IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY, et al., *Plaintiffs,*	)	
v.	)	Civil Action No. 6:20-cv-00176
UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., *Defendants.*	)	

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

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PRELIMINARY STATEMENT AND INTEREST OF THE *AMICI CURIAE*

Amici curiae are the States of Illinois, Idaho, Alaska, California, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, 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 Combined Cross-Motion for Summary Judgment and opposition to Plaintiffs' Motion for Summary and a Preliminary Injunction. 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 Plaintiffs R.J. Reynolds Tobacco Company; Santa Fe Natural Tobacco Company, Inc.; ITG Brands, LLC; and Liggett Group 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] Four other States—Florida, Minnesota, Mississippi, and Texas—settled their claims against the tobacco companies before the MSA was

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

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.

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, while 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 and the other settlements are powerful tools, but they work 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.

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 this is not a valid substantial interest. 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 spurious First Amendment attacks.

ARGUMENT

This case involves the deadliest product sold in America, and one of the most addictive. Over forty years of experience with small, obscurely placed, and text-only warning labels on cigarette packs has demonstrated that they simply do not work; studies confirm 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 thought 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, 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 lethal and addictive products carry warning labels that effectively inform consumers of the risks those products entail.

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 interest in informing the public about health risks, including the lesser known health risks of tobacco, and that this interest justifies the warning requirements challenged here as allegedly violating Plaintiffs' First Amendment rights. Indeed, the *Amici* States regularly defend (and courts consistently uphold) state laws that have the purpose of imparting information to the public. The Plaintiffs, however, attempt to sidestep this precedent by asserting that the government may only assert a valid informational interest if it has first proven a propensity for a change in behavior when consumers receive the required information. R.J. Reynolds Brief at 3. But this argument—which would create a novel and dangerous prerequisite to disclosure requirements—has no basis in precedent and is contrary to the *Amici* States' shared experience in defending similar state laws.

A. The Graphic Warning Labels Are Intended To Inform Consumers Of Relevant Information About the Health Consequences of Using Cigarettes.

As an initial matter, 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 Plaintiffs argue that the government's rationale for the graphic health warning—informing consumers about the health risks of tobacco products—is disingenuous, and that its actual purpose is to discourage smoking. R.J. Reynolds Brief at 3. This argument, though, is belied by the language of the Cigarette Advertising and Labeling Act, which makes clear that Congress' 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 inform the public 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.

The Plaintiffs further claim that, "the government has no substantial interest in improving the public's understanding [of the risks of tobacco use] for its own sake, without any accompanying change in behavior," R.J. Reynolds Brief at 3, or prevention of consumer deception, *id.* at 19-22. This is incorrect. 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 providing consumers with information to enable consumers 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 has a substantial interest in ensuring that consumers are able to consider fully the risks and other consequences from using a product or service before they choose to use it—and can therefore protect their own health, safety, and economic interests—even if the information does not actually change consumers' ultimate decisions or address misleading advertising.

The *Amici* States have long known based on their experience 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. 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). 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). 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. As such, they are justified by a substantial government interest.

Examples of courts upholding these laws in First Amendment cases are not difficult to find. In *American Meat Institute v. Department of Agriculture*, 760 F.3d 18(D.C. Cir. 2014) (en banc), 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 translate to a change in consumer behavior, and the government was not required to show that it would. In *National Electric Manufacturers 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 that the packages be recycled. 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. R.J. Reynolds Brief at 39-41. In these matters, the court should defer to Congress' 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 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.").

II. THE PROPOSED WARNING LABELS ARE CONSISTENT WITH THE FIRST AMENDMENT.

As discussed, the government has a substantial interest in implementing a requirement that the Plaintiffs, as commercial speakers, disclose factual information to their consumers about the potential adverse health effects of their products. Because this disclosure does not prohibit commercial speech, but rather promotes the "free flow of commercial information," *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985), the proper test is whether "the disclosure requirements are reasonably related to the State's interest[,]" *id*. at 651. This constitutional test is lenient because the proposed warning labels serve the public interest of disclosing beneficial consumer information and are "consistent with the reasons for according constitutional protection

to commercial speech." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996) (plurality op.). In any event, because the government action was undertaken in part to counteract decades of deceptive conduct, the warning labels would survive even under the Plaintiffs' view of the applicable standard.

