

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 99-2496 (PLF)
)	
PHILIP MORRIS USA INC. <u>et al.</u> ,)	
)	
Defendants.)	

OPINION

The United States and the Public Health Intervenors (together, “plaintiffs”) have filed a Motion to Clarify the Application of Order #1015. See Plaintiffs’ Motion for Clarification Regarding the Application of Order #1015, As Amended, to HeatSticks Cigarettes (“Pls. Mot.”) [Dkt. No. 6325]. Plaintiffs ask the Court to clarify that the injunctive relief in Order #1015 – Final Judgment and Remedial Order (“Order #1015”) [Dkt. No. 5733] applies to “HeatSticks,” a tobacco product marketed by defendant Philip Morris USA, Inc. (“Philip Morris”). See id. at 1-2. Plaintiffs contend that HeatSticks are subject to the remedial provisions of Order #1015 because they fall within the definition of the term “cigarettes” as that term is used throughout Order #1015. See id. at 2-3; Order #1015 ¶¶ III.A, III.B.

Philip Morris responds that HeatSticks are not cigarettes within the meaning of Order #1015 because they differ from traditional cigarettes in key respects – namely, they do not produce smoke, they are not burned, and they did not exist when Order #1015 was issued. See Defendant’s Opposition to Plaintiffs’ Motion for Clarification and in the Alternative Motion to Modify Order #1015 (“Def. Opp.”) [Dkt. No. 6333] at 1-2. Philip Morris requests, if the Court

finds that HeatSticks are “cigarettes” as that term is used in Order #1015, that the Court modify Order #1015 to exempt HeatSticks from Order #1015’s remedies and the “corrective statements” remedy in particular. Id. at 2-4; see Order #1015 ¶ III.B. Philip Morris also asks the Court to modify Order #1015 to allow Philip Morris to market HeatSticks with Food and Drug Administration (“FDA”)-authorized statements about how HeatSticks are modified-risk tobacco products that reduce cigarette users’ exposure to harmful and potentially harmful chemicals. See Def. Opp. at 2-4.¹

The Court heard oral argument on these motions on July 20, 2022. Upon careful consideration of the parties’ oral and written arguments, the relevant legal authorities, and the entire record in this case, the Court will grant plaintiffs’ Motion to Clarify, having concluded that the term “cigarettes” as it is used in Order #1015 includes HeatSticks. The Court will grant in part Philip Morris’s Motion to Modify Order #1015, exempting HeatSticks from Paragraph 4 of Order #1015 and allowing Philip Morris to market HeatSticks in accordance with FDA’s marketing requirements. But the Court will deny the motion in part as it relates to Philip Morris’s request to exempt HeatSticks from Order #1015’s anti-fraud provisions and corrective statements remedy.²

¹ Plaintiffs do not oppose Philip Morris’s request to modify Paragraph 4 of Order #1015 to permit HeatSticks to be marketed with an FDA-authorized reduced-exposure claim. See Plaintiffs’ Partial Opposition to Philip Morris USA Inc.’s Motion to Modify Order #1015 With Respect to HeatSticks Cigarettes (“Pls. Partial Opp.”) [Dkt. No. 6338] at 4. Plaintiffs agree that this modification is “appropriate to promote the public health.” Id.

² The Court has reviewed the following documents in connection with the pending motions: Plaintiffs’ Motion for Clarification Regarding the Application of Order #1015, As Amended, to HeatSticks Cigarettes (“Pls. Mot.”) [Dkt. No. 6325]; Defendant’s Opposition to Plaintiffs’ Motion for Clarification and in the Alternative Motion to Modify Order #1015 (“Def. Opp.”) [Dkt. No. 6334]; Plaintiffs’ Partial Opposition to Philip Morris USA Inc.’s Motion to Modify Order #1015 With Respect to HeatSticks Cigarettes (“Pls. Partial Opp.”) [Dkt. No. 6338]; Plaintiffs’ Reply in Support of Their Motion for Clarification Regarding the Application

I. BACKGROUND

A. *United States v. Philip Morris*

Prior opinions summarize the detailed factual and procedural history in this case. See United States v. Philip Morris USA Inc., 436 F. Supp. 3d 1, 3-5 (D.D.C. 2019); United States v. Philip Morris USA Inc., 566 F.3d 1095, 1105-1110 (D.C. Cir. 2009) (per curiam); see generally United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1 (D.D.C. 2006).³

In brief, the United States brought this civil action in 1999 against Philip Morris, among other cigarette manufacturers and two tobacco-related trade organizations, under the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §§ 1961-1968.⁴ After substantial pretrial proceedings and discovery, and a nine-month bench trial, the Court found in 2006 that defendants had violated RICO “by engaging in a lengthy, unlawful conspiracy to deceive the American public about the health effects of smoking and environmental tobacco smoke, the addictiveness of nicotine, the health benefits from low tar, ‘light’ cigarettes, and their

of Order #1015, As Amended, to HeatSticks Cigarettes (“Pls. Reply”) [Dkt. No. 6339]; Defendant’s Reply in Support of Motion to Modify Order #1015 (“Def. Reply”) [Dkt. No. 6342]; Order #60 – Remand, Reinstating the Descriptor Ban (“Order #60 – Remand”) [Dkt. No. 6169]; Order #72 – Remand, Second Superseding Consent Order Implementing the Corrective Statements Remedy for Newspapers and Television (“Order #72 – Remand”) [Dkt. No. 6227]; June 3, 2022 Joint Status Report in Response to Order #124 – Remand (“JSR 1”) [Dkt. No. 6500]; June 21, 2022 Joint Status Report in Response to Order #124 – Remand (“JSR 2”) [Dkt. No. 6501]; Transcript of Oral Argument, United States v. Philip Morris USA, Inc., Civil Action No. 99-2496 (July 20, 2022) (“Oral Arg. Tr.”).

³ Judge Gladys Kessler presided over this case until her retirement, at which time the case was reassigned to the undersigned.

⁴ Although the motions at issue here only concern one defendant, Philip Morris USA, Inc., the defendants at trial included nine cigarette manufacturers and two tobacco-related trade associations. See United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 31 n.4. References in this Opinion to “defendants,” plural, refer to the tobacco manufacturer defendants subject to Order #1015. See Order #1015 ¶¶ II.

manipulation of the design and composition of cigarettes in order to sustain nicotine addiction.”

United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 26-27. Judge Gladys Kessler, who presided over the trial in this case, wrote:

Defendants’ business of manufacturing, selling and marketing tobacco products “present[s] opportunities to violate the law in the future.”. . . [A]s long as Defendants are in the business of selling and marketing tobacco products, they will have countless “opportunities” and temptations to take similar unlawful actions in order to maximize their revenues, just as they have done for the past five decades.

Id. at 909 (quoting United States v. Philip Morris Inc., 116 F. Supp. 2d 131, 149 (D.D.C. 2000)).

Judge Kessler concluded that there was a “reasonable likelihood” that these defendants would violate RICO again, warranting injunctive relief. United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 909, 911. Judge Kessler issued an injunctive remedial order, Order #1015, to “prevent and restrain” defendants’ future unlawful conduct. See id. at 923-37; Order #1015.⁵

Order #1015 imposed several forms of injunctive relief under Section 1962(c) and (d) of the RICO statute. See Order #1015 ¶¶ III, IV. In general, the Order enjoined defendants from engaging in future racketeering, including by making “material false, misleading, or deceptive statement[s]” and “conveying any express or implied health message or health descriptor for any cigarette brand.” Id. ¶ III.A.3, 4. Order #1015 also required defendants to issue public “corrective” statements with respect to the following five categories: “(a) the adverse health effects of smoking; (b) the addictiveness of smoking and nicotine; (c) the lack of any significant health benefit from smoking ‘low tar,’ ‘light,’ ‘ultra light,’ ‘mild,’ and ‘natural’

⁵ Order #1015 has been amended, and references to Order #1015 within this Opinion incorporate the amendments made in subsequent orders. See e.g., Order #60 – Remand, (amending Paragraph 4 of Order #1015); Order #72 – Remand (listing the corrective statements).

cigarettes; (d) Defendants’ manipulation of cigarette design and composition to ensure optimum nicotine delivery; and (e) the adverse health effects of exposure to secondhand smoke.” Id. at 4.

Examples of court-ordered corrective statements include:

Category A: Smoking kills, on average, 1,200 Americans. Every day.

Category B: Smoking is highly addictive. Nicotine is the addictive drug in tobacco.

Category C: **All** cigarettes cause cancer, lung disease, heart attacks, and premature death – lights, low tar, ultra lights, and naturals. There is no safe cigarette.

Category D: Cigarette companies control the impact and delivery of nicotine in many ways, including designing filters and selecting cigarette paper to maximize the ingestion of nicotine, adding ammonia to make the cigarette taste less harsh, and controlling the physical and chemical make-up of the tobacco blend.

Category E: There is no safe level of exposure to secondhand smoke.

See Order #72 – Remand at 2-4. Judge Kessler ordered the defendants to disseminate corrective statements through newspapers, television, advertisements, cigarette packages, retail displays, and the manufacturers’ corporate websites. See United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 928; Order #1015 ¶ III.B.

