UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,	)	
Plaintiff,	)	**Civil Action No. 99-2496 (GK)**
v.	)	
PHILIP MORRIS USA INC., *et al.*,	)	
Defendants.	)	

DEFENDANTS' MOTION FOR VACATUR

When issuing its injunctions in this case, this Court questioned "whether this litigation was the best vehicle for attempting to hold Defendants accountable" and to "address [the] broad-scale economic and social problems" at issue. *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1, 31 n.3 (D.D.C. 2006). It "might be far better and more appropriat[e]," the Court recognized, for "the body elected by the people, namely Congress, [to] step up to the plate and address national issues with such enormous economic, public health, commercial, and social ramifications." *Id.*

Congress did precisely that when it enacted the Family Smoking Prevention and Tobacco Control Act ("Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009). In explicit reliance on the findings of this Court, the Act establishes a far-reaching federal regulatory program governing the design, manufacturing, marketing, and distribution of tobacco products and the public dissemination of information about the health effects and addictiveness of smoking. § 2(47)-

(49).[1] The Act provides that the Food and Drug Administration ("FDA") is to be the "primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products" (§ 3(1)); creates a new Center for Tobacco Products to implement the Act's detailed regulatory mandates through administrative procedures analogous to those used to oversee other FDA-regulated products (§ 901(e)); and establishes "comprehensive restrictions on the sale, promotion, and distribution of [tobacco] products" in advance of further regulations to be promulgated by the FDA. §§ 2(6), 3(1). The Act requires tobacco manufacturers to pay hundreds of millions of dollars in annual "user fees" to fund the FDA's tobacco program (§ 919), and provides the FDA with an array of powerful enforcement tools to ensure manufacturers' compliance with the Act, including civil penalties, mandatory requests for information, no-tobacco-sale orders, and criminal investigations. §§ 103, 904(b); 21 U.S.C. § 331.

This newly established federal regulatory framework extinguishes the Court's jurisdiction over this case in whole (or, at least, in significant part). Under Article III of the Constitution and Section 1964(a) of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), this Court possesses jurisdiction to issue injunctive relief only where there is a "realistic threat" that the challenged activity will recur in the "reasonably near future" (*City of Los Angeles v. Lyons*, 461 U.S. 95, 106 n.7, 108 (1983)) and where the relief will "prevent and restrain" likely future RICO violations. 18 U.S.C. § 1964(a); *see also United States v. Philip Morris USA Inc.*, 396 F.3d 1190, 1198 (D.C. Cir. 2005) ("*Disgorgement Opinion*"). Neither of these jurisdictional

[1] All citations to the Family Smoking Prevention and Tobacco Control Act are to the section of the Act itself (reproduced at 123 Stat. 1776), except in the case of Section 101(b) of the Act, which amends Chapter IX of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* That section is cited through references to Sections 900 to 919 of the amended FDCA.

requirements is satisfied here because the extensive federal regulatory program established and funded by the Act eliminates any reasonable likelihood that Defendants will engage in future joint racketeering activity of the type this Court found and on which it premised its forward-looking injunctive relief. Because the Act moots the Government's claims, the Court should vacate its injunctions and underlying factual findings, and dismiss the case in its entirety.

Moreover, even if the Court retains jurisdiction over some aspects of this case, it should decline to exercise that jurisdiction because the Act vests the FDA with primary jurisdiction over the design, manufacturing, marketing, and distribution of tobacco products. The FDA possesses unique regulatory expertise in matters of public health. If the Court were to exercise overlapping regulatory authority with respect to tobacco products, there would be an unacceptable risk of inconsistent regulatory determinations that would impair the FDA's role as the "primary Federal regulatory authority" in this area.

At a minimum, the Court should vacate or modify specific aspects of its injunctions. Even if the Court possesses jurisdiction over some portions of this case and can exercise that jurisdiction without impairing the FDA's regulatory primacy, several elements of the injunctions—including the prohibitions on the use of "light" and "low tar" descriptors and the requirement that Defendants make corrective statements about the health risks of smoking—are both plainly beyond this Court's jurisdiction and manifestly incompatible with the FDA's regulatory authority.

PROCEDURAL BACKGROUND

1. The United States filed this suit in 1999, alleging that Defendants violated RICO by associating together to operate a racketeering enterprise for the purpose of deceiving the American public about the health effects and addictiveness of tobacco products. After a bench

trial, this Court found that Defendants had violated RICO and that there was a reasonable likelihood that Defendants would violate RICO in the future. *See Philip Morris USA Inc.*, 449 F. Supp. 2d at 908-13. Based on its findings regarding the likelihood of future RICO violations, the Court entered a series of injunctions that restrain Defendants' future speech and conduct. The injunctions require Defendants to obey the law by refraining "from committing any act of racketeering . . . relating in any way to the manufacturing, marketing, promotion, health consequences or sale of cigarettes" and from making "any material false, misleading, or deceptive statement or representation . . . that misrepresents or suppresses information concerning cigarettes." *Id.* at 938. The injunctions also specifically require, among other things, that Defendants remove "light" and "low tar" descriptors from the packages and brand names of their cigarettes and publicly disseminate corrective statements about the health effects of smoking. *Id.* at 938-39.

On appeal, the D.C. Circuit affirmed in substantial part, but vacated portions of the remedial order and remanded for further proceedings. *See United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1150 (D.C. Cir. 2009).

2. Following the D.C. Circuit's decision, Congress enacted the Family Smoking Prevention and Tobacco Control Act, which grants the FDA sweeping regulatory authority over virtually every aspect of Defendants' business. Under the Act, the FDA possesses broad authority to regulate tobacco products, including the tar, nicotine, and other constituent yields of tobacco products and the ingredients used in those products; to require Defendants to report and disclose information about the health effects and addictiveness of tobacco products; to review and authorize new or modified tobacco products prior to their introduction; to regulate the manufacturing of tobacco products; and to regulate tobacco product labeling and advertising.

More specifically, the Act authorizes the FDA "to set national standards controlling the manufacture of tobacco products" (§ 3(3)), and "to regulate the levels of tar, nicotine, and other harmful components of tobacco products." §§ 3(5), 907(a)(4). The Act also imposes detailed reporting and disclosure requirements on tobacco companies. For example, manufacturers are required to submit to the FDA a "listing of all ingredients, including tobacco, substances, compounds, and additives that are . . . added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand." § 904(a)(1). Moreover, the FDA is authorized to require the testing of tobacco products' "constituents, ingredients, and additives" (§ 915(b)(1)), and to order manufacturers to make public disclosures "relating to the results of the testing of tar and nicotine through labels or advertising or other appropriate means." § 915(b)(2).

