R.J. REYNOLDS TOBACCO COMPANY et al v. UNITED STATES FOOD AND DRUG ADMINISTRATION et al Doc. 32

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

R.J. REYNOLDS TOBACCO COMPANY, LORILLARD TOBACCO COMPANY, COMMONWEALTH BRANDS, INC., LIGGETT GROUP LLC, and SANTA FE NATURAL TOBACCO COMPANY, INC.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, MARGARET HAMBURG, Commissioner of the United States Food and Drug Administration, and KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,

Defendants.

Civil Action No. 11-01482 (RCL)

SUPPLEMENTAL MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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Pursuant to the Court's invitation at oral argument, this memorandum briefly addresses three points relevant to Plaintiffs' Motion for Preliminary Injunction that were raised by the Court at argument.

1. During oral argument, the Court asked both parties whether Congress had specifically considered the First Amendment implications of the graphic warnings embodied in the Rule. Plaintiffs have reviewed the Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (the "Act"), and its legislative history, and have been unable to identify any indication that Congress considered such First Amendment implications.

The Act was introduced in the 111th Congress as H.R. 1256. *See* H.R.1256, 111th Cong. (Mar. 3, 2009). In its original form, the bill gave FDA discretion "to require color graphics to accompany the text" and "increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package," but required FDA to justify such warnings under the APA and "find that such a change would promote greater public understanding of the risks associated with the use of tobacco products.'' *Id.* § 202(b). As introduced, however, the bill did not itself require the new warnings to include graphic images or occupy 50 percent of the front and back of cigarette packages. On June 10, 2009, H.R. 1256 was amended to expand the size of the warnings and require the inclusion of color graphics. *See* 155 Cong. Rec. S6406-12 (June 10, 2009); Act § 201(a) (June 11, 2009). The bill was enacted by the Senate the following day, June 11, 2009, and passed by the House on June 12, 2009. *See* 155 Cong. Rec. S6501 (June 11, 2009); 155 Cong. Rec. H6660 (June 12, 2009).

We have been unable to identify any indication in the legislative history that Congress considered the First Amendment implications of these changes or of the warnings requirement generally. Nor does the Act include any congressional findings that the new warnings will: (1) increase public understanding of the risks associated with tobacco use; (2) further the government's interest in reducing smoking rates, or (3) be more effective than the many less-restrictive warnings

possible (including, most obviously, the less obtrusive warnings contained in prior versions of the bill). *See* Act § 2.

2. During argument, the Court also inquired about the evidentiary record. As Plaintiffs explained, the FDA's Regulatory Impact Analysis and experimental study of 18,000 individuals demonstrate that the warnings (1) have no statistically significant impact on smoking rates, (2) do not increase the likelihood that smokers will quit or non-smokers will start smoking, and (3) do not increase knowledge of the risks of smoking. The other evidence cited by the Government, moreover, does not address any of these issues either. Instead, it simply tests "salience"—that is, whether shocking graphics are more noticeable than the current warnings. This, however, is irrelevant absent any empirical evidence that they change smoking behavior. After all, the Government does not have an interest in shocking people just for the sake of shocking them.

In short, as the Surgeon General said back in 1994, because the risks of tobacco use are universally known, anti-smoking strategies that, like the new warnings, are premised on the "assumption" that "young people had a deficit of information that could be addressed by presenting them with health messages in a manner that caught their attention and provided them with sufficient justification not to smoke," are "not effective" at reducing smoking. *See* SJ Mem. at 15. Or as Dr. David Hammond, an anti-tobacco researcher that the Government regularly relies upon, recently explained: "There is no way to attribute . . . declines [in smoking] to the new health warnings given that [they] are typically introduced against a backdrop of other tobacco control measures, including changes in price/taxation, mass media campaigns and smoke-free legislation."[1] The Government's own scientists therefore concede that there is no empirical evidence that the warnings are effective. This is dispositive in a First Amendment case in which the Government bears the burden of proof.

