Heads of Exec. Dep'ts &

Agencies, *Disclosure and Simplification as Regulatory Tools* (June 18, 2010), *available at* https://tinyurl.com/oiradisclosurememo ("Disclosure Memo").

These kinds of disclosure requirements appeal to governments for obvious reasons. Regulators, especially at the state and local levels, often face resource constraints. Compelled disclosure requirements are attractive because they provide a low-cost—to the government, at least—way to advance regulators' preferred message, without many of the technical or political difficulties associated with developing new or complex substantive regulatory regimes, or speaking with the government's own voice.

A relaxed means-end test under *Zauderer* makes compelled disclosures even more appealing to governments. Under this Court's gloss on *Zauderer*, "the government meets its burden of showing that the mandate advances its interest in making the 'purely factual and uncontroversial information' accessible to the recipients." *Am. Meat Inst.*, 760 F.3d at 26 (quoting *Zauderer*, 471 U.S. at 651)); *but see Nat'l Inst. of Family & Life Advocates*, 138 S. Ct. at 2377 ("California has the burden [under *Zauderer*] to prove that the unlicensed notice is neither unjustified nor unduly burdensome."). If courts do not rigorously police the stated justifications for disclosure rules, a government can more easily pass *Zauderer*'s test and require a company to make a statement that toes the government line.

This case shows how an easier-to-meet *Zauderer* standard has given the

government an incentive to rely on little more than speculation. The government's analysis here lags far behind its own standard for disclosure rules, and the efforts it has made to justify disclosures in the past. In the preamble, the government rejected a commenter's suggestion that "the record is not sufficient to support the conclusion that the rule will be effective and that further study is necessary," relying solely on its own characterization of a single, three-page behavioral study to do so. WAC Disclosure Rule, 84 Fed. Reg. at 20,746–20,747. In fact, the government *admitted* that it "lack[s] data to quantify" whether and to what extent consumers will misunderstand the disclosure. *Id.* at 20,756.

The government's own standards for disclosure rules require more. "To the extent feasible, and when existing knowledge is inadequate, agencies should consider several alternative methods of disclosure and test them before imposing a disclosure requirement." Disclosure Memo at 5. Consistent with that requirement, the government has at least attempted to support other proposed disclosure requirements with studies showing that the mandated disclosures are likely to be effective to inform consumers. For example, before issuing a recent proposal for new cigarette-warning labels, the FDA conducted a consumer-research study to determine whether several possible warning statements would promote a greater understanding of the risks associated with cigarette smoking. Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 84 Fed. Reg.

42,754, 42,767–42,769 (proposed August 16, 2019). After this initial study, the FDA used communication-science research to refine the list of possible warnings. *Id.* at 42,768–42,769. The warning statements that survived this scrutiny were subjected to additional consumer testing before being included in the proposed rule. *Id.* at 42,769.

To expand *Zauderer* even further by defining the scope of permissible government interests to include *regulatory* goals would only increase the incentive for governments to turn to disclosure requirements. Rather than build the kind of detailed legislative or regulatory record that could support direct regulatory measure, the government need only come up with an explanation for why a disclosure rule "advances its interest" in achieving a regulatory goal. *Am. Meat Inst.*, 760 F.3d at 26. A government could thus hijack a company's advertisement or price display to pursue a policy outcome and claim that the disclosure requirement gives the company an incentive to change its behavior to avoid the disclosure—as with the SEC's conflict-free minerals disclosure requirement—or would give consumers information that would cause them to put pressure the disclosing company to change its behavior—as this rule appears designed to do.

Either way, the government would be using these so-called disclosures to "burden the speech of others in order to tilt public debate in a preferred direction." *Sorrell*, 564 U.S. at 578–579. Sometimes these disclosures will—as with the

SEC's conflict-free minerals requirement—force a company to disparage itself. And other times these disclosures will—as this rule appears to do—force a company to make a one-sided statement that tarnishes its reputation. This "kind of forced" speech compels companies to contribute to a policy debate against their will in a manner that "is antithetical to the free discussion that the First Amendment seeks to foster." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality op.).

It not hard to imagine why or how a government could turn to disclosure requirements to try and achieve regulatory goals that it cannot through direct regulation. For example, rather than enacting controversial legislation that would require landowners to retrofit buildings to a degree that satisfies the government's standards, a government may compel property owners—even those who have already significantly reinforced their buildings—to issue advertisements notifying tenants that the buildings in question are "unreinforced" and may not withstand an earthquake. *Cf. Masonry Bldg. Owners of Or. v. Wheeler*, 394 F. Supp. 3d 1279, 1298 (D. Or. 2019). Rather than enacting greenhouse-gas emission regulations, a government could require companies to disclose how their valuation would change under different climate-change scenarios. *Cf.* Climate Risk Disclosure Act of 2019, S. 2075, 116th Cong. (2019). Or, to give an example closer to this case, rather than regulating pharmaceutical prices directly, a government could require

companies to disclose their profits for a given drug. The list of potential disclosures is vast, and the creep of government actions under *Zauderer* renders them entirely plausible.

The government's preferred view of *Zauderer* would give it endless authority to pursue its own policy goals by making companies state facts that the government believes will influence consumers' opinions in ways that will allow the government to achieve its policy objectives. The message that the government requires the company to relay may consist of "facts," but the policy goals the facts further are intensely controversial. *Cf. Am. Beverage Ass'n*, 871 F.3d at 895–896 (invalidating beverage warning as "misleading and, in that sense, untrue" because it took sides where "there is still debate" (internal quotation marks omitted)); *Am. Meat Inst.*, 760 F.3d at 27 (recognizing "possibility" that some "one-sided" disclosures would be "controversial"). The government is essentially allowing itself to pursue a controversial policy outcome while avoiding the political fallout that comes with explicitly taking a position on the underlying issue. This Court should reject this attempt to expand *Zauderer*.

None of this is to say the government cannot pursue a goal of lower drug prices. The government can regulate commercial activity directly through the legislative and regulatory processes and within the Constitution's constraints. Or the government can use its own considerable resources "to promote a program, to

espouse a policy, or to take a position." *Walker v. Texas Div., Sons of Confederate Veterans, Inc.*, 135 S. Ct. 2239, 2246 (2015). When the government speaks in this way, "it represents its citizens and it carries out its duties on their behalf." *Id.* But what the government *cannot* do is require citizens to "utter or distribute speech bearing a particular message" that is "favored by the Government." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641–642 (1994); *see also Riley v. Nat'l Fed'n of Blind of N.C., Inc.*, 487 U.S. 781, 800 (1988) (similar). The Court should not allow the government to do so here.

CONCLUSION

For these foregoing reasons and those in Plaintiffs' brief, the Court should affirm.

Respectfully submitted,

/s/ Sean Marotta

ILYA SHAPIRO
CATO INSTITUTE
1000 Massachusetts Avenue, N.W.
Washington, D.C. 20001
(202) 842-0200
ishapiro@cato.org

SEAN MAROTTA
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600
sean.marotta@hoganlovells.com

Counsel for Amicus Curiae

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CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limits of Fed. R. App. P. 32(a)(7) and Fed. R. App. P. 29(a)(5) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 3,727 words.

2. This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman.

/s/ Sean Marotta
Sean Marotta

CERTIFICATE OF SERVICE

I certify that on November 19, 2019, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Sean Marotta
Sean Marotta