The Act's advertising and labeling requirements are equally extensive. The Act prohibits the use of tar and nicotine descriptors, such as "light," "mild," or "low," in cigarette brand names and advertising, absent explicit FDA authorization. § 911(a), (b), (g)(1). Such authorization can only be granted where the FDA determines that the product will "significantly reduce harm and the risk of tobacco-related disease to individual users; and benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." § 911(g)(1).

The Act also required the FDA to promulgate regulations restricting the sale, distribution, and use of cigarettes. § 102; *see also* 21 C.F.R. § 1140.2. Those regulations went into effect on June 22, 2010, and, among other things, prohibit the sale of cigarettes to persons under the age of 18 and impose a range of restrictions on the marketing, labeling, and advertising of cigarettes. For example, manufacturers may not distribute branded merchandise (such as t-shirts and hats), offer non-tobacco product gifts in consideration for the purchase of cigarettes, or conduct a

sponsorship in the name of a cigarette brand. 21 C.F.R. § 1140.34(a)-(c); *see also* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 75 Fed. Reg. 13,225 (Mar. 19, 2010). Pursuant to its regulatory mandate, the FDA is currently considering regulations that would impose restrictions on the location and content of outdoor cigarette advertising. *See* Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act, 75 Fed. Reg. 13,241 (Mar. 19, 2010).

The Act further specifies a series of warnings that must appear on all cigarette packages and advertising. § 201(a). Those warnings include: "WARNING: Cigarettes are addictive"; "WARNING: Tobacco smoke can harm your children"; "WARNING: Cigarettes cause fatal lung disease"; "WARNING: Cigarettes cause cancer"; and "WARNING: Smoking can kill you." *Id.* The warning must comprise the top 50% of both the front and rear of the package "in a manner that contrasts, by typography, layout, or color, with all other printed material on the package," and 20% of all tobacco advertising. § 201(a). The FDA may mandate additional or different warnings if "such a change would promote greater public understanding of the risks associated with the use of tobacco products." § 202(b); *see also* § 906(d)(1).

Within two years of the Act's enactment, the FDA is required to "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the" textual warnings prescribed by Congress. § 201(a). The FDA has published a set of 36 proposed graphic warning labels for public comment. *See* Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524 (Nov. 12, 2010); *see also* http://www.fda.gov/downloads/TobaccoProducts/Labeling/CigaretteProductWarningLabels/UCM232425.pdf (reproducing proposed graphic warnings). According to the FDA, the proposed graphic warnings—in conjunction with the textual warnings established by Congress—"are designed to clearly and

effectively convey the negative health consequences of smoking on cigarette packages and in cigarette advertisements" and "would promote greater public knowledge of the health risks of using cigarettes." 75 Fed. Reg. at 69,526. The FDA also published, and sought comments regarding, the "results from a research study that quantitatively evaluated the relative impact of certain color graphics on consumer attitudes, beliefs, perceptions, and intended behaviors related to cigarette smoking." Required Warnings for Cigarette Packages and Advertisements; Research Report, 75 Fed. Reg. 75,936, 75,936 (Dec. 7, 2010).[2]

In furtherance of its public-education efforts, the FDA intends to spend more than $45 million during Fiscal Year 2011 to "develop and disseminate public education campaigns to decrease initiation of tobacco product use," and to "create and launch a tobacco health literacy program . . . targeted at various populations, with a special emphasis on educating youth and adolescents across racial, ethnic, cultural, and social demographics." FDA, FY 2011 Congressional Budget Request 282, *at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM202324.pdf.

Finally, the Act affords the FDA formidable enforcement authority. The Act creates the Center for Tobacco Products—a new administrative body similar to those that oversee other FDA-regulated industries—to implement the Act's detailed regulatory mandates (§ 901(e)) and requires the FDA to develop an "action plan to enforce" the Act's restrictions and report to Congress regarding the Act's effectiveness. §§ 105, 106. Within the Center for Tobacco Products, the Office of Compliance and Enforcement is responsible for policing manufacturers'

[2] Defendants Altria Group, Inc., Philip Morris USA Inc., R.J. Reynolds Tobacco Co., and Lorillard Tobacco Co. have each filed comments with the FDA raising legal objections to various aspects of the FDA's proposed graphic warnings.

compliance with the Act and is equipped with a powerful arsenal of enforcement tools. *See* Center for Tobacco Products, Enforcement Action Plan for Promotion and Advertising Restrictions 16-19 (2010) (documenting enforcement tools), *at* http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM227882.pdf. For example, the FDA is authorized to remedy violations of the Act by imposing "no-tobacco-sale-order[s]" and severe monetary penalties. § 103. It also has the authority to issue requests compelling manufacturers to submit information in support of FDA investigations. § 904(b); *see also* Letter from Lawrence R. Deyton, Director, Center for Tobacco Products, to Tobacco Product Manufacturers (May 26, 2010) (requesting information from manufacturers regarding their use of menthol in tobacco products), *at* http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm214126.htm. Moreover, the FDA is authorized to inspect tobacco manufacturing facilities, 21 U.S.C. § 374; to detain tobacco products administratively (a tool previously reserved only for medical devices), *id.* § 334(g); to subject tobacco products to import holds, *id.* § 381; and to issue warning letters regarding violations, *see* FDA Regulatory Procedures Manual Ch. 4-1, *at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm. The FDA may also administratively require tobacco manufacturers to issue notification to the public to eliminate unreasonable risks of substantial harm to the public health. 21 U.S.C. § 387h(a).

The FDA has its own criminal investigation arm, the Office of Criminal Investigations ("OCI"). *See* FDA Regulatory Procedures Manual Ch. 6-5, *at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm. Because many violations of the Act are criminal violations under 21 U.S.C. § 331, OCI has broad authority to

investigate manufacturers' activities. The FDA may refer criminal matters to the Department of Justice for prosecution. *Id.* § 335.

