IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHILIP MORRIS USA, INC., SHERMAN GROUP HOLDINGS, LLC *Plaintiffs,*	)	
v.	)	Case No. 20-cv-1181 (KBJ)
UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., *Defendants.*	)	

BRIEF FOR THE STATES OF COLORADO, IDAHO, IOWA, ALASKA, CALIFORNIA, CONNECTICUT, DISTRICT OF COLUMBIA, DELAWARE, HAWAII, ILLINOIS, KANSAS, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OREGON, RHODE ISLAND, UTAH, VERMONT, VIRGINIA, AND WASHINGTON
AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS

PHIL WEISER
Attorney General of Colorado
1300 Broadway, 10th Floor
Denver, CO 80203

TOM MILLER
Attorney General of Iowa
1305 E. Walnut
Des Moines, IA 50319

LAWRENCE WASDEN
Attorney General of Idaho
700 W. Jefferson Street
Boise, ID 83720

Attorneys for Amici Curiae; complete counsel listing appears on signature pages

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PRELIMINARY STATEMENT AND INTEREST OF THE *AMICI CURIAE*

Amici curiae are the States of Colorado, Idaho, Iowa, Alaska, California, Connecticut, District of Columbia, Delaware, Hawaii, Illinois, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Rhode Island, Utah, Vermont, Virginia, and Washington ("*Amici* States"). The *Amici* States submit this brief to support the Defendants United States Food and Drug Administration, United States Department of Health and Human Services, Stephen M. Hahn, in his official capacity as Commissioner of the United States Food and Drug Administration, and Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, on their Consolidated Opposition to Plaintiffs' Motions for Summary Judgment and Preliminary Injunction and Cross-Motion for Summary Judgment. The *Amici* States have long fought against the deception surrounding the marketing and sale of cigarettes to protect the interests of their residents in making economic and health decisions based on accurate and relevant information.

The Amici States have also long enforced settlement agreements between the States and tobacco companies, including Plaintiff Philip Morris USA, Inc., and Sherman's 1400 Broadway N.Y.C., LLC, a wholly owned subsidiary of Plaintiff Sherman Group Holdings, LLC, concerning the marketing, sale and consumption of cigarettes, and have implemented state statutes and regulations furthering these efforts. The Master Settlement Agreement ("MSA"), executed November 23, 1998, is a "landmark agreement," *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 533 (2001), that settled the claims of 46 States, the District of Columbia, the Commonwealth of Puerto Rico, and four territories against the major tobacco manufacturers.[1]

[1] The MSA is available at https://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf Four other States—

Prior to the MSA and the other settlements, the States had amassed considerable evidence demonstrating that the major tobacco manufacturers had engaged in decades of fraud in denying the addictiveness of, and harm caused by, their products. Given that the MSA addressed numerous issues with the way that tobacco companies deceptively marketed their products, it was a significant victory for the States, for both public health and consumer protection reasons. The MSA's advertising restrictions were designed in part to remedy the tobacco manufacturers' fraud by, among other things, prohibiting the companies from materially misrepresenting the health consequences of using those products. MSA § III(r).

However, as the Supreme Court recognized in *Lorillard Tobacco*, 533 U.S. at 534, the MSA does not cover all cigarette advertising, sales practices, or even all tobacco manufacturers. Congress acknowledged this when it determined, in enacting the Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31, 123 Stat. 1776 (2009) (the "Act"), that "Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products." *Id.* § 2(7), 21 U.S.C. § 387 note (7). The MSA is a powerful tool, but it works best when paired with federal regulations, which can change and adapt to protect consumers in an ever-evolving marketplace.

The warning labels implemented by Congress and the FDA are consistent with the principles of the MSA and will promote both public health and consumer protection by increasing public understanding of the health consequences of tobacco use. In this case the States have a

Florida, Minnesota, Mississippi, and Texas—settled their claims against the tobacco companies before the MSA was executed. Each of the earlier settlements included some of the same advertising and marketing restrictions that are found in the MSA, and all included provisions prohibiting material misrepresentations concerning the health consequences of using tobacco products. Accordingly, what is said in this brief with respect to the MSA is equally true of those agreements.

particularly strong interest in ensuring that adequate warning information is required by federal regulation because the same statute that requires the warnings also preempts States from requiring their own warnings on cigarette labels and advertising. *See* 15 U.S.C. § 1334(b).

Finally, the *Amici* States utilize and are responsible for defending many regulations that have the primary purpose of informing consumers of relevant product information. The government's position here, that informing the public is itself a substantial interest, is at the core of these state regulations. The Plaintiffs argue that "FDA's interest in more effectively providing additional information to consumers solely to improve knowledge is too circular to be substantial." Pl. Br. at 55. The *Amici* States disagree. In the *Amici States*' experience, providing consumers with relevant information serves important consumer-protection and public health and safety goals. The *Amici States* thus have strong interests in demonstrating that this informational goal is a valid government interest, and in protecting their own state regulations from unfounded First Amendment attacks.