In multiple appeals, the D.C. Circuit has largely affirmed and re-affirmed Judge Kessler’s remedial order. See United States v. Philip Morris USA Inc., 566 F.3d at 1150. In particular, the D.C. Circuit upheld the corrective statements as within the scope of the Court’s authority under RICO, concluding that the statements would prevent and restrain future RICO violations. United States v. Philip Morris USA Inc., 801 F.3d 250, 257 (D.C. Cir. 2015) (“[T]he corrective-statement remedy was permissible under section 1964 because defendants, if compelled to tell the truth about cigarettes, would, at the same time, be ‘impaired in making false

and misleading assurances.” (quoting United States v. Philip Morris USA Inc., 566 F.3d at 1140)).

B. The Family Smoking Prevention and Tobacco Control Act

In 2009, one month after the court of appeals affirmed Order #1015 and Judge Kessler’s accompanying opinion, President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) into law. Pub. L. No. 111-31, 123 Stat. 1776 (2009); see United States v. Philip Morris USA Inc., 686 F.3d 832, 835 (D.C. Cir. 2012); Nicopure Labs, LLC v. FDA, 944 F.3d 267, 272 (D.C. Cir. 2019). The Tobacco Control Act “imposed stringent restrictions on the conduct of cigarette manufacturers” and “limited marketing by prohibiting distribution of branded merchandise, false or misleading labeling, and claims of reduced risk of harm (such as the use of descriptors like ‘light’ or ‘mild’) without prior approval of the FDA.” United States v. Philip Morris USA Inc., 686 F.3d at 835. The Tobacco Control Act also “strengthened warning labels by directing cigarette manufacturers to include one of several textual warnings on every pack” and granted FDA “the authority to impose monetary penalties” for failure to comply with labeling requirements. Id.; see 15 U.S.C. § 1333 (cigarette labeling and advertising requirements); 21 U.S.C. § 333 (penalties).

After the Tobacco Control Act became law, the tobacco manufacturers raised two claims that were ultimately rejected by both this Court and the D.C. Circuit. They argued: (1) that the Tobacco Control Act’s restrictions “eliminated any ‘reasonable likelihood’ they would commit future RICO violations;” and (2) that “the court should vacate the injunctions out of deference to the FDA’s newfound primary jurisdiction over cigarette sales and marketing.” United States v. Philip Morris USA Inc., 686 F.3d at 835. In rejecting these arguments, the D.C. Circuit affirmed the district court’s conclusion that “defendants were reasonably likely to commit

future RICO violations despite the passage of the Tobacco Control Act,” and that adjudication of this question “was squarely within [the district court’s] area of expertise.” *Id.* at 838-39. The court of appeals explained that

[Thirteen] years of litigation, nine months of trial, and 4000 findings of fact surely gave [the district court] unique insight into the defendants’ tendency to circumvent or ignore the law And while the Tobacco Control Act gave the FDA the authority to regulate much of the defendants’ conduct, it gave the FDA no particular insight into whether the defendants were likely to comply with those restrictions.

Id. at 838. Accordingly, tobacco manufacturers must market their products consistent with FDA requirements as well as Order #1015’s remedies.

C. HeatSticks and IQOS

Under the Tobacco Control Act’s regulatory regime, Philip Morris developed HeatSticks and the IQOS Tobacco Heating System (“IQOS system”). Def. Opp. at 4-5. The IQOS system involves three components: (1) the HeatStick, which contains “tobacco made from tobacco powder;” (2) the Holder, which “heats the tobacco material with an electronically controlled heat blade;” and (3) the Charger, which “recharges the holder after each use.” *Id.* at 4; see also Pls. Mot. at 3-6 (providing images of the Holder and Charger and specifying that “a HeatSticks cigarette includes a plug of tobacco wrapped in paper”). Philip Morris first applied to FDA for regulatory approval of its IQOS system in 2016. Def. Opp. at 4-5. Unlike conventional cigarettes, HeatSticks are “heated-tobacco” products that are not burned or combusted when used with the IQOS system. *Id.* at 4.



Image 1: The IQOS System, with HeatStick inserted into Holder (foreground) and Charger (background). See Pls. Mot. at 5.

Philip Morris developed this product for FDA approval pursuant to the Tobacco Control Act, which created two regulatory pathways for “novel tobacco products.” Def. Opp. at 5; see Nicopure Labs, LLC v. FDA, 944 F.3d at 272-73. The first pathway authorizes the marketing of “new” products, namely, “those not marketed in the United States as of February 2007.” 21 U.S.C. § 387j(c)(2)(A); see Def. Opp. at 5. This pathway requires the FDA to find that the “product’s public health harms do not exceed its benefits,’ taking into account ‘the population as a whole,’ i.e., both persons who currently use tobacco and those who do not.” Def. Opp. at 5 (quoting Nicopure Labs, LLC v. FDA, 944 F.3d at 271; 21 U.S.C. § 387j(c)(2)(A), (c)(4)). The second pathway authorizes “modified-risk products,” which are “products authorized to carry positive consumer messaging about exposure to harmful chemicals and/or risks of health effects.” Def. Opp. at 5. Modified-risk approval is “more stringent” than the first pathway, Nicopure Labs, LLC v. FDA, 944 F.3d at 271, and requires the FDA to find that the product and its messaging will “benefit the health of the population as a whole taking into account both users of tobacco products and those who do not currently use tobacco products.” 21 U.S.C. § 387k(g)(1)(B); see Def. Opp. at 5. FDA may authorize a modified-risk product to include in its marketing and informational materials claims that the product reduces users’ exposure to harmful substances (“reduced-exposure claims”) or reduces users’ risk of developing

tobacco-related diseases (“reduced-risk claims”). See 21 U.S.C. § 387k(g); Nicopure Labs, LLC v. FDA, 944 F.3d at 277; Def. Opp. at 5.

Philip Morris submitted a “Modified-Risk Tobacco Product Application” to FDA on November 18, 2016, which was followed by a “Premarket Tobacco Application” on May 15, 2017. See Def. Opp. at 6. In support of its application, Philip Morris provided FDA with over “two million pages of scientific evidence,” which was reviewed by the FDA’s Tobacco Products Scientific Advisory Committee, among other entities, and became the subject of a two-day hearing conducted in January 2018. See id. at 6-7. The FDA ultimately authorized HeatSticks and the IQOS system as a “new tobacco product,” pursuant to the first pathway, in April 2019, and as a “modified-risk tobacco product,” pursuant to the second pathway, in July 2020. See id. at 8-9; see also Pls. Partial Opp. at 4. The FDA granted Philip Morris’s request to include the following reduced-exposure claim on its marketing materials for IQOS products including on HeatSticks:

AVAILABLE EVIDENCE TO DATE:

- The IQOS system heats tobacco but does not burn it.
- This significantly reduces the production of harmful and potentially harmful chemicals.
- Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body’s exposure to harmful or potentially harmful chemicals.

Def. Opp. at 10 (emphasis added).

FDA did not, however, grant Philip Morris’s request to include a reduced-risk claim on IQOS products, meaning that Philip Morris cannot market HeatSticks and the IQOS system as reducing a person’s risk of developing tobacco-related illnesses when compared to

conventional cigarette use. Def. Opp. at 10.⁶ FDA also did not exempt Philip Morris from certain warnings under the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331 et seq., and did not alter existing requirements for nicotine warnings. See Def. Opp. at 9 (i.e., HeatSticks still must be marketed with the warning that: “This product contains nicotine. Nicotine is an addictive chemical”). The modified-risk authorization must be periodically renewed and is conditioned on Philip Morris submitting HeatSticks’ promotional materials for FDA review and completing extensive data collection “concerning consumers’ behavior in relation to the IQOS system, including as to younger populations.” Id. at 11.

II. LEGAL STANDARD

A. *Motion to Clarify*

There is no Federal Rule of Civil Procedure that specifically governs motions for clarification. See United States v. All Assets Held at Bank Julius, Baer & Co., 315 F. Supp. 3d 90, 99 (D.D.C. 2018). “The general purpose of a motion for clarification is to explain or clarify something ambiguous or vague, not to alter or amend.” United States v. Philip Morris USA, Inc., 793 F. Supp. 2d 164, 168 (D.D.C. 2011) (internal quotation omitted). Although a motion for clarification may not open the door to “re-litigat[ing] a matter that the court has considered and decided,” Sai v. Transp. Sec. Admin., Civil Action No. 14-0403, 2015 WL 13889866, at *3 (D.D.C. Aug. 19, 2015), courts in this circuit have encouraged parties to request clarification when they are uncertain about the scope of a ruling or its application “in a concrete context or

⁶ See also Scientific Review of Modified Tobacco Product Application (MRTPA) Under Section 911(d) of the FD&C Act – Technical Project Lead, U.S. FOOD & DRUG ADMIN. (June 29, 2020), <https://www.fda.gov/media/139796/download> <<https://perma.cc/KV4R-ZYTK>>, at 1-3, 8-11 (finding that Philip Morris’s proposed reduced-risk claims – that switching to IQOS reduces the risk of tobacco-related diseases and presents less risk of harm than continuing to smoke cigarettes – were “not substantiated”).

particular factual situation.” United States v. Philip Morris USA Inc., 793 F. Supp. 2d at 168-69; see, e.g., United States v. Volvo Powertrain Corp., 758 F.3d 330, 344 (D.C. Cir. 2014); Barnes v. District of Columbia, 289 F.R.D. 1, 12-13 (D.D.C. 2012).