A. The Proposed Warning Labels Satisfy The *Zauderer* Standard.

One of the key issues in this case is the breadth of the *Zauderer* standard. The *Amici* States agree with the government that the reasoning of *Zauderer* supports a broad interpretation. To support its ruling in *Zauderer*, the Court reasoned that, "[because] the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, appellant's constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Zauderer*, 471 U.S. at 651 (emphasis added). This cuts against the Plaintiffs' argument that *Zauderer*'s test should be limited to cases where the government relies on an interest in preventing consumer deception. R.J. Reynolds Brief at 20. As the D.C. Circuit noted, "*Zauderer*'s characterization of the speaker's interest in opposing forced disclosure of such information as 'minimal' seems inherently applicable beyond the problem of deception as other circuits have found." *Am. Meat Inst. v. USDA* ("AMI"), 760 F.3d 18, 22 (D.C. Cir. 2014). *See also AM Beverage Ass'n v. City & City of San Francisco*, 916 F.3d 749, 755-56 (9th Cir 2019) (en banc) (collecting cases confirming that interests other than deception can support disclosure requirements).

Other courts have also declined to limit *Zauderer* in the way the Plaintiffs propose. *See Disc. Tobacco City & Lottery, Inc. v. United States,* 674 F.3d 509, 556 (6th Cir. 2012), *cert. denied,* 133 S. Ct. 1996 (2013) ("*Zauderer*'s framework can apply even if the required disclosure's purpose is something other than . . . preventing consumer deception."); *Envtl. Def. Ctr., Inc. v. EPA*, 344 F.3d 832, 849 (9th Cir. 2003) (applying *Zauderer* to disclosure requirement informing public about

potential impact of stormwater discharge where there was no danger of consumer deception); *see also Beeman v. Anthem Prescription Mgmt., LLC,* 315 P.3d 71, 89 (Cal. 2013) ("Laws requiring a commercial speaker to make purely factual disclosures related to its business affairs, whether to prevent deception *or simply to promote informational transparency* . . . do not warrant intermediate scrutiny," but rather rational basis review) (emphasis added). These courts recognize what the Plaintiffs miss: *Zauderer* speaks to a wider range of government interests beyond simply correcting deception.

B. The Proposed Warning Labels Seek To Counter The Effects Of Conduct That Has Been Found To Be Deceptive, Fraudulent, And Ongoing.

While *Zauderer* should be applied more broadly than simply in cases involving deception, this case clearly satisfies the *Zauderer* test even under the Plaintiffs' narrower reading.

Media and advertising affect how those consuming it view the world. "The structure and content of the media undoubtedly cultivate certain tastes, expectations, and habits on the part of the audience." Webster, J. G., & Phalen, P., *The Mass Audience: Rediscovering the Dominant Model* (1997), at 46. "[B]ecause people learn how to act, at least in part, by observing what happens in the media, the media often help set the tone for how they act." *Philip Morris*, 449 F. Supp. 2d at 575. In *Philip Morris*, the court found the defendant tobacco companies "over the past fifty years, spent vast sums of money on advertising and promotion, ensuring that their brand imagery would be repeated frequently and in as many different media as possible so that the message is received by the maximum number of smokers and potential smokers." *Id.* The district court further found that many of the "fraudulent, deceptive, and misleading statements" made by the defendant tobacco companies were issued as "press releases, paid newspaper statements, pamphlets, and similar documents in the name of the corporate Defendants themselves," citing one particularly egregious example of a 1994 advertisement in the *New York Times* by Philip Morris "containing

misleading and deceptive statements on nicotine and addiction titled, 'Facts You Should Know.'" *Id.* at 895.

In view of the extensive findings in the *Philip Morris* case, and others, the Plaintiffs have no basis to argue that they have not engaged in deception. R.J. Reynolds Brief at 21. For that reason, the FDA warning labels should be evaluated in the context of the decades of egregious and purposefully deceptive advertisements meant to mislead the public about the dangers of cigarette use. *See, e.g.*, *Philip Morris*, 449 F. Supp. 2d at 146-383, 430-560, 692-839 (detailing the myriad ways in which tobacco companies, including Plaintiffs R.J. Reynolds and Liggett, have deceived the public for decades); *People ex rel. Lockyer v. R.J. Reynolds Tobacco Co.*, 116 Cal. App. 4th 1253 (Cal. Ct. App. 2004) (finding that R.J. Reynolds marketed its product to youth, in violation of subsection III(a) of the MSA); *State of Vermont v. R. J. Reynolds Tobacco Co.*, Vermont Superior Court, Chittenden Unit Dkt. #S1087-05 CnC (March 10, 2010) (finding that R.J. Reynolds violated subsection III(r) of the MSA, which prohibits deceptive claims regarding the health effects of cigarettes, when it marketed its Eclipse cigarette as less harmful than traditional cigarettes).