ARGUMENT

This case involves one of the deadliest and most addictive products sold in America. As the Supreme Court has noted, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA* v. *Brown & Williamson Tobacco Corp.*,529 U.S. 120, 161 (2000). Over forty years of experience with text-only warning labels on cigarette packs and advertising have demonstrated that they simply do not work; studies confirm that consumers no longer notice them, much less pay them any heed. *See* 84 Fed. Reg. 42,760-61 (Aug. 16, 2019) (discussing how current cigarette warnings do not attract public attention, are not remembered, and do not prompt consumers to think about the dangers of smoking).

In 2009, the U.S. Court of Appeals for the D.C. Circuit affirmed a judgment finding that the major cigarette companies—accounting for 99 percent of the U.S. cigarette market at the time that lawsuit was initiated—had engaged in a conspiracy of unprecedented magnitude and duration to deceive the American public about the lethal consequences of smoking and to addict them to a product the companies knew was deadly. *United States v. Philip Morris*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in relevant part*, 556 F.3d 1095 (D.C. Cir. 2009).

The same year, after receiving a report from the Institute of Medicine recommending that warning labels be changed for the first time since 1984, Congress passed legislation specifying the text, size, and placement of new warning labels, and directed the FDA to choose pictorial images to illustrate the warnings. *See* 15 U.S.C. § 1333(d). The warning labels reflect the unique magnitude of the problem they address—*i.e.*, the deadly and addictive nature of the product and the unparalleled threat this product and its marketing pose to American youth. As explained below, the government has a significant interest in informing the public about potential harms, which includes ensuring that consumers know the dangers of smoking. The First Amendment, moreover, does not prevent the government from requiring that dangerous and addictive products and their advertising carry warning labels that effectively inform consumers of the risks they will bear if they choose to use those products.

I. THE FDA HAS A SUBSTANTIAL INTEREST IN INFORMING CONSUMERS' UNDERSTANDING OF THE DANGERS OF SMOKING

It is well-established that the government has a valid and substantial interest in informing the public about health risks, including the lesser-known health risks of tobacco. This government interest amply justifies the warning requirements challenged here as allegedly violating Plaintiffs' First Amendment rights, whether the Court applies the First Amendment standard of *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), applicable to mandatory factual disclosures,

or the "intermediate scrutiny" of *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Commission of New York*, 447 U.S. 557 (1980), applicable to restrictions on commercial speech..

Indeed, the *Amici* States regularly defend (and courts consistently uphold) against First Amendment challenges state laws that have the purpose of imparting information to the public. The Plaintiffs, however, reject this rationale as a valid governmental interest and contend that "[t]he point of informing consumers about risks is to create more informed decision-making—but to show that the Rule facilitated better decisions, FDA would have to show that consumers would appreciate risks differently or make different choices." Pl. Br. at 55-56. But this argument—which would create a novel and dangerous prerequisite to disclosure requirements—has no basis in precedent and would undermine the *Amici* States' ability to defend against First Amendment challenges to their laws that impose such requirements.

A. Governments Have a Substantial Interest in Providing Consumers with Accurate and Relevant Information to Guide Their Purchasing Decisions

The government has a substantial interest in informing consumers about the health risks of using tobacco by requiring warnings on cigarette packages and advertising of cigarettes. "The Supreme Court has said 'there is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial," *Edenfield v. Fane*, 508 U.S. 761, 113 S.Ct. 1792, 123 L.Ed.2d 543 (1993), and that government has a substantial interest in 'promoting the health, safety, and welfare of its citizens,' *Rubin v. Coors Brewing Co*., 514 U.S. 476, 115 S.Ct. 1585, 131 L.Ed.2d 532 (1995)." *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999). This interest is particularly salient here in view of the decades of deception by the tobacco industry concerning the health consequences of using tobacco products, as extensively documented in *United States v. Philip Morris, supra*. Moreover, the court in that case found in 2006 that "Defendants have not ceased engaging in unlawful activity," and that there was a

reasonable likelihood that they would continue to do so in the future. 449 F. Supp. 2d at 910.

The Plaintiffs argue that the government's rationale for the graphic health warnings—informing consumers about the health risks of tobacco products—is not a valid or substantial one absent a demonstration that the warnings affect consumer behavior. This argument, though, is belied by the language of the Cigarette Advertising and Labeling Act, which makes clear that Congress's express purpose is to inform the public regarding any adverse health effects of cigarette smoking:

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby . . . the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes.