Rule 65(d) of the Federal Rules of Civil Procedure requires every order granting an injunction to “state its terms specifically” and “describe in reasonable detail . . . the act or acts restrained or required.” FED. R. CIV. P. 65(d)(1)(B)-(C). To prevent uncertainty and confusion on the part of the enjoined party, an injunction must provide “explicit notice of precisely what conduct is outlawed.” United States v. Philip Morris USA Inc., 566 F.3d at 1137 (quoting Schmidt v. Lessard, 414 U.S. 473, 476 (1974)); see also 11A CHARLES ALAN WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE § 2955 (3d ed. 2022) (“The drafting standard established by Rule 65(d) is that an ordinary person reading the court’s order should be able to ascertain from the document itself exactly what conduct is proscribed.”). Moreover, an injunction must be “narrowly tailored to remedy the harm” that it addresses. J.D. v. Azar, 925 F.3d 1291, 1336 (D.C. Cir. 2019) (quoting Gulf Oil Corp. v. Brock, 778 F.2d 834, 842 (D.C. Cir. 1985)); see ALPO Petfoods, Inc. v. Ralston Purina Co., 913 F.2d 958, 972 (D.C. Cir. 1990) (“The law requires that courts closely tailor injunctions to the harm that they address.”). An order providing relief under RICO must limit its remedies to those that “prevent and restrain’ future RICO violations,” a mandate that the D.C. Circuit construes “narrowly, permitting only remedies that, through reasonably direct means, keep RICO violators from again violating the Act.” United States v. Philip Morris USA Inc., 801 F.3d at 257. In keeping with these principles, courts generally “resolve ‘omissions or ambiguities in [an injunction]’ in favor of the enjoined party.” United States ex rel. Yelverton v. Fed. Ins. Co., 831 F.3d 585, 587 (D.C. Cir. 2016) (citing 11A WRIGHT, MILLER & KANE, FEDERAL PRACTICE AND PROCEDURE § 2955).

Nevertheless, an injunction must be understood in light of the circumstances surrounding its entry. Common Cause v. Nuclear Regul. Comm'n, 674 F.2d 921, 927 (D.C. Cir. 1982); see Milk Wagon Drivers Union of Chi., Loc. 753 v. Meadowmoor Dairies, Inc., 312 U.S. 287, 298 (1941) (“[A]n injunction must be read in the context of its circumstances.”); Nat’l Org. for Women v. Operation Rescue, 37 F.3d 646, 657 (D.C. Cir. 1994) (the “meaning” of an injunction’s terms “is constrained by the context in which they are actually used in the injunction”). An injunction is “subject to reasonable interpretation” based on the fair meaning of its text and the harm it was tailored to address. Alley v. U.S. Dep’t of Health & Hum. Servs., 590 F.3d 1195, 1207 (11th Cir. 2009); see Nat’l Org. for Women v. Operation Rescue, 37 F.3d at 657 (considering “the context of ongoing unlawful [conduct]” when interpreting “language in the injunction”); United States v. Philip Morris USA Inc., 778 F. Supp. 2d 8, 11 (D.D.C. 2011) (interpreting Order #1015 by reading its language “in conjunction with the purpose to be accomplished” by the injunction); see, e.g., Schering Corp. v. Illinois Antibiotics Co., 62 F.3d 903, 906-08 (7th Cir. 1995) (disfavoring “narrow literalism” when interpreting injunctions); In re Baldwin-United Corp (Single Premium Deferred Annuities Ins. Litig.), 770 F.2d 328, 339 (2d Cir. 1985) (considering “the context of the entire injunction” and “the judge’s decision upon issuing the injunction” when construing ambiguous provisions); Alabama Nursing Home Ass’n v. Harris, 617 F.2d 385, 388 (5th Cir. 1980) (injunction’s terms are to be “reasonably construed”); United States v. Christie Indus., Inc., 465 F.2d 1002, 1007 (3d Cir. 1972) (“The language of an injunction must be read in the light of the circumstances surrounding its entry . . . and the mischief that the injunction seeks to prevent.”).

B. Motion to Modify

Rule 60(b)(5) of the Federal Rules of Civil Procedure provides that “the court may relieve a party or its legal representative from a final judgment” if “applying [the judgment] prospectively is no longer equitable.” FED. R. CIV. P. 60(b)(5). A court has the “power to modify [an] original injunction so as to effectuate its intended purpose and result.” 1250 24th St. Assocs. Ltd. P’ship v. Brown, 684 F. Supp. 326, 328 (D.D.C. 1988); see United States v. W. Elec. Co., 46 F.3d 1198, 1202 (D.C. Cir. 1995) (“The power of a court of equity to modify a decree of injunctive relief . . . is long-established, broad, and flexible.” (quoting N.Y. State Ass’n for Retarded Child., Inc. v. Carey, 706 F.2d 956, 967 (2d Cir. 1983))); see also 11A WRIGHT, MILLER & KANE, FEDERAL PRACTICE AND PROCEDURE § 2961.

Rule 60(b)(5) is “an avenue for demonstrating that significantly changed circumstances warrant reexamination and modification of an order.” LaShawn A. ex rel. Moore v. Fenty, 701 F. Supp. 2d 84, 95 (D.D.C. 2010), aff’d sub nom. LaShawn A. ex rel. Moore v. Gray, 412 F. App’x 315 (D.C. Cir. 2011); see Horne v. Flores, 557 U.S. 433, 439 (2009) (“Rule 60(b)(5) provides the vehicle” to argue that changed circumstances warrant modification of an existing injunction). The party requesting modification bears the burden of demonstrating that “significant changed circumstances” – including factual and legal circumstances – warrant modification. Gov’t of Province of Manitoba v. Zinke, 849 F.3d 1111, 1117 (D.C. Cir. 2017) (citing Horne v. Flores, 557 U.S. at 447); see Rufo v. Inmates of Suffolk Cnty. Jail, 502 U.S. 367, 384 (1992) (“A party seeking modification . . . may meet its initial burden by showing [] a significant change either in factual conditions or in law.”). Modification is appropriate where changed circumstances render an injunction’s continued enforcement “detrimental to the public interest.” Horne v. Flores, 557 U.S. at 447; see Rufo v. Inmates of Suffolk Cnty. Jail, 502 U.S.

at 384. If the moving party demonstrates significant changed circumstances, a court can enter a modification that is “suitably tailored” to the changed circumstances. Gov’t of Province of Manitoba v. Zinke, 849 F.3d at 1117, 1122; see Rufo v. Inmates of Suffolk Cnty. Jail, 502 U.S. at 391 (“Once a court has determined that changed circumstances warrant a modification the focus should be on whether the proposed modification is tailored to resolve the problems created by the change in circumstances. A court should do no more.”).

C. First Amendment Principles

First Amendment protections extend to “commercial speech,” namely, “advertising pure and simple.” Zauderer v. Off. of Disciplinary Couns., 471 U.S. 626, 637 (1985). Commercial speech includes “material representations about the efficacy, safety, and quality of the advertiser’s product, and other information asserted for the purpose of persuading the public to purchase the product.” United States v. Philip Morris USA Inc., 566 F.3d at 1143. “Under a commercial speech inquiry, it is the [government’s] burden to justify its content-based law as consistent with the First Amendment.” Sorrell v. IMS Health Inc., 564 U.S. 552, 571-72 (2011). As the D.C. Circuit has made clear in this case, commercial speech “receives a lower level of protection under the First Amendment,” and burdens imposed on commercial speech “receive a lower level of scrutiny.” United States v. Philip Morris USA Inc., 566 F.3d at 1142. See Zauderer v. Off. of Disciplinary Couns., 471 U.S. at 651; Am. Meat Inst. v. Dep’t of Agric., 760 F.3d 18, 26-27 (D.C. Cir. 2014) (en banc).

The Supreme Court has held that the government has a legitimate interest in “preventing consumer deception” and may “prevent the dissemination of commercial speech that is false, deceptive, or misleading” without running afoul of the First Amendment. Zauderer v. Off. of Disciplinary Couns., 471 U.S. at 638, 651; see United States v. Philip Morris USA Inc.,

855 F.3d 321, 327 (D.C. Cir. 2017). Not only can the government prevent deceptive commercial speech, but it can also require truthful speech in certain contexts. Zauderer v. Off. of Disciplinary Couns., 471 U.S. at 650. When it comes to commercial advertising, the D.C. Circuit has made clear that the government’s legitimate interest may go “[b]eyond . . . correcting misleading or confusing commercial speech” and may extend to “requiring disclosure of ‘purely factual and uncontroversial information.’” Am. Meat Inst. v. Dep’t of Agric., 760 F.3d at 21-23, 27. Where the government has a legitimate interest in requiring certain disclosures, those disclosures must “directly advance the government’s interest and show a reasonable fit between means and ends” to be valid under the First Amendment. Id. at 26; see Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York, 447 U.S. 557, 564 (1980). The D.C. Circuit has explained that a “reasonably crafted mandate to disclose ‘purely factual and uncontroversial information’ about attributes of the product or service being offered” is an appropriate way for the government to ensure “that consumers receive particular information.” Am. Meat Inst. v. Dep’t of Agric., 760 F.3d at 26 (emphasis added); see Zauderer v. Off. of Disciplinary Couns., 471 U.S. at 651. Accordingly, when the government has an interest in providing consumers with “purely factual and uncontroversial information,” the government can mandate the disclosure of such truthful, uncontroversial information so long as the disclosure requirement is not “unjustified or unduly burdensome” and does not “chill[] protected commercial speech.” Zauderer v. Off. of Disciplinary Couns., 471 U.S. at 651; see Am. Meat Inst. v. Dep’t of Agric., 760 F.3d at 26.