[1] Hammond D., Health Warnings Messages on Tobacco Products: A Review, 20 Tobacco Control 327, 331 (March 2011) *available at* http://tobaccocontrol.bmj.com/content/early/2011/05/23/tc.2010.037630.abstract.

3. During oral argument, this Court also asked both parties about its authority to enter the preliminary injunction that Plaintiffs have requested. As Plaintiffs have explained, subject to the balancing test governing preliminary relief, this Court has inherent equitable authority to issue an injunction preventing irreparable injury pending review of Plaintiffs' claims. *See Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946) ("Power is … resident in the District Court … to do equity and mould each decree to the necessities of the particular case…. In addition, the court may go beyond the matters immediately underlying its equitable decision and decide whatever other issues and give whatever other relief may be necessary under the circumstances. Only in that way can equity do complete rather than truncated justice."). Here, the relief Plaintiffs have requested is the only relief capable of avoiding the irreparable harm they have identified; it therefore falls well within this Court's equitable power.

In light of the Court's questioning at oral argument, Plaintiffs add that courts frequently employ their broad equitable power to fashion interim relief appropriate to a variety of situations. These remedies underscore the flexibility of the Court's equitable power to tailor relief to the facts of the case. For example, in *Society of the Sisters of the Holy Names of Jesus and Mary v. Pierce*, 296 F. 928, 933 (D. Or. 1924), the district court preliminarily enjoined a compulsory public education law even though it was not scheduled to take effect for approximately two and half years. The court explained that "although the time at which the act is to become effective is somewhat remote, it is quite apparent, from the allegations of the bills, the work of destruction of complainants' occupation has already set in" (because the law deterred parents from enrolling in private schools). *Id.* On review, the Supreme Court expressly approved of this reasoning, stating that "[i]f no relief had been possible prior to the effective date of the Act, the injury would have become irreparable. Prevention of impending injury by unlawful action is a well recognized function of courts of equity." *Pierce v. Society of Sisters*, 268 U.S. 510, 536 (1925). The same is true here: there is no dispute that, absent

preliminary relief, Plaintiffs will be forced to expend millions of dollars and thousands of employee hours to comply with warnings that are likely to be held unconstitutional.

Likewise, in *Friends for All Children v. Lockheed Aircraft*, 746 F. 2d 816 (D.C. Cir 1984), the court granted a preliminary injunction that, rather than barring any party from taking a particular action, affirmatively required Lockheed to create a $450,000 fund for accident victims, even though there had been no determination of the amount of Lockheed's liability. This unusual remedy was within the courts' inherent equitable power because "the delay inherent in trying the case to compute the amount of the defendant's liability w[ould] result in irreparable injury." *Id.* at 831.

And in *Northern Pipeline Construction Co. v. Marathon Pipe Line Co.*, 458 U.S. 50 (1982), the Supreme Court held that the Bankruptcy Act of 1978 violated the constitution by vesting judicial power in judges who lacked the protections of Article III. Yet the Court relied on its inherent authority to stay its judgment for several months so that Congress could transition smoothly to a constitutional bankruptcy system. *Id.* at 88 (plurality opinion) ("This limited stay will afford Congress an opportunity to reconstitute the bankruptcy courts or to adopt other valid means of adjudication, without impairing the interim administration of the bankruptcy laws."). That is, the Court gave the Government a reasonable compliance period following its decision even though the Government had *conclusively lost* on its constitutional argument. *A fortiori*, this Court has the power to give Plaintiffs a reasonable compliance period if, as Plaintiffs have argued, they have a strong likelihood of *success* on their constitutional claim.

As the foregoing examples illustrate, this Court has broad authority to grant relief where justified by the strength of Plaintiffs' claims on the merits, the need to avoid irreparable injury, the balance of the equities, and the public interest. Each of these factors likewise tips decisively in Plaintiffs' favor here.

Respectfully Submitted,

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/s/ Noel J. Francisco

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