Office of the Attorney General
Washington, D. C. 20530

March 15, 2013

The Honorable John Boehner
Speaker
U.S. House of Representatives
Washington, DC 20515

Re: R.J. Reynolds v. Food & Drug Administration, No. 11-5332 (D.C. Cir.)

Dear Mr. Speaker:

Consistent with 28 U.S.C. 530D, I write to inform you that on March 14, 2013, the Department of Justice decided not to file a petition for a writ of certiorari seeking review of the decision of the United States Court of Appeals for the District of Columbia Circuit in the above-referenced case. A copy of the decision is enclosed.

The Family Smoking Prevention Tobacco Control Act of 2009 (Act), Pub. L. No. 111-31, 123 Stat. 1776, grants the Food and Drug Administration (FDA) authority to regulate cigarettes and other tobacco products. The Act provided for revision of both the text and the format of preexisting cigarette health warnings required on cigarette packaging and advertising, including by requiring that product labels and cigarette advertisements contain one of nine specified warnings on a rotating basis.[1] The Act requires that the warnings occupy 50% of the front and rear panels of cigarette packs and that the text of the warning appear in conspicuous and legible type; it also requires that the warnings occupy 20% of cigarette advertisements. 15 U.S.C. 1333(a)(2).[2] The Act also directs the Secretary of Health and Human Services to "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany" the required text warnings. 15 U.S.C. 1333(d). FDA published for public comment 36 proposed images, see 75 Fed. Reg. 69,526 (Nov. 12, 2010), and then selected nine images (one for each warning) after reviewing more than 1000 comments and the results of an 18,000-person consumer study testing the relative effectiveness of each image, see 76 Fed. Reg. 36,628 (June 22, 2011).

Plaintiff cigarette manufacturers filed suit to enjoin the required warnings, contending that the Act and its implementing regulations violate their rights under the First Amendment. See R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1211 (D.C. Cir. 2012). The district

---

[1] The Act requires that each of the following nine statements appear on a rotating basis following the word "WARNING": (1) Cigarettes are addictive; (2) Tobacco smoke can harm your children; (3) Cigarettes cause fatal lung disease; (4) Cigarettes cause cancer; (5) Cigarettes cause strokes and heart disease; (6) Smoking during pregnancy can harm your baby; (7) Smoking can kill you; (8) Tobacco smoke causes fatal lung disease in nonsmokers; (9) Quitting smoking now greatly reduces serious risks to your health. 15 U.S.C. 1333 note.

[2] Section 1333, as amended, is reproduced as a note to 15 U.S.C. 1333 (Supp. V 2011).

court granted plaintiffs' motion for a preliminary injunction and subsequently granted their motion for summary judgment. See ibid. Reviewing FDA's regulation requiring the specified graphic warnings under strict scrutiny, the district court concluded that the regulation violates the First Amendment and enjoined its enforcement. See id. at 1208, 1212-1213.

On appeal, a divided panel of the D.C. Circuit affirmed. The court of appeals analyzed the regulation under the intermediate level of scrutiny articulated in Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, 447 U.S. 557, 566 (1980), that is applicable to restrictions on commercial speech. Reynolds, 696 F.3d at 1217-1222. Under that standard, the court explained, the government was required to establish that the graphic warning requirements FDA adopted "are narrowly tailored to achieve a substantial government goal." Id. at 1217 (quoting United States v. Philip Morris USA Inc., 566 F.3d 1095, 1143 (D.C. Cir. 2009), cert. denied, 130 S. Ct. 3501 (2010)). The court concluded that the graphic warnings failed to meet that standard. Id. at 1217-1222. Assuming that the government has a substantial interest in encouraging current smokers to quit and dissuading other consumers from beginning to smoke, the court concluded that FDA had not established that "the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke." Id. at 1219-1220. Although the court noted FDA's reliance on "the 'international consensus' surrounding the effectiveness of large graphic warnings," it found that FDA failed to present evidence that the use of such warnings has "directly caused a material decrease in smoking rates in any of the countries that now require them." Id. at 1219. The court also rejected as too vague the government's interest in "effectively communicating health information" to consumers about the negative health consequences of smoking. Id. at 1221. The court therefore vacated the graphic warning requirements in FDA's regulations and remanded the matter to the agency. Id. at 1222.

Judge Rogers dissented. Reynolds, 696 F.3d at 1222-1238. She agreed with the panel majority that the district court erred in subjecting the graphic warning requirements to strict scrutiny, concluding that "the speech as issue — proposing the sale of cigarettes — is indisputably commercial speech." Id. at 1222. But she would have applied the "less exacting scrutiny" the Supreme Court articulated in Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985), rather than the Central Hudson standard, "[b]ecause the warning labels present factually accurate information and address misleading commercial speech, as defined in Supreme Court precedent." 696 F.3d at 1222-1223; see id. at 1225-1232. Under the Zauderer standard, she explained, "the government need show only that the warning label requirement is reasonably related to its stated and substantial interest in effectively conveying this information to consumers." Id. at 1222-1223. Given the significant public health risks posed by tobacco use and the tobacco industry's history of deceiving consumers into believing that cigarettes are safe, Judge Rogers would have upheld the graphic warnings requirements under either the Zauderer or Central Hudson framework. Id. at 1233-1236.[3]

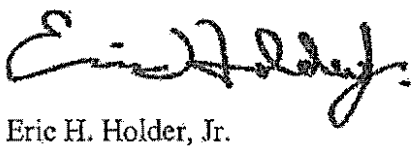
The Department of Justice in this case has vigorously defended the constitutionality of the graphic warnings adopted by FDA in regulations issued pursuant to the 2009 Act, including

[3] Judge Rogers agreed with the panel majority, however, that the regulatory requirement that cigarette labels include the phone number "1-800-QUIT-NOW" violates the First Amendment. App., infra, 1234, 1236-1237.

by filing a petition for rehearing en banc, which was denied on December 5, 2012. The court of appeals did not hold the provision of the Act directing FDA to promulgate graphic-warning regulations facially invalid. Rather, the court held that the particular graphic warnings adopted in FDA's regulations violated the First Amendment, based on the record before FDA in the rulemaking proceedings, and it remanded the matter to the agency. FDA therefore remains free to conduct new rulemaking proceedings under the Act, and it can address issues identified by the court of appeals and other relevant issues in such proceedings. The Department of Health and Human Services (HHS) has informed this Department that FDA will undertake research to support a new rulemaking consistent with the Tobacco Control Act. In these circumstances, the Solicitor General has determined, after consultation with HHS and FDA, not to seek Supreme Court review of the First Amendment issues at the present time. If a court of appeals were to set aside new regulations issued by FDA at a later date, there will be an opportunity to seek full Supreme Court review at that time.

The time within which to file a petition for certiorari will expire on April 5, 2013, after one extension of time. Please do not hesitate to contact us if you have any questions.

Sincerely yours,



Eric H. Holder, Jr.
Attorney General

Enclosures