

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	Civil Action No. 99-CV-2496 (GK)
)	Next scheduled court appearance:
and)	OCTOBER 15, 2012
)	
TOBACCO-FREE KIDS ACTION FUND,)	
<i>et al.</i> ,)	
)	
Plaintiff-Intervenors,)	
)	
v.)	
)	
PHILIP MORRIS USA, INC., <i>et al.</i> ,)	
)	
Defendants.)	

**PUBLIC HEALTH INTERVENORS’ RESPONSE TO DEFENDANTS’
SUPPLEMENTAL BRIEF REGARDING THE GOVERNMENT’S
PROPOSED CORRECTIVE STATEMENTS**

As the Public Health Intervenors have explained, the D.C. Circuit’s recent rulings in this case reaffirm this Court’s extraordinarily broad discretion in addressing Defendants’ massive and multi-faceted fraud, and the proposed Corrective Statements fall well within that discretion. Intervenors’ Supplemental Brief (“Int. Br.”) (DN 5986) at 3-5. Defendants’ contrary contention that the Court’s discretion is seriously constrained by the D.C. Circuit’s ruling in an Administrative Procedure Act (“APA”), 5 U.S.C. § 706, challenge to an FDA rulemaking in a separate case – *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.* (“*R.J. Reynolds*”), No. 11-5332, 2012 WL 3632003 (D.C. Cir. Aug. 24, 2012) – is far off the mark, for several reasons.

First, the panel majority in *R.J. Reynolds* rejected the *Zauderer* “relaxed standard” of review, *id.* at *3 n.5 – whereby a disclosure mandate passes First Amendment scrutiny so long as it is “reasonably related to the State’s interest,” *id.* at *4 – on the grounds that the *Zauderer*

standard only applies where “there is a self-evident – or at least ‘potentially real’ – danger that an advertisement will mislead consumers.” *Id.* at *6 (emphasis added) (quoting *Ibanez v. Fla. Dep’t of Bus. & Prof’l Regulation*, 512 U.S. 136, 146 (1994)). Thus, because the Court found that the FDA had not issued the regulations as “a remedial measure designed to counteract specific deceptive claims made by the Companies,” the *Zauderer* standard did not apply. *Id.* at *7 (emphasis added).

Of course, here, by contrast, the corrective statements remedy is expressly intended to “counteract specific deceptive claims” by Defendants, *id.*, and, in particular, to circumscribe Defendants’ ability to make “false and misleading assurances about, for instance, smoking-related diseases or the addictiveness of nicotine” *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1140 (D.C. Cir. 2009). Indeed, as the D.C. Circuit recently reaffirmed, Defendants’ “RICO violations *will continue* in most of the areas in which they have committed violations in the past,” in light of their “‘countless (future) opportunities and temptations to take similar unlawful actions.” *United States v. Philip Morris USA, Inc.*, 686 F.3d 832, 834 (D.C. Cir. 2012) (quoting *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 909, 912 (D.D.C. 2009)). Accordingly, contrary to Defendants’ contentions, Def. Br. at 6-7, *R.J. Reynolds* does not change the fact that the *Zauderer* standard of review applies here.

Far more on point than *R.J. Reynolds* is the D.C. Circuit’s recent ruling in *Spirit Airlines, Inc. v. Dep’t of Transp.*, 687 F.3d 403 (D.C. Cir. 2012). That case involved a Department of Transportation (“DOT”) regulation requiring airlines to prominently display the total price of airline tickets, including taxes. In considering the airline’s First Amendment challenge, the Court found that the *Zauderer* standard applied because the regulation was “‘directed at

misleading commercial speech,” and imposed a “disclosure requirement rather than an affirmative limitation on speech.” *Id.* at 412 (quoting *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339 (2010)) (emphasis in original).¹

Accordingly, the Court explained, the regulation need only be “reasonably related to the State’s interest in preventing deception of consumers.” *Id.* (quoting *Zauderer*, 471 U.S. at 651). Therefore, because the proposed Corrective Statements are also directed at “misleading” statements by Defendants, the *Zauderer* standard similarly applies here.²

Second, having concluded that a higher level of scrutiny applies, the Court in *R.J. Reynolds* determined that the FDA had a significant burden to demonstrate that the graphic warning labels at issue would achieve the agency’s stated purpose. The Court rejected the agency’s explicit statement that its purpose was to effectively communicate information to consumers, and instead concluded that the governmental interest should be viewed as “encourag[ing] current smokers to quit and dissuad[ing] other consumers from ever buying cigarettes.” *R.J. Reynolds*, 2012 WL at *9. The Court then rejected the graphic warning labels because it found that, contrary to the evidence presented by the Government, the record did not

¹ The Court distinguished the stricter First Amendment test that was applied in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm. of New York*, 447 U.S. 557, 572 (1980), on the ground that *Central Hudson* involved “prohibiting speech,” while the DOT Rule (like the proposed Corrective Statements) “simply require[s]” affirmative disclosures. 687 F.3d at 412-13. As the Court explained, the “constitutionally protected interest in *not* providing [] required factual information is minimal.” *Id.* at 413 (quoting *Milavitz*, 130 S. Ct. at 1340).