15 U.S.C. § 1331. Nor is this goal an aberration. As discussed below, numerous federal, state, and local laws require that the public be informed of a product's potential adverse health or safety effects, or of other important product information.

B. There Are Many Laws Whose Primary Purpose Is to Inform Consumers of Relevant Product Information

There are many laws requiring the disclosure of health, safety, or other relevant information where the government's primary interest, whether it be federal, state, or local, is in accord with the First Amendment value of providing consumers with information to enable them to be fully informed about the products they purchase so that they are empowered to make well-informed decisions about their own health, safety, and well-being. Such laws are enacted because the government—rather than mandate or prohibit consumers' choices—opts instead to ensure that consumers are able to consider fully the risks and other consequences from using a product or service before they make their own choices whether or not to use it, even if the information does

not actually change consumers' ultimate decisions or address misleading advertising. These laws may be intended to improve consumer health or prevent deception, but their primary purpose is to inform the public of relevant information to allow the public to make educated decisions. Accordingly, they are justified by a substantial government interest.

Based on their experience, the *Amici* States have long known that maintaining well-informed consumers is itself an important public goal. To this end, federal, state, and local governments have passed numerous disclosure laws designed to promulgate truthful factual information about the risks to safety, heath, or the environment from certain products or services, even in situations where, unlike here, there is no history of consumer deception. As the First Circuit observed: "There are literally thousands of similar regulations on the books, such as product labeling laws, environmental spill reporting, accident reports by common carriers, [and] SEC reporting as to corporate losses." *Pharm. Care Mgmt. Ass'n v. Rowe,* 429 F.3d 294, 316 (1st Cir. 2005) (concurring opinion).

For example, regulators require warning labels about products that may contain chemicals or other hazardous materials. *E.g.*., 15 U.S.C. § 2605(a)(3) (authorizing the EPA to require warning labels on chemicals); 21 C.F.R. § 201.57 (FDA mandated drug warning labels, including warnings for specific hazards); N.Y. Envtl. Conserv. Law § 33-0707 (authorizing regulators to require disclosure of pesticide formulas); N.Y. Envtl. Conserv. Law § 37-0915, et seq. (disclosure of chemicals in children's products). Federal, state, and local laws mandate that establishments or companies that sell alcoholic beverages warn patrons that drinking alcohol may cause health problems and birth defects. *E.g.*, 27 C.F.R. § 16.21; 24 Rules of City of N.Y. § 1-01 (alcohol). And regulations mandate that certain sellers fully inform consumers about policies regarding product warranties or payment refunds. *E.g.*, 16 C.F.R. § 455.2 (Federal Trade Commission

mandates for automobile dealers, requiring warranty information in "Buyers' Guides"); N.Y. Gen. Business Law § 218-A (requiring retail mercantile establishments to post refund policies).

Examples of courts upholding these laws in First Amendment cases are not difficult to find. In *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc) ("AMI"), the D.C. Circuit upheld a federal law mandating disclosure of country-of-origin information for food products, including meat. The court explained that consumers may be interested in buying products from their own country, or perhaps avoiding food from other countries due to potential deleterious effects on their health. *AMI*, 760 F.3d at 23. The court did not consider whether the required information would actually result in a change in consumer behavior, and the government was not required to show that it would. As the D.C. Circuit observed, requiring evidence of a measure's effectiveness in applying *Zauderer* "is hardly necessary when the government uses a disclosure mandate to achieve a goal of informing consumers about a particular product trait, assuming of course that the reason for informing consumers qualifies as an adequate interest." *Id*. at 26.

In *Nat'l Elec. Manuf. Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001), the Second Circuit upheld a Vermont statute requiring manufacturers to place labels on their packaging that informed their customers of the mercury in their products, and to advise consumers that the packages should be recycled. The court noted that such "disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the 'marketplace of ideas.' Protection of the robust and free flow of accurate information is the principal First Amendment justification for protecting commercial speech, and requiring disclosure of truthful information promotes that goal." Id. at 114. The court reasoned that the law was justified by its purpose to "better inform consumers about the products they purchase" and therefore was "inextricably intertwined with the goal of increasing consumer awareness of the presence of

mercury in a variety of products." *Id*. at 115. *Accord Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2376 (2018) (Court did not question "the legality of health and safety warnings long considered permissible").

C. The Court Should Defer to Congress on the Details of the Graphic Warnings

The Plaintiffs complain that the size and placement of the graphic warnings make the Rule unduly burdensome. Pl. Br. at 42-46. In these matters, the court should defer to Congress's judgment that the size and placement of the graphic warnings are appropriate.