The FDA is amply funded and fully staffed to carry out this regulatory mission. The Act requires tobacco manufacturers to pay annual "user fees" of up to $700 million to fund the FDA's regulation of tobacco products. § 919. In Fiscal Year 2011, the FDA will allocate more than $64 million of these user fees to the Center for Tobacco Products' compliance and enforcement activities. FDA, FY 2011 Congressional Budget Request, *supra*, at 275. The FDA has engaged in an aggressive recruitment and hiring effort since the enactment of the Act, with a goal of reaching 194 full-time equivalent employees in the tobacco program at the end of Fiscal Year 2010 and 370 full-time equivalent employees at the end of Fiscal Year 2011. *Id.* at 279.[3]

3. After the enactment of the Act, Defendants filed petitions for rehearing en banc in the D.C. Circuit that argued, among other things, that the Act extinguishes any case or controversy

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[3] In a separate lawsuit, Defendants R.J. Reynolds Tobacco Co. and Lorillard Tobacco Co. have challenged the constitutionality of some of the Act's marketing restrictions, including the ban on color or graphics in advertising, *see* 21 C.F.R. § 1140.32(a); the new warning labels, *see* §§ 201(a), 206 (amending 15 U.S.C. § 1333(a), (b), (d), (e)), §§ 204(a), 205(a) (amending 15 U.S.C. § 4402(a), (b), (d)), § 903(a)(8)(b)(ii); parts of the Modified Risk Tobacco Products Requirement ("MRTPR"), *see* § 911(b)(2)(A)(i), (iii), (g)(1); the restrictions on brand-name merchandise, *see* 21 C.F.R. § 1140.34(a), brand-name sponsorships, *see id.* § 1140.34(c), continuity programs, *see id.* § 1140.34(b), and free samples, *see id.* § 1140.16(d); and the ban on references to the efficacy of FDA regulations, § 103(b). The lawsuit does *not* challenge the MRTPR's restriction on tobacco products "us[ing] the descriptors 'light,' 'mild,' or 'low' or similar descriptors." § 911(b)(2)(A)(ii). The Western District of Kentucky invalidated the bans on color or graphics in advertising and references to the efficacy of FDA regulations but upheld the other provisions. *See Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 541 (W.D. Ky. 2010). Both sides appealed, and the action is currently pending in the Sixth Circuit. *See Discount Tobacco City & Lottery, Inc. v. United States*, Nos. 10-5234 & 10-5235 (6th Cir.). Defendants Altria Group Inc., Philip Morris USA Inc., and British American Tobacco (Investments) Limited are not parties to this lawsuit.

under Article III and removes any possible jurisdictional basis for prospective relief under Section 1964(a) of RICO. Defendants also filed a separate suggestion of mootness that highlighted specific provisions of the new law that eliminate any case or controversy under Article III. In response, the Government insisted that this Court was the appropriate forum in which to litigate the Act's implications. *See* Plaintiff's Opposition to "Suggestion of Mootness and Motion for Partial Vacatur" 3 (Aug. 17, 2009) ("Defendants may, of course, urge the district court to modify its injunction in light of the new legislation."). The D.C. Circuit denied rehearing and the suggestion of mootness.

Defendants then pressed the mootness argument in their petitions for writs of certiorari to the U.S. Supreme Court, and the Government again urged denial on the ground that "Petitioners can assert their claim that the injunction in this case should be modified in light of the new law in the district court, which is the appropriate forum to consider it in the first instance." Brief for the United States in Opposition 55 (May 25, 2010); *see also* Brief in Opposition of the Tobacco-Free Kids Action Fund 6 (May 25, 2010) ("the continuing propriety of the descriptor ban is an inherently factual matter that belongs before the district court").

After the Supreme Court denied all parties' petitions for certiorari, this Court issued an order directing the parties to submit praecipes addressing, among other topics, "the impact, if any, of the Family Smoking Prevention and Tobacco Control Act, P.L. 111-31 (2009)." D.E. 5819 (Aug. 12, 2010). The parties submitted their praecipes on September 7, 2010. At a status conference held on September 15, 2010, the Court gave the parties 60 days to negotiate regarding the remaining issues in this case. In their ensuing status reports, and at the status conference held on December 20, 2010, the parties reported that, despite good-faith efforts, they were unable to reach agreement regarding the impact of the Act on this Court's jurisdiction.

D.E. 5841, at 5 (Nov. 24, 2010). The Court thereafter entered a further order requiring the Government to submit its proposed corrective statements on February 3, 2011. D.E. 5846 (Dec. 22, 2010). On February 4, 2011, the Government filed those proposed statements under seal. This Court unsealed the statements on February 23, 2011. D.E. 5871. After a status conference on February 24, 2011, it ordered Defendants to file "a brief addressing the impact of the FDA Act" on this Court's injunctions by March 3, 2011. D.E. 5878 (Feb. 25, 2011).

SUMMARY OF ARGUMENT

This Court should vacate its injunctions and underlying factual findings in light of the Family Smoking Prevention and Tobacco Control Act, and dismiss this case in its entirety.

The Act extinguished this Court's jurisdiction under both Article III and Section 1964(a) of RICO. 18 U.S.C. § 1964(a). This Court's constitutional authority to entertain a claim for prospective injunctive relief "is dependent upon the likelihood of a recurrence of the allegedly unlawful conduct." *City of Los Angeles v. Lyons*, 461 U.S. 105, 107 n.8 (1983). Similarly, jurisdiction under Section 1964(a) "is limited to forward-looking remedies that are aimed at future violations" of RICO. *United States v. Philip Morris USA Inc.*, 396 F.3d 1190, 1198 (D.C. Cir. 2005). The stringent FDA oversight that the Act imposes on Defendants' design, manufacturing, marketing, and distribution of tobacco products—which is backed up by hundreds of millions of dollars in annual "user fees" paid by Defendants to the FDA and powerful regulatory enforcement tools—eliminates any reasonable likelihood that Defendants will engage in the future in the type of joint racketeering activity on which this Court based its injunctive relief. Any remaining possibility of future RICO violations is simply too remote to satisfy the requirements of Article III or the additional jurisdictional requirements imposed by Section 1964(a). The Government's claims are therefore moot.

Moreover, even if this Court does retain constitutional and statutory jurisdiction over the Government's claims, it should decline to exercise that authority based on the doctrine of primary jurisdiction. Congress responded to this Court's call for legislative action by enacting an extensive federal regulatory program that makes the FDA "the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products." § 3(1). The existence of an overlapping federal regulatory framework imposed pursuant to this Court's injunctions could interfere with the implementation of the FDA's expert regulatory decision-making and result in conflicting regulatory obligations. In deference to the FDA's authority over the tobacco industry, the Court should vacate its injunctions and permit the FDA to fulfill its congressionally imposed regulatory mandate.