² Contrary to Defendants’ contention, Defs.’ Suppl. Br. (“DN 5985”) (“Def. Br.”) at 7, because the *Zauderer* test applies, the Court need not inquire whether the proposed Corrective Statements are the least restrictive means to advance the government’s interest. *See Zauderer*, 471 U.S. at 651, n.14 (“Because the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed, we do not think it appropriate to strike down such requirements merely because other possible means by which the State might achieve its purposes can be hypothesized”).

support the conclusion that the proposed graphic warnings would significantly reduce smoking rates. *Id.* at *10.

Here, by contrast, this Court has held, and the Court of Appeals has affirmed, that the Defendants are likely to attempt to mislead the public in the future, just as they have for decades. Accordingly, the proposed Corrective Statements are “*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 misperceptions.” *Philip Morris USA Inc.*, 566 F.3d at 1144-45 (emphasis added). Where, as here, the harm that the Defendants’ misleading statements has caused and is likely to continue to cause is “potentially real, not merely hypothetical,” the Court need only be satisfied that the corrective statements are “reasonably related to the State’s interest in preventing deception of consumers.” *R.J. Reynolds*, 2012 WL at *14,15 (quoting *Zauderer* and *Ibanez*).³

Rather than comparing the proposed Corrective Statements to the FDA graphic warning labels, the Court should instead compare them to the *other* remedial measures the D.C. Circuit has already approved in this case. For example, Defendants strenuously objected, on First Amendment and other grounds, to this Court’s general injunction against further acts of racketeering, claiming that the injunction was too broad and did not “sufficiently specify the acts restrained.” *Philip Morris USA Inc.*, 566 F.3d at 1137. Rejecting these objections, the D.C.

³ As Judge Williams explained in concurring in the disgorgement ruling in this case, the test for appropriate remedies is whether they will have “a genuine tendency to ‘prevent and restrain’ [the defendants’] future violation.” *United States v. Philip Morris USA Inc.*, 396 F.3d 1190, 1204 (D.C. Cir. 2005); *see also, e.g., United States v. Microsoft Corp.*, 253 F.3d 34, 102 (D.C. Cir. 2001) (explaining that a remedial decree “by necessity ‘involves predictions and assumptions’”) (quoting *Ford Motor Co. v. United States*, 405 U.S. 562, 578 (1972)); *SEC v. Capital Gains Research Bureau, Inc.*, 375 U.S. 180, 193 (1963) (remedial disclosures permitted where they will serve as a “mild prophylactic” against further misconduct).

Circuit ruled that while such a general injunction “may be broad, [] *breadth is warranted* to prevent further violations where, as here, a proclivity for unlawful conduct has been shown.” *Id.* (emphasis added). More recently, the D.C. Circuit reiterated this broad remedial authority in refusing even to review this Court’s clarification of the disaggregated marketing data remedy. *Philip Morris USA, Inc.*, 686 F.3d at 843-45. In short, the D.C. Circuit found that the administrative record compiled by the FDA in *R.J. Reynolds* constrained the FDA’s discretion to require graphic warning labels. Here, by contrast, as the D.C. Circuit has repeatedly emphasized, the record emphatically supports this Court’s broad discretion to impose equitable remedies for misconduct that has been found likely to occur in the future. The proposed Corrective Statements are well within that discretion.

Third, R.J. Reynolds does not support Defendants’ effort to further delay implementation of this vital remedy by demanding an evidentiary hearing concerning the proposed Corrective Statements. Def. Br. at 9-10. There was no evidentiary hearing in that case, as is generally the case in a suit under the APA. Rather, plaintiffs simply challenged the adequacy of the agency’s regulation in light of the record the agency had compiled.

Similarly, here, the issue is whether the record before this Court – *i.e.*, the Court’s own extensive Findings of Fact – adequately supports the government’s proposed remedy on Corrective Statements. Thus, there is no reason to further delay the imposition of these much needed remedies by allowing Defendants to take discovery or otherwise challenge the factual accuracy of the governments’ submission. Indeed, the D.C. Circuit already rejected Defendants’ bid for an evidentiary hearing before imposing this remedy. 566 F.3d at 1138-39.