III. DISCUSSION

Order #1015 permanently enjoins defendants from “committing any act of racketeering . . . relating in any way to the manufacturing, marketing, promotion, health

consequences, or sale of cigarettes in the United States.” Order #1015 ¶ III.A.1 (emphasis added); see Pls. Mot. at 2. It prohibits defendants from engaging in marketing that “misrepresents or suppresses information concerning cigarettes,” Order #1015 ¶ III.A.3, and from “conveying any express or implied health message or health descriptor for any cigarette brand.” Id. ¶ III.A.4. Order #1015 also requires that the defendants “affix to cigarette packaging” certain corrective statements. Id. ¶ III.B.7.a. The parties and the Court agree that these anti-fraud and corrective statement provisions of Order #1015 apply to “cigarettes.” Pls. Mot. at 2; Def. Opp. at 15. The parties disagree about whether HeatSticks are “cigarettes” and thus are subject to these remedial provisions.⁷

Plaintiffs ask the Court to clarify that HeatSticks “are ‘cigarettes’ under Order #1015” to ensure that the Order’s remedies extend to this new product. Pls. Mot. at 2, 15. Philip Morris, on the other hand, asks the Court to clarify that HeatSticks do not fall within Order #1015’s scope because they are not “cigarettes” – and, in the alternative, asks that the Court modify Order #1015 to exclude HeatSticks, thus exempting HeatSticks from Order #1015’s remedies and the corrective statements remedy, in particular. See Def. Opp. at 3-4, 27. Finally, if the Court were to find that HeatSticks fall within the scope of Order #1015 and decline to exempt HeatSticks from the Order’s remedies, Philip Morris requests that the Court modify

⁷ Order #1015 also contains remedies that are not specific to “cigarettes.” For instance, Order #1015 provides that the defendants shall maintain Internet Document Websites where members of the public can access documents “produced to the Government in this case” and documents produced in subsequent litigation “concerning smoking and health, marketing, addiction, low-tar or low-nicotine cigarettes, or less hazardous cigarette research.” Order #1015 ¶ III.C.10.a; see Order #1021 [Dkt. No. 5765] (clarifying the Internet Document Website remedy); United States v. Philip Morris USA Inc., Civil Action No. 99-2496, 2023 WL 4057501, at *6 (D.D.C. June 19, 2023) (clarifying that Order #1015’s Internet Document Website remedy requires defendants to publish discovery materials produced in In re JUUL Labs, Inc., Marketing, Sales Practices, and Products Liability Litigation, MDL No. 19-2913 (N.D. Cal.)).

Order #1015 to allow Philip Morris “to make statements authorized by FDA” on HeatSticks packaging. *Id.* at 3.

A. Plaintiffs’ Motion for Clarification

Plaintiffs state that “[a]n injunction must be understood in light of the circumstances surrounding its entry, including the trial court’s findings of fact . . . and the mischief that the injunction seeks to prevent.” Pls. Mot. at 6 (citing United States v. Philip Morris USA Inc., 566 F.3d at 1137; Common Cause v. Nuclear Regul. Comm’n, 674 F.2d at 927). They argue that the circumstances surrounding the entry of Order #1015 demonstrate that HeatSticks constitute “cigarettes” as the term is used throughout Order #1015. Pls. Mot. at 7. Specifically, plaintiffs suggest that Judge Kessler intended for Order #1015’s remedies to reach tobacco products like HeatSticks because she consistently referred to similar heated-tobacco products as “cigarettes” throughout trial and in her written opinion. *Id.* at 7-12; Pls. Reply at 6-7. Plaintiffs also argue that Judge Kessler ultimately found – “without qualification as to the type or kind of cigarette” – that Philip Morris “would continue to engage in fraud and deception concerning their tobacco products.” Pls. Mot. at 12.

Philip Morris urges a stricter reading of Order #1015 because “[i]t is a bedrock requirement that ‘courts closely tailor injunctions to the harm that they address.’” Def. Opp. at 15 (quoting ALPO Petfoods Inc. v. Ralston Purina Co., 913 F.2d at 972). Philip Morris argues that non-conventional tobacco products “played no part in the liability findings giving rise to the injunctions,” and therefore that “cigarettes” refer only to the traditional, combustible cigarettes on which Judge Kessler based her legal conclusions about the manufacturers’ RICO liability. Def. Opp. at 17-18. Philip Morris further asserts that interpreting “cigarettes” to encompass HeatSticks will not “prevent and restrain” future RICO violations because the restraints Judge

Kessler devised “were crafted based on the trial evidence regarding traditional combustible cigarettes.” Def. Opp. at 19. Philip Morris argues that “courts always ‘resolve omissions or ambiguities in the order in favor of the enjoined party,’” *id.* at 15 (quoting United States ex rel. Yelverton v. Fed. Ins. Co., 831 F.3d at 587), and that “where speech is concerned, an injunction should be ‘narrowly construed’ ‘to prohibit only [speech] that can be restrained consistent with the First Amendment.’” Def. Opp. at 15 (quoting United States v. Raymond, 228 F.3d 804, 816 (7th Cir. 2000)).

Plaintiffs persuasively argue that the meaning of the term “cigarette” “is clear from the way the parties and the Court used the term” during trial, including when discussing “less hazardous cigarettes” that existed at the time of trial and were substantially similar to HeatSticks. Pls. Mot. at 2. For the reasons that follow, the Court agrees with the plaintiffs that, because Judge Kessler was well aware of non-combustible, heated-tobacco products, referred to such products as “cigarettes,” and did not exempt such products from the Order’s remedies, those products – such as HeatSticks – should be understood to be “cigarettes” subject to the Order’s remedies.

1. HeatSticks are “Cigarettes” Subject to Order #1015’s Remedies

As plaintiffs observe, in Judge Kessler’s findings of fact, she referred to “non-conventional” tobacco products – including those closely resembling HeatSticks – as “cigarettes.” *See* Pls. Mot. at 8-9, 11-12; United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 399. Judge Kessler discussed these products in the context of the government’s claim that the tobacco manufacturers deliberately chose not to “develop and market less hazardous cigarettes” to avoid “undermin[ing] the commercial viability of their existing brands.” United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 384-85. Although Judge Kessler concluded

that the government failed to establish a “gentleman’s agreement” among the manufacturers’ to “not develop a less hazardous cigarette,” she nevertheless found extensive facts relating to several non-traditional, heat-not-burn “cigarettes” by a preponderance of the evidence. *Id.* at 384-85, 427.⁸ Judge Kessler “discussed for nearly 50 pages . . . a host of unconventional technologies not present in conventional cigarettes,” including products that were “non-combustible and produced a nicotine-containing aerosol by heating tobacco at a temperature below that which causes combustion.” *Pls. Mot.* at 7-9; see *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d at 384-430.

Plaintiffs maintain that Judge Kessler “consistently referred to [these] products as ‘cigarettes’” while evaluating the evidence and making certain findings of facts. *Pls. Mot.* at 7 (quoting *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d at 384-430 (emphasis added)). Plaintiffs are correct. See *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d at 399 (describing Philip Morris’s early efforts to develop an “electrically heated cigarette” (emphasis added)); *id.* at 403 (another tobacco manufacturer “actively pursued a program to develop, and ultimately market, a cigarette that heated, rather than burned, tobacco” (emphasis added)); *id.* at 410 (tobacco manufacturer “shifted its focus to development of another cigarette that reduced the burning temperature to reduce the formation and delivery of harmful constituents” (emphasis added)); *id.* at 430 (“[A]dvertising which focused on the health benefits of these newly developed cigarettes could have overcome the consumer resistance to them.” (emphasis added)). That Judge Kessler consistently referred to tobacco products that were

⁸ Judge Kessler’s findings of facts were “supported by the record and proved by at least a preponderance of the evidence,” even if those findings did not ultimately support a finding of liability under RICO. *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d at 30. Her findings were often “direct quote[s] from a witness’s written or oral testimony” or “taken directly from a proposed finding submitted by one of the parties.” *Id.*

similar to HeatSticks as “cigarettes” weighs strongly in favor of the plaintiffs’ preferred interpretation of Order #1015. See Alabama Nursing Home Ass’n v. Harris, 617 F.2d at 388 (deference is owed to “the court who issued” the injunction when interpreting the terms of the injunction).