At a minimum, several specific aspects of the injunctions should be modified or vacated as a result of jurisdictional deficiencies and incompatibility with the FDA's primary jurisdiction—including the prohibitions on the use of "light" and "low tar" descriptors and on false statements about cigarettes, and the requirement that Defendants make corrective statements about the health risks of smoking. The invalidity of these provisions is particularly apparent because the Act explicitly prohibits the use of descriptors (in the absence of FDA authorization), grants the FDA responsibility to determine whether cigarette labeling and advertising are false or misleading, and establishes a detailed federal regulatory framework for disseminating smoking-related health information to the public through communications developed by Congress and the FDA, including through graphic warning labels on cigarette packages and advertising currently being considered by the FDA.

ARGUMENT

"The objection that a federal court lacks subject-matter jurisdiction may be raised by a party, or by a court on its own initiative, at any stage in the litigation, even after trial and the entry of judgment." *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 506 (2006) (citation omitted); *see also* Fed. R. Civ. P. 12(h)(3) (requiring dismissal of an action "at any time" the Court determines that "it lacks subject-matter jurisdiction"). "'As a court of limited jurisdiction, this Court is under a continuing obligation to examine its jurisdiction any time it appears to be in question.'" *Patterson v. D.C. Hous. Auth.*, 691 F. Supp. 2d 117, 118 (D.D.C. 2010) (quoting *Sturdza v. United Arab Emirates*, 658 F. Supp. 2d 135, 137 (D.D.C. 2009)). Because the final judgment entered by this Court in 2006 was vacated by the D.C. Circuit, this Court is required under Fed. R. Civ. P. 12(h)(3) to ensure that it possesses subject-matter jurisdiction—and, if so, to consider whether it should defer to the primary jurisdiction of the FDA—before entering a new judgment on remand.

The Court remains under the obligation to examine its subject-matter jurisdiction—and to consider whether to defer to the primary jurisdiction of the FDA—even if this motion is considered under Fed. R. Civ. P. 60(b)(5). That rule authorizes a court to "relieve a party . . . from a final judgment, order, or proceeding" where "applying it prospectively is no longer equitable." The rule "encompasses the traditional power of a court of equity to modify its [judgment] in light of changed circumstances." *Frew ex rel. Frew v. Hawkins*, 540 U.S. 431, 441 (2004); *see also Pasadena City Bd. of Educ. v. Spangler*, 427 U.S. 424, 437 (1976). The standard for granting relief under Rule 60(b)(5) is a "flexible" one: The moving party "must establish that a significant change in facts or law warrants revision of the [judgment] and that the proposed modification is suitably tailored to the changed circumstance." *Rufo v. Inmates of*

Suffolk Cnty. Jail, 502 U.S. 367, 393 (1992). The enactment of a new federal statute directly applicable to the issues addressed by an existing injunction is one such "change in . . . law" that may "warrant[ ]" relief under Rule 60(b)(5). *See Horne v. Flores*, 129 S. Ct. 2579, 2601 (2009) (describing Congress's enactment of the No Child Left Behind Act as a "potentially significant 'changed circumstance'" because it "marked a dramatic shift in federal education policy").

I. THE COURT LACKS JURISDICTION OVER THIS ACTION UNDER ARTICLE III AND RICO.

Federal courts are courts of limited jurisdiction. "'They possess only that power authorized by Constitution and statute, which is not to be expanded by judicial decree.'" *United States v. Philip Morris USA Inc.*, 396 F.3d 1190, 1197 (D.C. Cir. 2005) ("*Disgorgement Opinion*") (quoting *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994)). Under Article III of the Constitution, the exercise of judicial power requires the existence of a live case or controversy. *See, e.g.*, *Larsen v. U.S. Navy*, 525 F.3d 1, 4 (D.C. Cir. 2008). To satisfy the Constitution's case-or-controversy requirement in a suit seeking injunctive relief, the plaintiff must establish that there is a "realistic threat" that the challenged activity would recur in "the reasonably near future" in the absence of such relief. *City of Los Angeles v. Lyons*, 461 U.S. 95, 106 n.7, 108 (1983).

Moreover, even if a suit seeking injunctive relief under RICO satisfies the requirements of Article III, the plaintiff still must meet the statutory requirements for obtaining injunctive relief under Section 1964(a) of RICO, which confers jurisdiction on federal courts only "to prevent and restrain" RICO violations that are reasonably likely to occur in the future. 18 U.S.C. § 1964(a); *see also Disgorgement Opinion*, 396 F.3d at 1198.

These constitutional and statutory requirements are not satisfied simply because jurisdiction existed at the time suit was filed. Jurisdiction must persist throughout the duration of

the litigation; if, at any point throughout the proceedings, jurisdiction is no longer present, the case must be dismissed as moot. *See Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974). For example, the D.C. Circuit held that the Government's claims against the Council for Tobacco Research-USA, Inc. ("CTR") and The Tobacco Institute, Inc. ("TI") were moot because both entities have been dissolved. *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1135 (D.C. Cir. 2009). In light of their dissolution, there was "no reasonable likelihood of future [RICO] violations" by CTR or TI, and the D.C. Circuit therefore vacated the judgment as to CTR and TI, and remanded with directions to dismiss those Defendants. *Id.*; *see also* D.E. 5846 (Dec. 22, 2010) (dismissing CTR and TI).

A claim for injunctive relief also becomes moot when intervening federal legislation eliminates any reasonable likelihood that the conduct at issue will be repeated in the future. Issuing an injunction ordering the defendant "to do what Congress has already mandated would be a mere academic exercise" and "no longer necessary to compel the result plaintiff seeks." *Bethany Med. Ctr. v. Harder*, 693 F. Supp. 968, 975 (D. Kan. 1988); *see, e.g.*, *Green v. Mansour*, 474 U.S. 64, 66-67 (1985) (claim for an injunction against a State's alleged violation of federal welfare law was mooted by intervening congressional legislation that foreclosed the State's prior method for calculating benefits); *Bullfrog Films, Inc. v. Wick*, 959 F.2d 778, 779-81 (9th Cir. 1992) (claim for an injunction against enforcement of a federal agency's regulations was rendered moot by intervening congressional legislation that prohibited the agency's prior policy).