Courts have long recognized the necessity, and constitutionality, of such a contextual approach to governmentally prescribed communication to consumers. Even with regard to a far less serious legacy of misrepresentation, for example, the U.S. Court of Appeals for the D.C. Circuit noted the need for effective corrective speech:

> To be sure, current and future advertising of Listerine, when viewed in isolation, may not contain any statements which are themselves false or deceptive. But reality counsels that such advertisements cannot be viewed in isolation; they must be seen against the background of over 50 years in which Listerine has been proclaimed—and purchased—as a remedy for colds. When viewed from this perspective, advertising which fails to rebut the prior

> claims as to Listerine's efficacy inevitably builds upon those claims; continued advertising continues the deception, albeit implicitly rather than explicitly . . . .
>
> Under this reasoning the First Amendment presents no direct obstacle. The Commission is not regulating truthful speech protected by the First Amendment, but is merely requiring certain statements which, if not present in current and future advertisements, would render those advertisements themselves part of a continuing deception of the public.

Warner-Lambert Co. v. FTC, 562 F.2d 749, 769 (D.C. Cir. 1977) (upholding FTC order requiring manufacturer to include in its advertisements the disclaimer "Listerine will not help prevent colds or sore throats or lessen their severity"); *see also Novartis Corp. v. FTC*, 223 F.3d 783, 789 (D.C. Cir. 2000) (applying standard in context of drug advertising).

Given the long history and pervasive effects of tobacco industry deceit and its effect on consumer perceptions, even cigarette advertising and brand imagery that would not appear deceptive in isolation constitutes "part of a continuing deception of the public," *Warner-Lambert*, 562 F.2d at 769, absent highly visible, vividly conveyed warnings. *See Philip Morris*, 449 F. Supp. 2d at 927 (finding this precedent "particularly applicable" to cigarette advertising). As the court of appeals in *Philip Morris* found:

> [w]hen deciding whether to smoke cigarettes, tobacco consumers must resolve initial reservations (or lingering qualms) about the potential for cancer, the risk of addiction, or the hazardous effects of secondhand smoke . . . . Defendants' prevarications about each of these issues suggests full awareness of this obvious fact; reasonable purchasers of cigarettes would consider these statements important.

United States v. Philip Morris USA Inc., 566 F. 3d 1095, 1123 (D.C. Cir 2009).

The FDA's graphic warning labels at issue in this case provide more information to the public about the potential health consequences of smoking, information that could help counteract

the effect that decades of deception by the cigarette manufacturers have had on the public. The opinion of the district court in *Phillip Morris* underscores the necessity of these warnings:

> Defendants understood that most individuals, when starting to smoke, do not adequately appreciate the full risk associated with smoking to make an informed decision about whether or not to engage in smoking behavior. In fact, the evidence shows that most people's knowledge of the nature and consequences of diseases caused by smoking tends to be superficial . . . .
>
> Using the sophisticated and well-organized machinery created to serve their agenda, Defendants fraudulently denied the adverse health effects of smoking for at least 40 years in order to sustain the appearance of an open controversy about the link between smoking and disease, and thereby maintain and enhance the cigarette market and their collective revenues.

449 F. Supp. 2d 1 at 856. That conspiracy created a social context that made it attractive for consumers, particularly vulnerable young people, to experiment with cigarettes. The sordid history of deceitful marketing laid out in excruciating detail in *Philip Morris* wholly justifies the FDA's proposed warning labels even under the Defendants' constricted interpretation of *Zauderer.*

Death and Disease. Eight of the FDA's warning labels inform consumers clearly and directly of the death and disease resulting from smoking. They state, respectively:

(a) "WARNING: Smoking causes head and neck cancer" accompanied by an image of the head and neck of a woman in her fifties who has a visible neck cancer tumor protruding from the right side of her neck just below her jawline caused by cigarette smoking;

(b) "WARNING: Smoking causes bladder cancer, which can lead to bloody urine" accompanied by an image showing a gloved hand holding a urine specimen cup containing bloody urine resulting from bladder cancer caused by cigarette smoking;

(c) "WARNING: Smoking can cause heart disease and strokes by clogging arteries" accompanied by an image of a . . . man in his sixties in an open hospital gown who has

a large, recently-sutured incision running down the middle of his chest and is undergoing post-operative monitoring;

(d) "WARNING: Smoking causes COPD, a lung disease that can be fatal" accompanied by an image of a . . . man in his fifties with an oxygen tank and a nasal canula under his nose supplying oxygen;

(e) "WARNING: Smoking reduces blood flow, which can cause erectile dysfunction" accompanied by an image of a …man in his fifties sitting on the edge of a bed, leaning forward, one elbow resting on each knee, his head is tilted down, with his forehead pressed into the knuckles of his right hand and his female partner behind him looking off in another direction;

(f) "WARNING: Smoking reduces blood flow to the limbs, which can require amputation" accompanied by an image depicting the feet of a person who had several toes amputated due to tissue damage resulting from peripheral vascular disease caused by cigarette smoking;

(g) "WARNING: Smoking causes type 2 diabetes, which raises blood sugar" accompanied by an image of a personal glucometer device being used to measure the blood glucose level of a person with type 2 diabetes caused by cigarette smoking; and

(h) "WARNING: Smoking causes cataracts, which can lead to blindness" accompanied by an image depicting a close-up of the face of an approximately 65 year old man whose right pupil has a large cataract caused by cigarette smoking.