Plaintiffs focus, in particular, on Philip Morris’s “Accord,” an electrically heated cigarette that Philip Morris developed in the 1980s and 1990s. See United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 399-400; Pls. Mot. at 8-10. Plaintiffs contend that Accord and the IQOS system for HeatSticks have the “same basic construction and means of consumption.” Pls. Mot. at 8. Both products use a processed tobacco insert and heat, rather than burn, the tobacco using an electric heating element. See id.; Def. Opp. at 4; United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 399-400.



Image 2: Side-by-side of Accord (left) and IQOS/HeatSticks (right). See Pls. Mot. at 9.

As plaintiffs point out, witnesses at trial and attorneys for Philip Morris “repeatedly characterized the materially-identical Accord product as [a ‘cigarette’].” Pls. Mot. at 9 (quoting the Philip Morris CEO, who stated that the Accord system used the company’s “electrically heated cigarette’ technology”). Judge Kessler, too, referred to Accord as a cigarette. See id. at 10. For example, Judge Kessler wrote:

To smoke Accord, the smoker inserts a cigarette into the end of the heating device. When a smoker inhales on the inserted cigarette, the inhalation triggers the device's electrical heating element, which heats the cigarette to a temperature below that necessary to create combustion and delivers smoke to the smoker.

United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 399 (emphasis added); see Pls. Mot. at 10. Similarly, to use the IQOS system, a user “insert[s] the HeatStick into the Holder,” which “heats the tobacco material with an electronically controlled heating blade.” Def. Opp. at 4. The “Holder’s temperature controls ensure that the HeatSticks are never ignited,” so the device produces a nicotine aerosol without creating combustion. Id. The technical similarity between HeatSticks and Accord strongly suggests that Judge Kessler would have also described HeatSticks as “cigarettes,” just as she described Accord as a “cigarette.” See United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 399; see also id. at 399-400, 403-415 (discussing R.J. Reynolds’s “heated tobacco cigarettes,” the Premier and Eclipse, and noting that Philip Morris developed Accord to compete with these other alternative cigarette products).

Judge Kessler’s opinion supports a more capacious understanding of the term “cigarette” than Philip Morris advocates. Throughout her opinion, Judge Kessler distinguished between “traditional,” “conventional cigarettes,” and other “less hazardous,” “electrically heated cigarettes,” such as Accord. See, e.g., United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 399-401. These products varied in tobacco delivery methods and nicotine levels, but each was still a “cigarette” within the scope of Order #1015. See id. Although Judge Kessler often did use the term “cigarette” to refer to the traditional, combustible product, neither her opinion nor Order #1015 purported to limit the definition of “cigarette” to only this traditional understanding of the word. As plaintiffs observe, Order #1015 does not distinguish between conventional cigarettes subject to the remedies imposed and the kinds of non-traditional products that Philip Morris

contends are excluded from the Order’s requirements. Pls. Reply at 6; see id. (“[W]ithout providing any mechanism in Order #1015 to distinguish truly ‘alternative and lower-risk’ cigarettes from all other cigarettes, the Order’s scope would be beholden to the linguistic ingenuity of tobacco company lawyers.”). Because Judge Kessler did not exclude from the reach of Order #1015 any of the non-traditional, non-combustible cigarettes that she discussed in her accompanying opinion, the Court agrees with the plaintiffs that the “only reasonable interpretation is the simplest one: ‘cigarettes’ means all cigarettes.” Id. at 7.⁹

Philip Morris nevertheless argues that alternative tobacco products similar to HeatSticks “played no part in the liability findings giving rise to the injunctions,” and thus Order #1015 does not extend to such alternative tobacco products. Def. Opp. at 17-18. Philip Morris argues, for example, that the corrective statements are less applicable to HeatSticks than they are to conventional cigarettes because HeatSticks do not produce secondhand smoke and were never marketed as “low tar.” Id. at 22-24. Philip Morris maintains, therefore, that, “given the evidence introduced at trial and the Court’s ultimate findings, the term ‘cigarette’ as used in Order #1015 is best read as limited to traditional, combustible cigarettes.” Def. Opp. at 16. This argument is not persuasive. Notwithstanding the technical differences between HeatSticks and conventional cigarettes, nothing in Judge Kessler’s opinion suggests that she believed “less hazardous” products were exempt from Order #1015 because they were not “cigarettes.” See United States

⁹ Judge Kessler’s opinion, in fact, contains a host of “cigarette” modifiers, including: “conventional cigarettes,” “traditional cigarettes,” “low-” and “high-nicotine cigarettes,” “low-tar cigarettes,” “full flavor cigarettes,” “reduced exposure cigarettes,” “less hazardous cigarettes,” “charcoal-filtered cigarettes,” “tobacco-burning cigarettes,” and “electrically heated cigarettes.” See generally United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 248, 310-38, 386-93, 400-05, 428. Judge Kessler’s consistent use of the term “cigarettes” to describe many different tobacco products counsels against the narrow interpretation that Philip Morris puts forth.

v. Philip Morris USA, Inc., 449 F. Supp. 2d at 430. The fact that Judge Kessler, when making findings of fact, consistently described non-traditional, heat-not-burn products as “cigarettes” suggests otherwise – even though she was ultimately not persuaded that the tobacco manufacturers tacitly agreed to hinder the development of these kinds of alternative tobacco products. See id. at 403, 427 (finding that the government failed to prove a “gentleman’s agreement” among defendants not to develop less hazardous cigarettes). The Court agrees with plaintiffs that “the corrective statement remedy restrains defendants’ conduct with respect to cigarettes generally.” Pls. Reply at 10 (emphasis added). This remedy is not limited to the specific products that existed at the time of trial and formed the basis for Judge Kessler’s conclusions of law. See United States v. Philip Morris USA Inc., 801 F.3d at 260 (corrective statements prevent manufacturers from making false claims about cigarettes, “whatever their new look”).

Philip Morris also seeks to distinguish HeatSticks from conventional, combustible cigarettes because HeatSticks are not “smoked” in the same way that traditional cigarettes are smoked. See Def. Opp. at 16 (emphasizing that Order #1015 “refer[s] repeatedly to products that are ‘smoked’ . . . [and] mentions ‘smoke’ or ‘smoking’ eleven times”). As Philip Morris explains, “HeatSticks are never ignited,” and “neither smoke nor ash is generated.” Id. at 4; see id. at 2 (HeatSticks is “a product that does not generate smoke”). Instead, Philip Morris repeatedly states that HeatSticks produce “aerosol,” which contains a “reduced formation of harmful chemicals . . . as compared to cigarette smoke.” Id. at 4, 6, 8. The plaintiffs, for their part, analogize again to Accord, which both Judge Kessler and Philip Morris previously referred to as a device that is “smoked” despite its lack of combustion and its utilization of heat-not-burn technology. See United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 399 (describing

how Accord “heats the cigarette to a temperature below that necessary to create combustion and delivers smoke to the smoker” (emphasis added)); see also Pls. Mot. at 9 (quoting testimony from Philip Morris’s technical consultant, Jerry Whidby, Ph.D., in which he discussed “cigarettes that generate smoke by heating rather than burning tobacco, such as Accord” (emphasis added)); id. at Ex. 11 (Accord advertisement, which was introduced at trial, read: “The Accord Cigarette is designed to be smoked only in the Accord Lighter” (emphasis added)). Judge Kessler’s opinion also calls into question the distinction between “smoke” and “aerosol” that Philip Morris emphasizes. See United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 404 (“The smoke from conventional cigarettes that burn tobacco is an aerosol generated by . . . the combustion, pyrolysis and distillation of tobacco. In contrast, [R.J. Reynolds’ smokeless, heat-not-burn product] Premier’s smoke was an aerosol generated primarily by distilling and condensing glycerol and volatile tobacco constituents.” (emphasis added)).

Regardless of whether HeatSticks are smoked or produce smoke, that an aerosol is produced and inhaled by a HeatSticks user is sufficiently similar to how smoke is produced and inhaled by a conventional cigarette smoker. See Pls. Mot. at Ex. 7 (IQOS frequently-asked-questions page explains that “HeatSticks are designed for the same length of time and number of puffs as traditional cigarettes” and that HeatSticks “provide tobacco taste that replicates as much as possible what adult smokers expect”); Oral Arg. Tr. at 5:15-21 (plaintiffs’ counsel argued that “HeatSticks have also been designed to have the essential characteristics of a traditional cigarette. . . . The same number of puffs, the same tobacco taste”). In this case, “the context of the court’s decision to issue an injunction” resolves the ambiguity identified by the parties about Order #1015’s use of the term “cigarettes.” Common Cause v. Nuclear Reg. Comm’n, 674 F.2d at 927. Judge Kessler’s opinion referenced both “less hazardous” and “electrically heated”

cigarettes, and this Court therefore concludes that HeatSticks are “cigarettes” for the purpose of understanding Order #1015. See United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 399, 430.