This case presents a textbook example of mootness. When this Court issued injunctive relief in 2006, it found that such relief was appropriate because Defendants were reasonably likely to commit RICO violations in the future. *See United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1, 908-13 (D.D.C. 2006). Specifically, the Court found that Defendants had violated

RICO by joining together as an "associated in fact" RICO enterprise that engaged in racketeering activity designed to conceal the health risks and addictive nature of smoking cigarettes, and that there was a reasonable likelihood that Defendants would engage in similar RICO violations in the future. *Id.* at 851-78. But the Act bans or subjects to extensive federal regulatory oversight the very activities on which this Court premised its future-violations determination.

For example, in crafting its injunctive relief, the Court relied on the fact that Defendants still marketed "low tar" cigarettes. *Philip Morris USA Inc.*, 449 F. Supp. 2d at 910. But the Act now bans the use of "light" and "low tar" descriptors, absent a finding by the FDA that a product "significantly reduce[s] harm." § 911(a), (b), (g)(1). The Court also found that Defendants still denied manipulating nicotine delivery. *See Philip Morris USA Inc.*, 449 F. Supp. 2d at 910. The Act, however, forecloses any possibility of future nicotine manipulation by giving the FDA broad authority to regulate nicotine in cigarettes and to require the submission of nicotine-related information. §§ 904(a)(2), 907(a)(4). And, while the Court faulted Defendants for allegedly failing to admit nicotine specifically creates and sustains addiction, *see Philip Morris USA Inc.*, 449 F. Supp. 2d at 910, the Act mandates that cigarette packages include, as one of several rotating warnings, the printed disclaimer that "Cigarettes are addictive." § 201(a).

More broadly, the FDA is now the "primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products" (§ 3(1)), with authority "to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products" (§ 3(3)), to "over[see] . . . the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products" (§ 3(4)), "to regulate the levels of tar, nicotine, and other harmful components of tobacco products" (§ 3(5)), and "to require tobacco product manufacturers to disclose research which has

not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products." § 3(6).

In addition to foreclosing any reasonable likelihood of future racketeering activity, the Act eliminates any reasonable likelihood that Defendants will associate together in the future as a RICO enterprise. *See Boyle v. United States*, 129 S. Ct. 2237, 2245 n.4 (2009) (RICO applies only to jointly conducted racketeering activity). The Master Settlement Agreement ("MSA") dismantled TI and CTR, the industry organizations that the Government contended Defendants used to operate their enterprise in the past, and also prohibited Defendants from engaging in future joint racketeering activity of the type challenged in this suit. MSA § III(o). The FDA's pervasive regulatory authority over the tobacco industry's design, manufacturing, and marketing of cigarettes will foreclose any future efforts by Defendants to associate together for improper purposes. *See* Center for Tobacco Products, Enforcement Action Plan, *supra*, at 10 (outlining the FDA's "multipronged approach" to enforcing the Act's requirements, which includes "surveillance, inspections, [and] enforcement actions"). Indeed, the FDA possesses powerful enforcement mechanisms to ensure Defendants' compliance with the Act and is amply funded to carry out its enforcement role. The statutorily mandated user fees—which are paid directly by tobacco manufacturers and not subject to the congressional appropriations process—are expected to generate $4.5 billion for the FDA's tobacco program between 2009 and 2018. § 919. In Fiscal Year 2011, alone, those fees will total $450 million. *Id.* The FDA can use that funding to deploy a panoply of enforcement tools against tobacco manufacturers, including no-tobacco-sale orders, civil penalties, mandatory requests for information, inspections, administrative detention of tobacco products, import holds, warning letters, mandatory public notification orders, and criminal investigations. §§ 103, 904(b); 21 U.S.C. §§ 331, 334(g), 335, 374, 381, 387h(a).

Thus, regardless of whether the MSA is sufficient, standing alone, to prevent Defendants from associating together in the future as a RICO enterprise, the FDA's broad regulatory authority unquestionably eliminates any reasonable likelihood of such future activity.

In light of the extensive federal regulatory requirements imposed by the Act, there is no "realistic threat" or reasonable likelihood that the RICO violations on which this Court premised its forward-looking injunctive relief will reoccur in the future. *Lyons*, 461 U.S. at 106 n.7; *see also Disgorgement Opinion*, 396 F.3d at 1198. The Court therefore lacks continuing jurisdiction over this case under either Article III or RICO, and should vacate its injunctions and factual findings and dismiss the case in its entirety. *See United States v. Schaffer*, 240 F.3d 35, 38 (D.C. Cir. 2001) (en banc) (per curiam); *Clarke v. United States*, 915 F.2d 699, 700, 706-07 (D.C. Cir. 1990) (en banc) (citing *United States v. Munsingwear*, 340 U.S. 36, 39 & n.2 (1950)); *see also Lawrence Seaway Pilots Ass'n v. Collins*, 2005 WL 1138916, at *2 (D.D.C. May 13, 2005) ("vacatur is not simply a tool used by appellate courts, as district courts have also used the doctrine to vacate their own opinions").[4]

[4] The provision in the Act requiring that it not be construed to "affect any action pending in Federal, State, or tribal court" (§ 4(a)(2)) does not preserve the Court's jurisdiction. This declaration that the Act does not alter the substantive law applicable in pending cases cannot alter the constitutional requirement that jurisdiction "to seek [an] injunction . . . depend[s] on whether [the plaintiff] [is] likely to suffer future injury" from the challenged conduct. *Lyons*, 461 U.S. at 105. Nor does it amend the statutory requirement under Section 1964(a) that jurisdiction is limited to forward-looking injunctive relief that "prevent[s] and restrain[s]" likely future RICO violations. *See Hagen v. Utah*, 510 U.S. 399, 416 (1994) ("repeals by implication are disfavored").

II. THIS COURT SHOULD DEFER TO THE FDA'S PRIMARY JURISDICTION OVER THE TOBACCO INDUSTRY.

Even if the Court retains jurisdiction over some, or all, aspects of this case, it should not exercise that jurisdiction because the Act vests primary jurisdiction over the tobacco industry in the FDA. If this Court were to exercise jurisdiction, any court-ordered relief would interfere with the implementation of the agency's expert regulatory judgment and potentially generate conflicting federal regulatory requirements. Those concerns are particularly acute here because the FDA possesses unique regulatory expertise about smoking-and-health issues and because the Court's general and specific injunctions would inevitably give rise to requirements on a number of smoking-related issues that are inconsistent with the regulatory requirements established by the FDA.