Congress has the benefit of decades of experience in regulating tobacco companies' advertisements and the adequacy of their health warnings, having first implemented rules in 1965. *See* Pub. L. No. 89-92. It is based on that extensive experience that Congress determined that "[t]he current Surgeon General warnings on tobacco products are ineffective in providing adequate warnings about the dangers of tobacco products." H.R. REP. NO. 111-58(I), at 4 (2009). Congress is therefore the best institution to "amass and evaluate the vast amounts of data" on the issue, and deference should be accorded to its judgment. *Walters v. National Ass'n of Radiation Survivors*, 473 U.S. 305, 331 n.12 (1985); *see Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 196 (1997) ("Even in the realm of First Amendment questions . . . deference must be accorded to [Congress'] findings as to the harm to be avoided and to the remedial measures adopted for that end.").

CONCLUSION

The States as *amici curiae* respectfully request that the Court grant Defendants' cross-motion for summary judgment, deny Plaintiffs' motion for summary judgment, and deny—as moot or on the merits—Plaintiffs' motion for a preliminary injunction.

Respectfully submitted,

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PHIL WEISER
Attorney General
State of Colorado

/s/ Eric R. Olson
Eric R. Olson
Solicitor General
State of Colorado
1300 Broadway, 10th Floor
Denver, CO 80203
(720) 508-6000

TOM MILLER
Attorney General
State of Iowa
1305 E. Walnut
Des Moines, IA 50319

LAWRENCE WASDEN
Attorney General
State of Idaho
700 W. Jefferson Street
Boise, ID 83720

(counsel listing continues on next two pages)

CLYDE "ED" SNIFFEN, JR.
Acting Attorney General
State of Alaska
1031 W. 4th Avenue, Suite 200
Anchorage, AK 99501

XAVIER BECERRA
Attorney General
State of California
1300 I Street, Suite 1740
Sacramento, CA 95814

WILLIAM TONG
Attorney General
State of Connecticut
165 Capitol Avenue
Hartford, CT 06106

KARL A. RACINE
Attorney General
District of Columbia
400 6th Street N.W.
Washington, D.C. 20001

KATHLEEN JENNINGS
Attorney General
State of Delaware
820 N. French Street
Wilmington, DE 19801

CLARE E. CONNORS
Attorney General
State of Hawai'i
425 Queen Street
Honolulu, HI 96813

KWAME RAOUL
Attorney General
State of Illinois
100 West Randolph Street
Chicago, Illinois 60601

DEREK SCHMIDT
Attorney General
State of Kansas
120 S.W. 10th Avenue, 2nd
Floor Topeka, KS 66612

JEFF LANDRY
Attorney General
State of Louisiana
P.O. Box 94095
Baton Rouge, LA 70804

AARON FREY
Attorney General
State of Maine
State House Station 6
Augusta, ME 04333

BRIAN E. FROSH
Attorney General
State of Maryland
200 Saint Paul Place
Baltimore, MD 21202

MAURA HEALEY
Attorney General
Commonwealth of Massachusetts
One Ashburton Place
Boston, MA 02108

DANA NESSEL
Attorney General
State of Michigan
P.O. Box 30212
525 W. Ottawa Street
Lansing, MN 48909

KEITH ELLISON
Attorney General
State of Minnesota
102 State Capitol
75 Rev. Dr. Martin Luther King, Jr.
Boulevard
St. Paul, MN 55155

TIM FOX
Attorney General
State of Montana
215 N. Sanders
Helena, MT 59620

AARON D. FORD
Attorney General
State of Nevada
100 N. Carson Street
Carson City, NV 89701

GURBIR S. GREWAL
Attorney General
State of New Jersey
25 Market Street
P.O. Box 080
Trenton, NJ 08625

HECTOR BALDERAS
Attorney General
State of New Mexico
P.O. Drawer 1508
Santa Fe, NM 87504

LETITIA JAMES
Attorney General
State of New York
28 Liberty Street
New York, NY 10005

JOSHUA H. STEIN
Attorney General
State of North Carolina
P.O. Box 629
Raleigh, NC 27602

ELLEN F. ROSENBLUM
Attorney General
State of Oregon
1162 Court Street NE
Salem, OR 97301

PETER F. NERONHA
Attorney General
State of Rhode Island
150 S. Main Street
Providence, RI 02903

SEAN REYES
Attorney General
State of Utah
State Capitol, Room 236
Salt Lake City, UT 84114

TJ DONOVAN
Attorney General
State of Vermont
109 State Street
Montpelier, VT 05609

MARK HERRING
Attorney General
Commonwealth of Virginia
202 North Ninth Street
Richmond, VA 23219

ROBERT W. FERGUSON
Attorney General
State of Washington
1125 Washington Street SE
PO Box 40100
Olympia, WA 98504