2. Applying Order #1015 to HeatSticks is Consistent with Judge Kessler’s RICO Findings

Beyond the specific definition of the term “cigarette,” plaintiffs further argue that Judge Kessler “did not except heated-tobacco cigarettes or any other type of cigarette from the scope of Order #1015,” and that, given the breadth of Judge Kessler’s conclusions as to RICO liability, Order #1015 must apply to heat-not-burn cigarettes such as HeatSticks. See Pls. Mot. at 12-13; Pls. Reply at 7-11. Judge Kessler’s conclusions bear repeating:

Defendants’ numerous misstatements and acts of concealment and deception were made intentionally and deliberately . . . as part of a multi-faceted, sophisticated scheme to defraud. . . . [A]s long as Defendants are in the business of selling and marketing tobacco products, they will have countless “opportunities” and temptations to take similar unlawful actions in order to maximize their revenues, just as they have done for the past five decades. . . .

Defendants also . . . den[ied] that they manipulate the design and content of cigarettes in order to assure adequate nicotine delivery to create and sustain smokers’ addiction. Such RICO violations are reasonably likely to continue.

United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 909, 912 (emphasis added).

The remedies imposed by Judge Kessler were not limited to any specific tobacco products in particular, and her findings were predicated on the defendants’ deceptive behavior while engaged “in the business of selling and marketing tobacco products.” United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 909. Plaintiffs assert that HeatSticks “undoubtedly are part of [the] business of selling and marketing tobacco products.” Pls. Reply at 9 (“A key design feature of the HeatSticks cigarette is that it delivers nicotine with addictive effect similar

to a conventional cigarette.”). The Court agrees. Because HeatSticks present another opportunity for Philip Morris to take “unlawful action” to “maximize their revenues,” it is entirely appropriate that HeatSticks fall within the scope of the injunctive relief Judge Kessler ordered. United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 909; see also United States v. Spectrum Brands, Inc., 924 F.3d 337, 357-58 (7th Cir. 2019) (considering “the sequence of events that led to the final injunction” and “the spirit of the court’s injunction” when clarifying the injunction’s provisions).

For its part, Philip Morris argues that “applying to HeatSticks the same restraints that were crafted based on the trial evidence regarding traditional combustible cigarettes will do nothing to ‘prevent and restrain’ future racketeering activity.” Def. Opp. at 19 (citing 18 U.S.C. § 1964(a); United States v. Philip Morris USA Inc., 436 F. Supp. 3d at 15-16). Philip Morris asserts that requiring corrective statements for HeatSticks is “nonsensical” because “[t]here is no ‘previously hidden truth’ about HeatSticks, and thus there is nothing to correct.” Def. Opp. at 22; see also Def. Reply at 5 (“No court, and obviously not this one, has found that Philip Morris USA misled consumers about HeatSticks.”). Philip Morris argues that injunctive relief must be “tailored to ‘the violation found.’” Def. Opp. at 19 (quoting United States v. Philip Morris USA Inc., 566 F.3d at 1118). Because HeatSticks and the IQOS system were “not the subject of any violation found at trial” and “did not even exist” at the time of trial, Philip Morris maintains that applying Order #1015 to this product does nothing to “prevent and restrain” future RICO violations, thereby exceeding the scope of the Court’s authority under RICO. Def. Opp. at 4, 19.

The Court disagrees. It concludes that applying Order #1015’s remedies to HeatSticks falls squarely within the Court’s RICO authority and Judge Kessler’s intent in issuing

the Order. RICO allows courts to craft “forward looking remedies . . . aimed at future violations.” United States v. Philip Morris USA Inc., 396 F.3d 1190, 1198 (D.C. Cir. 2005). As Judge Kessler explained, “Rule 65(d) does not require the District Court to predict exactly what the Defendants will think of next.” United States v. Philip Morris USA, Inc., 477 F. Supp. 2d 191, 196 (D.D.C. 2007) (quoting S.C. Johnson & Son, Inc. v. Clorox Co., 241 F.3d 232, 241 (2d Cir. 2001) (quotations and alterations omitted)). That HeatSticks did not exist at the time of trial and were not the subject of Judge Kessler’s findings of liability is irrelevant. Order #1015’s remedies address the manufacturers’ intentional omission of truthful information about nicotine, addiction, and the health consequences of using cigarettes. See United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 925-27. The corrective-statement remedy restrains manufacturers “from making false and deceptive claims about cigarettes generally.” Pls. Partial Opp. at 9 (emphasis added). Like conventional cigarettes, HeatSticks are tobacco products designed to deliver nicotine, see Def. Opp. at 9-10, and marketing this product presents an opportunity for Philip Morris to use deceit to increase its bottom line. United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 909. Philip Morris’s arguments – distinguishing HeatSticks from traditional cigarettes and construing the Court’s remedial authority under RICO as circumscribed by the Court’s factual findings about traditional cigarettes – are unavailing.

Moreover, the D.C. Circuit’s decisions about the corrective statements demonstrate that, even where a tobacco manufacturer is otherwise prohibited from making certain health-related claims about certain products, the corrective statements continue to “prevent[] and restrain[] defendants from making false health assurances about these cigarettes, whatever their new look.” United States v. Philip Morris USA Inc., 801 F.3d at 260. In 2012, for instance, the D.C. Circuit rejected the manufacturers’ arguments that the Tobacco Control

Act's stringent marketing regime mooted Order #1015 by making it unlikely that the manufacturers would violate RICO in the future. United States v. Philip Morris USA Inc., 686 F.3d at 836-37. And in 2015, the D.C. Circuit rejected a challenge to Judge Kessler's injunction where the tobacco manufacturers had argued that the Tobacco Control Act's ban on the terms "light" and "low tar" rendered the corrective statements about "light" and "low tar" cigarettes moot. United States v. Philip Morris USA Inc., 801 F.3d at 259-60. The court of appeals confirmed that the "light" and "low tar" corrective statements apply to all cigarettes – not just those cigarettes that had previously been marketed as "light" or "low tar" – and broad application of the corrective statements impairs the manufacturers from "making false and misleading assurances" by "simultaneously requir[ing] [manufacturers] to tell the truth," regardless of the product the corrective statements accompany. United States v. Philip Morris USA Inc., 855 F.3d at 383 (citing United States v. Philip Morris USA Inc., 566 F.3d at 1140). HeatSticks are "cigarettes" within the meaning of Order #1015, and applying Order #1015's remedial provisions to HeatSticks cigarettes is consistent with the Court's authority to impose remedies under RICO.

B. Defendant's Motion to Modify Order #1015

Philip Morris argues that, even if HeatSticks constitute "cigarettes" for the purpose of interpreting Order #1015, the Court should modify Order #1015 to exclude HeatSticks from its remedies – and specifically, from the corrective statements remedy. Def. Opp. at 3. Philip Morris also asks the Court, at minimum, to modify Order #1015 to exempt HeatSticks from the Order's prohibition on health-related descriptions, so that HeatSticks marketing can comply with FDA regulations. Id.; Def. Reply at 1.

The Court has the authority under Rule 60(b) of the Federal Rules of Civil Procedure to “relieve a party” from the provisions of Order #1015 if applying the Order prospectively “is no longer equitable,” or for “any other reason that justifies relief.” FED. R. CIV. P. 60(b)(5), (6). Courts applying Rule 60(b) require that a movant demonstrate “significant changed circumstances” before modifying a final order or judgment. Gov’t of Province of Manitoba v. Zinke, 849 F.3d at 1117, 1122. Philip Morris argues that changed factual and legal circumstances as well as First Amendment implications warrant the requested modifications to Order #1015. Def. Opp. at 27. Plaintiffs object to Philip Morris’s proposed general exemption for HeatSticks, but do not object to a narrow modification allowing Philip Morris to market HeatSticks using FDA-authorized statements. See Pls. Partial Opp. at 4.

1. Changed Legal and Factual Circumstances

Philip Morris argues that the FDA’s regulation and authorization of HeatSticks constitute changed factual and legal circumstances that justify a modification to Order #1015. In 2009, the FDA gained “comprehensive regulatory authority over the marketing of tobacco products” under the Tobacco Control Act. Def. Reply at 1; see Pub. L. No. 111-31, 123 Stat. 1776 (2009). Philip Morris explains in great detail that, in compliance with FDA’s new authority and regulations, the company submitted millions of pages of scientific research on the IQOS system to FDA, and that FDA’s experts extensively scrutinized this data. Def. Opp. at 6-8, 21. After this years-long regulatory process, “FDA has concluded that HeatSticks are expected to benefit public health as a whole when marketed with the authorized messaging,” including claims that switching from conventional cigarettes to HeatSticks and the IQOS system reduces a person’s exposure to potentially harmful chemicals. Def. Reply at 1. According to Philip Morris, including corrective statements in HeatSticks’ marketing would “risk serious

consumer confusion” and “would undermine FDA’s objective” to encourage traditional cigarette users to switch to HeatSticks. Given the developments in the regulatory landscape, Philip Morris requests that the Court modify Order #1015 to exempt HeatSticks from its provisions. Id. at 2.