Where a regulatory agency and federal court share jurisdiction over a matter, the doctrine of primary jurisdiction calls for the court to forgo judicial action in order to permit the regulatory process to run its course. *See, e.g.*, *United States v. W. Pac. R.R. Co.*, 352 U.S. 59 (1956); *Tex. & Pac. Ry. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426 (1907). The doctrine "is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties," and "comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *W. Pac. R.R. Co.*, 352 U.S. at 63, 64. The doctrine of primary jurisdiction recognizes that administrative agencies often possess expertise in their particular areas of regulatory authority that courts of general jurisdiction cannot possibly hope to duplicate and is intended to minimize the risk of inconsistent outcomes between judicial proceedings and administrative action. *See, e.g., Allnet Commc'n Serv., Inc. v. Nat'l Exch.*

Carrier Ass'n, 965 F.2d 1118, 1120 (D.C. Cir. 1992); *Himmelman v. MCI Commc'ns Corp.*, 104 F. Supp. 2d 1, 4 (D.D.C. 2000).

Where Congress confers primary jurisdiction over a specific subject on a federal regulatory agency, courts exercising their equitable powers should give due weight to the division of responsibility between administrative agencies and the courts. *See Atchison, Topeka & Santa Fe Ry. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 819 (1973) (plurality opinion). Courts should refrain from issuing an injunction that "might substantially interfere with the function of the administrative agency" (*id.*) or differ from the regulatory balance the agency might strike under its mandate from Congress. These principles are particularly important when determining the propriety of broad injunctive relief that interferes with the regulatory discretion that Congress has afforded to an administrative agency.

In *Atchison*, for example, the Supreme Court reversed a three-judge district court's order enjoining a railroad from implementing certain rate increases, resting its decision upon "[p]roper regard for [the] division of function" between agencies and courts. 412 U.S. at 819 (plurality opinion). The plurality explained that "it would be surprising if [the court's equity] power could be exercised to the extent that it might substantially interfere with the function of the administrative agency." *Id.* As envisioned by Congress, the Interstate Commerce Commission had "developed a close understanding of the various interests and . . . [might] draw upon its experience to illuminate, for the courts, the play of those interests in a particular case." *Id.* at 820-21. Given that regulatory expertise, the district court should have let the agency act first and refrained from expressing its views on matters of policy entrusted to the agency's discretion. "The fact that issuing an injunction may undercut the policies served by the doctrine of primary jurisdiction," the plurality concluded, is "an important element to be considered when a federal

court contemplates such action." *Id*. at 821; *see also, e.g.*, *Ellis v. Tribune Television Co.*, 443 F.3d 71, 85 (2d Cir. 2006) (invalidating an injunction because it "interfered with the . . . authority" of the Federal Communications Commission "to determine whether a waiver [of its licensing requirements] is warranted"); *Allnet*, 965 F.2d at 1119 (holding that the Federal Communications Commission had primary jurisdiction over a suit regarding access charges and the adequacy of filed tariffs); *Israel v. Baxter Labs., Inc.*, 466 F.2d 272, 280-82 (D.C. Cir. 1972) (declining to issue an injunction determining whether a drug was "safe and effective" because Congress had afforded the FDA primary jurisdiction over the issue).

These considerations have controlling force here. Under the doctrine of primary jurisdiction, the Court should dissolve its injunctions in deference to the federal regulatory framework that Congress established in explicit response to—and reliance upon—the findings of this Court. *See* § 2(47)-(49) (discussing this Court's findings regarding youth marketing and nicotine manipulation). Congress has explicitly designated the FDA the "primary" regulatory authority with respect to the "manufacture, marketing, and distribution of tobacco products," and vested the FDA with far-reaching authority over the tobacco industry. § 3(1). While the Act itself imposes a number of explicit regulatory requirements on the industry—such as the prohibition on the use of "light" and "low tar" descriptors in cigarette brand names and advertising (§ 911(a), (b), (g)(1))—it also includes a number of open-ended provisions that confer on the FDA, an agency with longstanding expertise in public-health issues, a substantial amount of discretion in selecting the means for accomplishing the Act's regulatory objectives. *See, e.g.*, § 202(b) (authorizing the FDA to develop additional warning labels beyond those specified in the Act); § 911(g)(1) (authorizing the FDA to approve "modified risk product[s]" where they significantly reduce the risk of harm); § 915(b)(2) (authorizing the FDA to order

manufacturers to make public disclosures "relating to the results of the testing of tar and nicotine" yields of cigarettes).

The FDA has already begun to exercise that regulatory discretion with regard to numerous aspects of tobacco manufacture, marketing, and distribution. *See, e.g.*, 75 Fed. Reg. 69,524 (requesting comments regarding proposed graphic warnings on cigarette packages and advertising); *id.* at 13,241 (requesting comments regarding regulations that would restrict the location and content of outdoor cigarette advertising); Letter from Lawrence R. Deyton, Director, Center for Tobacco Products, to Tobacco Product Manufacturers, *supra* (requesting information from the tobacco industry to assist the FDA in "study[ing] the issue of the impact of the use of menthol in cigarettes on the public health" and formulating a "report and recommendations"); FDA, Draft Guidance for Industry: Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products under the Federal Food, Drug, and Cosmetic Act, *at* http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatory Information/ucm191911.htm.

As this Court recognized when it issued its injunctive relief in 2006, it lacks the institutional capacity to develop and implement a nationwide policy regulating the tobacco industry. *Philip Morris USA Inc.*, 449 F. Supp. 2d at 31 n.3. Determinations about acceptable health risks, the accuracy of health claims, and the desirability of specific warnings, for example, would "necessarily turn on facts to which [this] [C]ourt[ ] would probably not have ready access." *Pegram v. Herdrich*, 530 U.S. 211, 221 (2000). Indeed, the FDA possesses unique regulatory expertise about public-health issues, and the Court's injunctions could give rise to requirements on a number of smoking-related matters that are inconsistent with the regulatory requirements established by the FDA. Such conflicting regulatory standards would impair the

FDA's implementation of its congressional mandate to become the "primary Federal regulatory authority" over the tobacco industry and would create intolerable uncertainty for regulated entities. *See* § 2(44) ("The Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health."). The doctrine of primary jurisdiction was developed precisely to avoid such potential conflicts and, more generally, out of respect for the administrative discretion of the expert agency charged with implementing Congress's broad regulatory mandate.