The Supreme Court's recent ruling in *Milavetz* is instructive in this regard. That case concerned the required disclosure of a factually "accurate statement" that a law firm is "'a debt relief agency,'" in light of the services it provides. 130 S. Ct. at 1330-31. Rejecting the firm's argument that the Government "has adduced no evidence" supporting the disclosure requirement, the Court explained that no "survey" or other evidence need be collected where "the possibility of deception" is self-evident. *Id.* at 1340 (quoting *Zauderer*, 471 U.S. at 652-53). Applying that reasoning here, the existing record already establishes the likelihood of Defendants' ongoing deceptions, and, accordingly, the Court would be well within its discretion in ordering publication of the proposed Corrective Statements *irrespective* of the government's supporting materials. In light of this reality, there certainly is no basis for Defendants' claim that they have a right to challenge Dr. Blake's submission. *See also* Int. Reply To Defs.' Resp. ("Int. Reply") at 14-15 (DN 5890, Mar. 16, 2011 (further explaining why the court should reject Defendants' claimed entitlement to an evidentiary hearing); *accord Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 558 (6th Cir. 2012) ("[c]onstitutionality does not hinge upon some quantum of proof that a disclosure will realize the underlying purpose. A common sense analysis will do.").⁴

Finally, Defendants incorrectly seek to compare the *content* of the graphic warning labels, which the D.C. Circuit panel majority concluded were "primarily intended to evoke an emotional response," *R.J. Reynolds*, 2012 WL at *7, with the content of the proposed Corrective

⁴ Nor is there any basis for Defendants' suggestion that the Court should "direct the parties to mediate and reach agreement" on the content of corrective statements. Def. Br. at 10. While Defendants have long objected to the proposed Corrective Statements, since the case was remanded in the summer of 2010 they have failed to present a concrete alternative that they would find acceptable. Their failure to propose alternative language to the Court speaks volumes regarding whether the parties would ever reach such an agreement.

Statements. Although the Intervenors do not agree with the majority's conclusion in *R.J. Reynolds* on the content or impact of the warning labels, the Court found that the graphic warning labels did not contain an "accurate statement" about cigarettes," but rather were "inflammatory images" that should be treated as "unabashed attempts to evoke emotion (and perhaps embarrassment)" *Id.* at *8, *14.

While Defendants self-servingly assert that the proposed Corrective Statements are similarly infirm, there can be no legitimate dispute that the proposed statements *do* contain entirely "accurate statement[s] about cigarettes." *Id.*; *see also* Int. Resp. To Proposed Corr. Stmt (DN 5883, Mar. 3, 2011) at 13-14. Contrary to Defendants' further attempt to paint the proposed Corrective Statements as no different from the graphic warning labels found deficient in *R.J. Reynolds*, the proposed Corrective Statements are not "naked appeals to emotion" proposed "because they elicit feelings of condemnation, revulsion, and anger in viewers." Def. Br. at 4-5.⁵

The proposed Corrective Statements are entirely accurate, and cannot be legitimately disputed in light of this Court's factual findings. The public has a right to know these true facts about this product as a means of preventing Defendants from continuing to deceive consumers about these extremely important matters – including letting the public know that the contrary information they have previously heard is inaccurate. *See, e.g.*, "For decades, we denied that we controlled the level of nicotine in cigarettes" (Topic D).

⁵ As the government has explained in detail, the proposed Corrective Statements were chosen because they proved the most effective at achieving their intended purpose, not because they were inflammatory. *See* DN 5891 at 15-18; DN 5930 at 12-20.

As Defendants note, Def. Br. at 2, the Court in *R.J. Reynolds* was also concerned that the graphic warning labels at issue there may be “misinterpreted by consumers,” Def. Br. at 2, quoting 2012 WL at * 7, so that, for example, the picture of a “man smoking through a tracheotomy hole might be misinterpreted as suggesting that such a procedure is a common consequence of smoking” *Id.* Here, by contrast, there is no basis for misinterpreting the entirely accurate proposed Corrective Statements. *See* Int. Reply at 8-10. Thus, for example, while Defendants continue to complain that admitting that they “‘manipulated cigarettes to make them more addictive’ is plainly open to misinterpretation,” Def. Br. at 5, this is what in fact the Court *found*. *E.g.* FF 1759 (“As established by the Findings of Fact set forth in this section, cigarette company Defendants researched, developed and implemented many different methods and processes to *control the delivery and absorption of the optimum amount of nicotine that would create and sustain a smoker’s addiction*”) (emphasis added); *see also* 566 F.3d at 1134 (noting that on appeal Defendants “offer no rebuttal to the[] factual finding[]” that “despite the MSA Defendants still . . . falsely denied manipulating nicotine delivery”).⁶

⁶ For these same reasons the proposed Corrective Statements cannot be deemed controversial, even though Defendants strenuously disagree with them. *See Milavetz*, 130 S. Ct. at 1340 (challengers’ “preference” against mandated disclosure “lacks any constitutional basis”); *see also Disc. Tobacco*, 674 F.3d at 559 n.8 (explaining that under *Zauderer* a disclosure requirement need only be “factual [and] accurate,” and if so need not also be “noncontroversial”).

In sum, in light of the Court's overwhelming findings, the proposed Corrective Statements are entirely accurate and appropriate to address Defendants' ongoing fraud. Accordingly, the Public Health Intervenors urge that Defendants be directed to publish the Statements as soon as practicable.

Respectfully submitted,

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