Although plaintiffs are not opposed to modifying Order #1015 so that HeatSticks marketing may include the reduced-exposure claim, plaintiffs contend that HeatSticks should not be exempted altogether from Order #1015 merely because they are marketed subject to FDA authorization. Pls. Reply at 11. Plaintiffs argue that FDA authorization of the reduced-exposure claim justifies only a narrow modification to the prohibition on health-related statements and that this regulatory development is insufficient to exempt HeatSticks from Order #1015’s other requirements. See Pls. Partial Opp. at 4 (“[Philip Morris] has shown precisely one change in circumstances: FDA has authorized the marketing of HeatSticks cigarettes with a reduced-exposure claim.”).

The Court agrees with the plaintiffs that HeatSticks should not be exempt from Order #1015’s remedies merely because they are also regulated – however extensively – by FDA. After the Tobacco Control Act was enacted, Judge Kessler declined to vacate Order #1015 despite the manufacturers’ argument that “court-ordered relief would interfere with the implementation of the agency’s expert regulatory judgment.” United States v. Philip Morris USA, Inc., 787 F. Supp. 2d 68, 77 (D.D.C. 2011). The D.C. Circuit affirmed, agreeing that the district court maintained jurisdiction to oversee Order #1015’s remedies despite FDA’s new, broad regulatory authority. See United States v. Philip Morris USA Inc., 686 F.3d at 837-38. The Court’s injunction and the FDA’s regulations “target different conduct,” see United States v. Philip Morris USA, Inc., 787 F. Supp. 2d at 75, and serve different purposes: Order #1015 is designed to “prevent and restrain” future RICO violations, whereas FDA regulations must “set

national standards controlling the manufacture of tobacco products.” *Id.* at 78-79 (quoting Pub. L. No. 111–31, § 3(3), 123 Stat. at 1782, codified at 21 U.S.C. § 387). This Court yet again declines the invitation to treat FDA’s regulations as displacing Order #1015’s remedies.

Philip Morris argues that applying the corrective statements to HeatSticks marketing “would undermine the [reduced-exposure claims] FDA has found to be supported by the science.” Def. Opp. at 22. For example, Philip Morris suggests that the corrective statements about the number of smoking-related deaths per year “could seriously mislead consumers to conclude that the health risks of smoking combustible cigarettes and using HeatSticks are the exact same.” *Id.* at 24. See id. at 23-24 (corrective statements about secondhand smoke – which the IQOS system does not produce – could “seriously mislead consumers into thinking that HeatSticks produce secondhand smoke and that such smoke is the same between HeatSticks and combustible cigarettes”); *id.* at 24 (corrective statements about nicotine could mislead consumers “into thinking that Defendant designed HeatSticks to have more nicotine than combustible cigarettes” (emphasis in original)). Philip Morris argues that because the corrective statements would undermine the FDA-authorized health claims, requiring the inclusion of the corrective statements in HeatSticks packaging would “discourage consumers from switching to HeatSticks, which would thwart FDA’s objective to move consumers to products lower on the continuum of risk.” *Id.* at 25.

As plaintiffs observe, Philip Morris provides neither quantitative nor anecdotal evidence that “consumers will be misled if they see the corrective statements in connection with marketing for HeatSticks cigarettes.” Pls. Partial Opp. at 9, 11. Furthermore, plaintiffs accurately explain that the purpose of the corrective statements “is not to educate consumers” but to “restrain defendants from making contrary statements about cigarettes generally.” *Id.* at 9

(citing United States v. Philip Morris USA Inc., 801 F.3d at 262) (emphasis omitted); see United States v. Philip Morris USA Inc., 801 F.3d at 262-63 (in a civil RICO case, “[c]orrecting consumer misinformation” is “an impermissible objective,” whereas “prevent[ing] and restrain[ing] fraudulent statements” is a valid remedial purpose). Plaintiffs also highlight that “every corrective statement is required to appear” on every cigarette product, regardless of the cigarette product’s specific characteristics or the corrective statements’ applicability to that product. Pls. Partial Opp. at 2; see id. (cigarettes that were never labeled as “light” or “low tar” still must contain corrective statements about the misleading nature of these terms (citing Order #1015 ¶ III.A.4)). And although Philip Morris argues that the corrective statements are confusing when read in conjunction with FDA-authorized statements about the IQOS system, see Def. Opp. at 21-25, the corrective statements themselves are simple, easy-to-understand truths about cigarette use in general that do not contradict or reference the IQOS system in any way. See Order #72 – Remand; see also United States v. Philip Morris USA Inc. 566 F.3d at 1140, 1145 (corrective statements must convey “truthful” and “factual” information).¹⁰

Accordingly, the Court concludes that it is entirely sensible that HeatSticks may simultaneously include both FDA-authorized marketing statements and court-imposed corrective statements, each of which serves a different purpose and provides different information. Philip Morris has not demonstrated that the potential “confusion” resulting from these simultaneous

¹⁰ Although Philip Morris is correct that many of the corrective statements address attributes of traditional, combustible cigarettes, some of the corrective statements are applicable to – and are not misleading when applied to – HeatSticks. Examples of broad, generally applicable corrective statements, which are fairly applied to HeatSticks, include: “It’s not easy to quit,” “All cigarettes cause cancer, lung disease, heart attacks, and pre-mature death . . . there is no safe cigarette,” and “Cigarette companies control the impact and delivery of nicotine in many ways.” See Order #72 – Remand.

statements constitutes a changed circumstance that would warrant modifying Order #1015 to exempt HeatSticks from the corrective statements requirements altogether.

The fact that HeatSticks are a newly developed product that “did not exist at the time of trial” and were “never the subject of any misrepresentation,” Def. Reply at 2, 7, is irrelevant. HeatSticks’ novelty does not justify their exemption from Order #1015’s remedies. Judge Kessler “entered broad general injunctions . . . precisely because [she] intended Order #1015 to cover frauds and deceptions beyond those committed in the past.” Pls. Reply at 8. And, as discussed, Order #1015’s prohibition of deception “concerning cigarettes” is not limited to the traditional, combustible cigarettes underlying her findings of RICO liability. See Order #1015 ¶ III.A.3; United States v. Philip Morris USA, Inc., Civil Action No. 99-2496, 2023 WL 4057501, at *6 (D.D.C. June 19, 2023) (“[I]t was defendants’ conduct – rather than any specific product – that went to the heart of Order #1015’s remedies.”). The D.C. Circuit has already held that “[r]equiring Defendants to reveal the previously hidden truth about their products will prevent and restrain them from disseminating false and misleading statements . . . in the future.” United States v. Philip Morris, 566 F.3d at 1140. The corrective statements serve the goal of preventing future deception whether or not HeatSticks have been the subject of previous misrepresentations. The legal and factual changed circumstances here do not warrant the injunction’s modification.

2. Defendants’ Motion to Exempt HeatSticks From Paragraph 4 of Order #1015

Defendants request that “this Court should modify Order #1015 so that [Philip Morris] can market HeatSticks in accordance with FDA-authorized statements about their health effects.” Def. Reply at 1. “Plaintiffs agree to the Court’s modifying the one provision of Order #1015 that would stand in the way of [FDA-authorized] marketing.” Pls. Partial Opp. at 1.

Plaintiffs ask the Court to condition this exemption on Philip Morris’s compliance with FDA’s labeling requirements. See Proposed Order – Remand, Modifying Order #1015 to Permit Marketing of HeatSticks Cigarettes with Reduced-Exposure Claim [Dkt. No. 6340]. In relevant part, Paragraph 4 of Order #1015 provides:

All Defendants, Covered Persons, and Entities are permanently enjoined from conveying any express or implied health message or health descriptor [in the United States (or with direct, substantial, and foreseeable domestic effect)] for any cigarette brand either in the brand name or on any packaging, advertising or other promotional, informational or other material. Forbidden health descriptors include . . . words which reasonably could be expected to result in a consumer believing that smoking the cigarette brand using that descriptor may result in a lower risk of disease or be less hazardous to the health than smoking other brands of cigarettes.

Order #1015 ¶ III.A.4; Order #60 – Remand.

The “herculean scientific and technical review” that FDA conducted over several years culminated in the determination that the IQOS system “met the statutory standard of ‘appropriate for the protection of the public health.’” Def. Opp. at 8, 21 (quoting 21 U.S.C. § 387j(c)(2)(A)). FDA also concluded that the IQOS system is properly marketed as “reduc[ing] the production of harmful and potentially harmful chemicals” when compared to traditional, combustible cigarettes, and that including this health-related information on HeatSticks promotional material would “benefit the health of the population as a whole.” Def. Opp. at 1 (quoting 21 U.S.C. § 387k(g)(2)). These developments are “significant legal and factual changed circumstances” that warrant a narrow modification of Order #1015’s prohibition on health-related claims. See Gov’t of Province of Manitoba v. Zinke, 849 F.3d at 1117, 1121. Moreover, the Court agrees that it would be antithetical to the purpose of Order #1015 and the public interest to subject HeatSticks to Paragraph 4’s prohibition on health-related statements, because applying that paragraph to HeatSticks would “foreclose the dissemination of truthful

statements specifically authorized by FDA.” Def. Opp. at 19; see Horne v. Flores, 557 U.S. at 447 (“Rule [60(b)] provides a means by which a party can ask a court to modify or vacate a judgment or order if ‘a significant change either in factual conditions or in law’ renders continued enforcement ‘detrimental to the public interest.’” (quoting Rufo v. Inmates of Suffolk Cnty. Jail, 502 U.S. at 384)). Exempting HeatSticks from Paragraph 4’s prohibition on health-related statements – such that Philip Morris can include FDA-authorized statements on HeatSticks promotional, informational, and other material – is a “suitably tailored” modification to address these particular changed circumstances. Rufo v. Inmates of Suffolk Cnty. Jail, 502 U.S. at 383.