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 15638 (Mar, 18, 2020) (to be codified at 21 C.F.R. pt. 1141).

In *Philip Morris*, the district court found that by at least January 1964 the defendant tobacco companies "knew there was a consensus in the scientific community that smoking caused lung cancer and other diseases. Despite that fact, they publicly insisted that there was a scientific controversy and disputed scientific findings linking smoking and disease knowing their assertions were false." 449 F. Supp. 2d at 279. The district court then detailed how, for decades, the defendant tobacco companies continued to deny and obfuscate the link between cigarette smoking and the litany of health effects it causes all the while acknowledging the validity of the link internally. *Id.* at 279-330. The district court's exhaustive findings in *Philip Morris* concluded that "[c]igarette smoking causes disease, suffering, and death. Despite internal recognition of this fact, Defendants have publicly denied, distorted and minimized the hazards of smoking for decades." *Id.* at 146. Accordingly, the FDA warnings are necessary and justified as an effort to counteract this deception.

Secondhand Smoke. Two of the warning labels concern the effects of secondhand smoke. The text of the warning labels state:

> (a) "WARNING: Tobacco smoke can harm your children," and is accompanied by an image showing an 8- to 10-year-old boy wearing a hospital gown and receiving a nebulizer treatment for chronic asthma resulting from secondhand smoke exposure; and
>
> (b) "WARNING: Tobacco smoke causes fatal lung disease in Nonsmokers," and is accompanied by an image showing a pair of diseased lungs containing cancerous lesions from chronic secondhand smoke exposure. 85 Fed. Reg. 15638.

These warnings also counteract cigarette company deception. The district court in *Philip Morris* found that "Defendants crafted and implemented a broad strategy to undermine and distort the evidence indicting [secondhand smoke] as a health hazard." 449 F. Supp. 2d at 693. The district

court made voluminous findings documenting defendant tobacco companies' misrepresentation of evidence regarding secondhand smoke. *Id.* at 692-839. It found that even during the litigation, the defendant tobacco companies denied that secondhand smoke causes disease in nonsmokers, and R.J. Reynolds' website stated at the time "that there are still legitimate scientific questions concerning the reported risks of secondhand smoke." *Id.* at 795. The website further stated:

> Considering all of the evidence, in our opinion, it seems unlikely that secondhand smoke presents any significant harm to otherwise healthy nonsmoking adults at the very low concentrations commonly encountered in their homes, offices and other places where smoking is allowed. We recognize that exposure to high concentrations of secondhand smoke may cause temporary irritation, such as teary eyes, and even coughs and wheezing in some adults. In addition, there is evidence that secondhand smoke, like other airborne irritants, or allergens such as pollen and dust may trigger attacks in asthmatics.

Id. In affirming the district court's decision, the court of appeals found that "[d]efendants became aware that secondhand smoke poses a health risk to nonsmokers but made misleading public statements and advertisements about secondhand smoke in an attempt to cause the public to doubt the evidence of its harmfulness." *United States v. Philip Morris USA Inc.*, 566 F. 3d 1095, 1108 (D.C. Cir 2009).

Smoking during pregnancy. The text of another warning label states: "WARNING: Smoking during pregnancy stunts fetal growth," and is accompanied by an image of a newborn infant on a medical scale, and the digital display on the scale reads four pounds. 85 Fed. Reg. 15638. The court of appeals in *Philip Morris* found that "'Defendant companies willfully stat[ed] something which they knew to be untrue.' For example, the [district] court found that, in a televised interview in 1971, Philip Morris President Joseph Cullman III denied that cigarettes posed a health hazard to pregnant women or their infants, 'contradicting the information . . . Philip Morris's Vice

President for Corporate Research and Development, had given him two years earlier.'" 566 F. 3d at 1118-19 (quoting 449 F. Supp. 2d at 193-94, 895). Cullman, backed by the industry-controlled Tobacco Institute, notoriously observed that the lower birth-weight of smokers' babies was not a matter of concern because "[s]ome women would prefer to have smaller babies." 449 F. Supp. 2d at 193-94.

The scope of the deception perpetrated by major tobacco companies that are parties to this case, including its devastating impact on millions of Americans, its duration, its continuing effect on the more than 40 million Americans who smoke, and its potential effect on future generations of American youth, is highly relevant in determining the appropriateness of warnings designed to counter these effects. The Plaintiffs argue that are not deceiving consumers regarding the harmful nature of their products. R.J. Reynolds Brief at 22. Their decades of deception have not been undone. Because the graphic FDA warnings serve their crucial function of informing the public of the health consequences of smoking, and overcoming decades of deceit, they fully comport with the First Amendment.

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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