Accordingly, in deference to the FDA's congressionally imposed regulatory responsibilities, the Court should dissolve its injunctions and decline to exercise any jurisdiction it might possess over this case.

III. AT A MINIMUM, THE COURT SHOULD VACATE OR MODIFY SPECIFIC ASPECTS OF ITS INJUNCTIONS TO ALLEVIATE JURISDICTIONAL DEFICIENCIES AND CONFLICTS WITH THE FDA'S REGULATORY AUTHORITY.

Even if this Court determines that it retains jurisdiction over some aspects of this case and need not entirely defer to the FDA's primary jurisdiction, it should nevertheless vacate or modify several specific aspects of its injunctions that are jurisdictionally deficient or incompatible with the FDA's regulatory authority.

A. The Injunction Prohibiting The Marketing Of "Light" And "Low Tar" Cigarettes Should Be Vacated.

This Court should vacate its injunction prohibiting the marketing of "light" and "low tar" cigarettes because the Government's claims challenging the use of such descriptors are moot and

because the Court's injunction conflicts with Congress's determination that the FDA should exercise regulatory authority over the use of such descriptors.

The Court issued injunctive relief that prohibits Defendants from using the words "low tar," "light," "ultra light," and similar descriptors in the brand names and advertising of their cigarettes. *Philip Morris USA Inc.*, 449 F. Supp. 2d at 938. As of June 2010, however, the Act *bans* the use of such descriptors in the labeling or advertising of cigarettes, absent explicit authorization from the FDA. § 911(a), (b), (g)(1); *see also* FDA, Guidance for Industry and FDA Staff: Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products, *at* http://www.fda.gov/TobaccoProducts/ GuidanceComplianceRegulatory Information/ucm214597.htm.

These stringent restrictions on Defendants' use of "light" and "low tar" descriptors are part of the Act's comprehensive regulations governing the marketing and advertising of "modified risk tobacco product[s]." § 911(b)(1)-(b)(2)(A). No such products can be marketed absent explicit authorization from the FDA. § 911(a); *see also* FDA, Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products, *supra*, at 1-2. Even if such authorization is given, "light" and "low tar" descriptors may only be used in a manner that permits the public to "understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products." § 911(h)(1). The FDA must continually reassess the use of descriptors, and manufacturers marketing such products must conduct "postmarket surveillance and studies" to determine the impact on "consumer perception, behavior, and health." § 911(i)(1). The FDA is required to withdraw its authorization if new information undermines the approval of the product. § 911(j).

To date, Defendants have not even requested that the FDA approve the use of descriptors such as "light" and "low tar," and, in accordance with the Act's requirements, Defendants have now ceased their use of such descriptors in the marketing and advertising of their cigarettes. The Government's claims challenging the use of descriptors are therefore moot because there is no reasonable likelihood that Defendants will use "light" and "low tar" descriptors in the absence of explicit FDA authorization to do so. *Disgorgement Opinion*, 396 F.3d at 1198; *see also* FDA, Guidance for Industry and FDA Staff: Use of "Light," "Mild," "Low," or Similar Descriptors, *supra*, at 4 ("FDA has the authority to initiate, among other actions, injunction actions, civil money penalties, and/or criminal prosecution to address violations of the act").

Moreover, even if this Court retains jurisdiction over the Government's claims challenging descriptors, it should defer to the FDA's primary jurisdiction over this matter. This Court's injunction prohibiting the use of "light" and "low tar" descriptors conflicts with the FDA's discretion to authorize such descriptors in the future if the FDA makes a finding that the product "significantly reduce[s]" the health risks of smoking. § 911(a), (b), (g)(1). The Court's injunction does not contemplate the possibility of future FDA authorization, and instead imposes a blanket prohibition on the use of descriptors. Thus, in the event Defendants receive FDA authorization to use descriptors, they will not be able to avail themselves of that authorization without violating this Court's order.

Because the Court's injunction prohibiting the use of descriptors is therefore both jurisdictionally deficient and incompatible with the FDA's authority to regulate modified risk tobacco products, the Court should vacate this aspect of its injunctions.

B. The Injunction Prohibiting Defendants From Making False Statements Should Be Vacated.

The Court should also vacate the injunction prohibiting Defendants from making "any material false, misleading, or deceptive statement or representation, or engaging in any public relations or marketing endeavor that is disseminated to the United States public and that misrepresents or suppresses information concerning cigarettes." *Philip Morris USA Inc.*, 449 F. Supp. 2d at 938.

The Act establishes sweeping federal supervision over Defendants' marketing and advertising of cigarettes. Indeed, the Act specifically charges the FDA with responsibility for determining whether cigarette labeling and advertising are "false or misleading in any particular." § 903(a)(1), (a)(7). To fund that regulatory mandate, the Act provides for tobacco manufacturers to pay hundreds of millions of dollars a year in "user fees" to the FDA. § 919. It also provides the FDA will powerful tools to monitor manufacturers' compliance with the Act's labeling and advertising requirements—including mandatory requests for information, inspections, and criminal investigative authority. § 904(b); 21 U.S.C. § 374. If the FDA determines that the labeling or advertising for a particular product is false or misleading, then the product is considered "misbranded" and the manufacturer is subject to civil and criminal penalties. 21 U.S.C. §§ 332, 333.

In light of the FDA's extensive oversight of cigarette marketing and advertising, there is no reasonable likelihood that Defendants will make false or misleading statements about smoking. The Court should therefore vacate this aspect of its injunction due to the absence of jurisdiction under RICO and Article III. Moreover, even if the Court does retain jurisdiction to issue such relief, it should nevertheless vacate the prohibition on false or misleading statements because the FDA has primary jurisdiction to evaluate the accuracy of cigarette labeling and

advertising, and its impact on consumer behavior. *See* § 2(44). Creating an overlapping and potentially inconsistent framework of judicial oversight would inevitably impair the implementation of the FDA's expert regulatory judgments regarding the marketing and advertising of tobacco products. Vacatur is necessary to preserve the FDA's congressionally mandated primacy in this area.

C. The Injunction Requiring Defendants To Make Corrective Statements Should Be Vacated.

For similar reasons, the Court should vacate the injunction ordering Defendants to make corrective statements about the health effects and addictiveness of smoking.