The Court agrees with plaintiffs’ suggestion that this modification should be tailored to permit only the reduced-exposure claim that FDA has authorized in connection with HeatSticks’ modified-risk tobacco product authorization under Section § 387k(g)(2). See Proposed Order – Remand, Modifying Order #1015 to Permit Marketing of HeatSticks Cigarettes with Reduced-Exposure Claim [Dkt. No. 6340] at 1. The Court declines to condition this modification explicitly on the satisfaction of “all conditions of any order pertaining to HeatSticks cigarettes issued under section 910 and 911 of the Federal Food, Drug, and Cosmetic Act” and “any requirements for labeling, advertising, marketing, and/or promotional materials to be submitted to FDA in advance of use.” Id. at 2. Ensuring satisfaction of those conditions is more appropriately left to FDA. See Def. Reply at 11 (“[E]nsuring compliance with FDA-imposed marketing restrictions is the responsibility of FDA.”). The Court is satisfied that modifying Order #1015, such that Philip Morris can market HeatSticks using a reduced-exposure claim as authorized by FDA, sufficiently responds to the changed circumstances identified by Philip Morris and effectuates the purpose of Order #1015.

3. First Amendment Challenge

Philip Morris contends that “the government has no legitimate interest in compelling [it] to make the Corrective Statements in connection with HeatSticks.” Def. Opp. at 32. Specifically, Philip Morris argues that applying Order #1015 to HeatSticks would violate the First Amendment because it would result in “unwarranted compelled disclosures in the form of the Corrective Statements” that would actually force Philip Morris to make misleading and confusing statements. *Id.* at 30.¹¹ Philip Morris asserts that the corrective statements are “nonsensical with respect to a product [HeatSticks] that a company has never misled the public about, and misleading to the extent the findings underpinning the statements conflict with FDA’s determination about the IQOS system.” *Id.* at 31. Accordingly, Philip Morris argues, the government has no legitimate interest in compelling the corrective statements in HeatSticks packaging. *Id.* at 31-32. Contrary to Philip Morris’s assertions, the Court concludes that the government continues to have a legitimate interest in requiring the corrective statements, and the corrective statements are not misleading or confusing even as applied to HeatSticks. Requiring Philip Morris to include the corrective statements with HeatSticks packaging therefore does not compel speech in violation of the First Amendment.

As the D.C. Circuit has made clear, the “purely factual and uncontroversial information” contained in the corrective statements is “geared towards thwarting prospective efforts by Defendants to either directly mislead consumers or capitalize on their prior deceptions by continuing to advertise in a manner that builds on consumers’ existing

¹¹ Philip Morris also argues that Order #1015 violates the First Amendment by prohibiting “truthful, non-misleading speech,” *i.e.*, the FDA-authorized reduced-exposure claims. Def. Opp. at 28-29; Def. Reply at 8-9. Because the Court agrees that modifying Order #1015 to permit FDA-authorized statements is appropriate, this argument is moot.

misperceptions.” United States v. Philip Morris USA Inc., 566 F.3d at 1144-45 (emphasis added). Whether Philip Morris has made misleading statements about HeatSticks in particular is not dispositive, as the government’s interest is not limited to preventing deception about the specific products that were the subject of Philip Morris’s previous misleading statements. See United States v. Philip Morris USA, Inc., 477 F. Supp. 2d at 196 (noting that “it would be impossible to foresee” the tobacco manufacturers’ “ingenuity and creativity”). Rather, the government has a legitimate interest under the First Amendment in preventing future deceptive statements, regardless of the product that those statements might accompany. See, e.g., Am. Meat Inst v. Dep’t of Ag., 760 F.3d at 26 (mandatory disclosures of “purely factual and uncontroversial information” comports with the First Amendment when government interest is ensuring that consumers receive truthful information). Judge Kessler concluded that there was a reasonable likelihood that Philip Morris and the other tobacco manufacturers would violate RICO in the future by making false and deceptive claims about their products, and she did not limit this conclusion only to the tobacco products that existed at the time of trial. See United States v. Philip Morris, 449 F. Supp. 2d at 909. That Philip Morris has not made misleading statements about IQOS or HeatSticks at this point does not undermine the government’s legitimate interest in preventing future deception by tobacco manufacturers.

Philip Morris also suggests that because HeatSticks are materially different from the combustible cigarettes on which the corrective statements are predicated, applying the statements to HeatSticks will potentially confuse consumers and thus undermine the government’s interest in mandating the corrective statements. Def. Opp. at 30-31. This argument fails because Philip Morris mischaracterizes the government’s interest as preventing consumer confusion. The government’s interest is more accurately described as “prevent[ing]

defendants from misleading consumers through fraudulent marketing.” United States v. Philip Morris USA Inc., 801 F.3d at 254. Indeed, when evaluating the corrective statements, the D.C. Circuit “declined to adopt the government’s argument that the statements were necessary to correct and prevent ongoing consumer misconceptions about cigarettes.” Id. at 257 (citing United States v. Philip Morris USA Inc., 566 F.3d at 1140). Instead, the court of appeals described the government’s interest as requiring tobacco manufacturers to provide truthful information as well as impairing the ability of the tobacco manufacturers to “make false and misleading assurances, thereby violating RICO.” Id.; see Zauderer v. Off. of Disciplinary Couns., 471 U.S. at 651 (the government has a legitimate interest in “preventing consumer deception”); Am. Meat Inst v. Dep’t of Ag., 760 F.3d at 26 (government has a legitimate interest in “assuring that consumers receive particular information” when such “mandate[ed] disclosures correct deception”).

Although it is the government’s burden to demonstrate that the “imposition on speech meets the constitutional standard” under the First Amendment, Def. Reply at 10, the government has already done so with respect to the corrective statements. See United States v. Philip Morris USA Inc., 566 F.3d at 1144-45; see generally United States v. Philip Morris USA Inc., 855 F.3d at 321; United States v. Philip Morris USA Inc., 801 F.3d at 250; United States v. Philip Morris USA, Inc., 436 F. Supp. 3d at 16-17 (“[T]he court of appeals concluded that the corrective statements are a permissible restraint on the defendants’ commercial speech.”). Philip Morris’s speculation about consumer confusion does not give the Court a sufficient basis to call its prior First Amendment conclusions into question. Judge Kessler determined that the corrective statements remedy is “appropriate and necessary to prevent and restrain” the defendants, including Philip Morris, from making fraudulent statements in the future about their

products, and that “the defendants’ First Amendment rights did not prohibit this remedy.” United States v. Philip Morris USA Inc., Civil Action No. 99-2496, 2022 WL 1101730, at *2 (D.D.C. Apr. 13, 2022) (quoting United States v. Philip Morris USA, Inc., 436 F. Supp. 3d at 6); see also United States v. Philip Morris USA, Inc., 449 F. Supp. 2d at 926. The court of appeals agreed. See United States v. Philip Morris USA Inc., 855 F.3d at 325, 328.

Consistent with the RICO statute and the parameters of the First Amendment, Order #1015 imposes a forward-looking restraint on the defendants’ ability to disseminate false advertising – it does not require Philip Morris to rectify consumer misconceptions. See United States v. Philip Morris USA Inc., 801 F.3d at 257. The potential for consumer confusion does not undermine the government’s legitimate interest in mandating the corrective statements. The corrective statements as applied to HeatSticks thus do not constitute “compelled disclosures” in violation of the First Amendment. Nat’l Ass’n of Mfrs. v. Secs. Exch. Comm’n, 800 F.3d 518, 522 (D.C. Cir. 2015). Neither the First Amendment nor any of the changed circumstances identified by Philip Morris provide reason to modify Order #1015 by exempting HeatSticks from its requirements.

IV. CONCLUSION

After a nine-month bench trial featuring dozens of witnesses and thousands of exhibits, Judge Kessler issued a 1,600-page opinion and accompanying order, Order #1015. Plaintiffs have asked this Court to clarify whether Order #1015 covers HeatSticks and the IQOS system, which Philip Morris has developed in the years since Judge Kessler presided over this trial. Philip Morris has requested the Court to exempt HeatSticks from Order #1015’s requirements, citing new FDA authorizations and familiar First Amendment principles. For the reasons explained in this Opinion, the Court concludes that Order #1015 applies to HeatSticks

cigarettes, and the Court declines to create Philip Morris's requested exemption. The Court will, however, modify Order #1015 such that Philip Morris may include FDA-authorized reduced-exposure claims on HeatSticks advertising, promotional, informational, and other materials. A separate Order consistent with this Opinion shall issue this same day.

SO ORDERED.



PAUL L. FRIEDMAN
United States District Judge

DATE: 7/14/23