The Act mandates specific communications to the public about the health risks and addictiveness of smoking. For example, cigarette packages and advertising must include a series of rotating warnings about these specific issues. § 201(a). Those warnings state, among other things, that "Cigarettes are addictive," "Tobacco smoke can harm your children," "Cigarettes cause fatal lung disease," "Cigarettes cause cancer," and "Smoking can kill you." *Id.* In addition, the Act grants the FDA the authority to mandate additional or different textual warnings if "such a change would promote greater public understanding of the risks associated with the use of tobacco products." § 202(b). It also requires the FDA to promulgate regulations establishing graphic warnings to appear on all cigarette packages and advertising. § 201(a). Pursuant to that statutory obligation, the FDA has published for comment 36 proposed graphic warnings that, according to the FDA, "are designed to clearly and effectively convey the negative health consequences of smoking" to the public. 75 Fed. Reg. at 69,526. The proposed warnings were then evaluated in an agency-commissioned study designed to "[m]easure consumer attitudes, beliefs, and intended behaviors related to cigarette smoking in response to the proposed color graphics and their accompanying textual warning statements." *Id.* at 75,937.

The Act eliminates any reasonable likelihood that Defendants will mislead consumers about the health risks or addictiveness of smoking in the future. The Act mandates specific textual warning labels, authorizes the FDA to supplement those warnings with additional health communications, and provides the FDA with the funding and enforcement tools necessary to maintain stringent oversight of Defendants' marketing and advertising activities. The Act therefore extinguishes this Court's jurisdiction to order Defendants to make corrective statements because there is no reasonable likelihood that Defendants will commit future RICO violations and those statements thus will not prevent and restrain such violations. 18 U.S.C. § 1964(a).

Moreover, even if this Court retains jurisdiction to order Defendants to make corrective statements, it should nevertheless defer to the FDA's primary jurisdiction in this area. Under the Act, the determination as to what consumers should be told regarding the health consequences of smoking and the content of cigarettes rests within the expert regulatory judgment of the FDA. The agency has recently emphasized its "commit[ment] to providing Americans with the information they need to protect their children and to make choices about tobacco use." FDA, Strategic Priorities 2011-2015, at 29 (draft of Sept. 29, 2010), *at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/StrategicActionPlan/UCM226907.pdf. One of the agency's long-term objectives is to "[p]rovide the public with accurate, trustworthy, and accessible information about tobacco products" by "develop[ing] a communication and public education strategy to address the public health risks of tobacco products." *Id.* To that end, the FDA plans to spend more than $45 million in the next fiscal year to "develop and disseminate public education campaigns to decrease initiation of tobacco product use and increase . . . cessation." FDA, FY 2011 Congressional Budget Request, *supra*, at 282.

The corrective statements proposed by the Department of Justice were selected, at least in part, based on similar public-health considerations, including the statements' ability to affect "behavioral intentions around quitting smoking and staying quit in current and former smokers." Blake Report ¶ 11, D.E. 5875-1 (Feb. 23, 2011); *see also*, *e.g.*, *id.* ¶ 227 (Statement A chosen in part because "[i]t was . . . positively associated with behavioral intentions to stay quit among former smokers"); *id.* ¶¶ 226, 228 (Statement B chosen, in part, based on stay-quit intentions). Thus, if adopted by this Court, the corrective statements proposed by the Department of Justice would tread on the precise area that Congress directed the FDA to regulate. In so doing, they would impair the FDA's "communication and public education strategy" by altering the overall mix of public-health information available about smoking and by drawing attention away from the FDA's public-health communications.

The Department of Justice has not identified any public-health justification for impairing the FDA's regulatory mandate in this manner. The Department of Justice did not even test its proposed corrective statements against either the textual warnings required by the Act or the graphic warnings proposed by the FDA. Thus, there is absolutely no evidence that those corrective statements—or *any* corrective statements—would enhance the public's understanding of the health risks of smoking beyond the level already attributable to the statutorily mandated warning labels, proposed graphic warnings, and other public-health sources, including the FDA's multi-million-dollar public-education campaign.

In fact, in several respects, the corrective statements would affirmatively undermine the efforts of both Congress and the FDA to disseminate health information to the public. For example, under the terms of the injunctions, Defendants must distribute their corrective statements through cigarette package "onserts." *Philip Morris USA Inc.*, 449 F. Supp. 2d at 939.

But the Act directs that the statutorily mandated warnings comprise the top half of both the front and rear of the package (§ 201), and it is therefore likely that the onserts carrying the Court's prescribed corrective statements would partially conceal the statutory warnings required by Congress and implemented by the FDA. Moreover, Corrective Statement C proposed by the Department of Justice would require Defendants to disseminate information about the health risks of "light" and "low tar" cigarettes. The Act, however, already expressly prohibits Defendants from using such descriptors in the marketing of their cigarettes (in the absence of FDA authorization). § 911(a), (b), (g)(1). The reintroduction of these now-defunct marketing terms would inevitably confuse consumers and distract from the public-health message expertly formulated by the FDA. *See* § 2(45) ("Neither the Federal Trade Commission nor any other Federal agency except the Food and Drug Administration possesses the scientific expertise needed to implement effectively all provisions of the" Act).

In deference to the FDA's broad authority to communicate with the public about the health risks and addictiveness of smoking—and the decisions of both Congress and the FDA regarding the content and placement of warning labels on cigarette packages—the Court should vacate its injunction requiring Defendants to make corrective statements. At a minimum, any corrective statements that this Court does order should precisely track the text of the warnings mandated by the Act. Those warnings—which are subject to modification by the FDA—state that "Cigarettes are addictive," "Tobacco smoke can harm your children," "Cigarettes cause fatal lung disease," "Cigarettes cause cancer," "Cigarettes cause strokes and heart disease," "Smoking during pregnancy can harm your baby," "Smoking can kill you," "Tobacco smoke causes fatal lung disease in nonsmokers," and "Quitting smoking now greatly reduces serious risks to your health." § 201(a). Any inconsistencies between the court-ordered corrective statements and the

text of the statutorily mandated warning labels would undermine the judgment of Congress and the FDA regarding the most effective means of "promot[ing] greater public understanding of the risks associated with the use of tobacco products." § 202(b).

CONCLUSION

For the foregoing reasons, this Court should vacate its injunctions and factual findings, and dismiss this suit in its entirety.

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Respectfully submitted,

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