UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

R.J. REYNOLDS TOBACCO COMPANY, et al.,	)	
Plaintiffs,	)	
v.	)	No. 1:11-cv-1482 (RJL)
UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,	)	
Defendants.	)	

DEFENDANTS' MOTION TO ESTABLISH BRIEFING SCHEDULE AND MEMORANDUM IN SUPPORT

On Tuesday, August 16, 2011, plaintiff tobacco companies filed a 99-paragraph complaint challenging a regulation promulgated nearly two months ago by the Food and Drug Administration (FDA), which does not go into effect for over a year (September 22, 2012). Then on Friday, August 19, the tobacco companies filed a motion for preliminary injunction seeking to delay the September 2012 effective date until "15 months after a Final Judgment from this Court addressing Plaintiffs' claims." Also on August 19, plaintiffs filed a motion for summary judgment.

The Court has noticed a scheduling conference for August 23. Inasmuch as plaintiffs have submitted two lengthy motions and memoranda, the governmental parties believe that it would be helpful to apprise the Court of the government's position prior to the conference, and therefore move to establish a schedule for briefing both motions submitted by plaintiffs as well as the government's dispositive motion and the administrative record. As explained in greater detail below, plaintiffs took nearly two months after the final rule was issued to file their complaint and move the Court for a preliminary injunction and summary judgment. Defendants

seek a similar amount of time to respond to both of plaintiffs' motions, prepare and file their own dispositive motion, and compile and submit the administrative record.

The regulation in question implements an Act of Congress; the statute explicitly requires nine new health warning statements on cigarette packages and advertising, and directed FDA to issue regulations requiring "color graphics depicting the negative health consequences of smoking" to accompany the new warning statements. Family Smoking Prevention and Tobacco Control Act (the "Tobacco Control Act"), Pub. L. No. 111-31, § 201(a), sec. 4(a)(1) & 4(d) , 123 Stat. 1776, 1842-43, 1845 (2009) (to be codified at 15 U.S.C. § 1333(a) & (d)). The statute directed FDA to issue regulations containing the color graphics by June 22, 2011, following notice and comment rulemaking. *See id.* § 201(d), 123 Stat. at 1845.

Last year, plaintiffs Commonwealth Brands, Lorillard, and R.J. Reynolds challenged the public-health warning and other portions of the Tobacco Control Act by filing suit in Kentucky. The district court there rejected most of plaintiffs' challenges, but invalidated two aspects of the statute in a summary judgment ruling. *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010), *appeals argued sub nom. Discount Tobacco City & Lottery v. United States*, Nos. 10-5234 & 10-5235 (6th Cir. July 27, 2011). Although that case involved the statute rather than the regulation, in addressing the mandated warnings aspect of the statute, the district court rejected arguments similar to those made here. *Id.* at 528-32 (rejecting plaintiffs' claims that the statute "unconstitutionally compel[s] Plaintiffs to disseminate the Government's anti-tobacco message," *id.* at 528, and that the warnings are unnecessary because the public "is not only fully aware of [the] risks, but, in fact, substantially overestimates them," *id.* at 529). To the extent that plaintiffs merely reprise the same First Amendment arguments that were rejected

by the district court in *Commonwealth Brands* and that are currently pending before the Sixth Circuit (following oral arguments heard on July 27, 2011), they offer no basis for expedited briefing and review in a second forum. Plaintiffs' only newly available arguments relate to the FDA's exercise of its regulatory authority, and there is no basis to require the government to respond to plaintiffs' motions in this case without sufficient time to compile and address the rulemaking record upon which this Court will base its review.

For these reasons and the reasons discussed below, the governmental parties believe that the following consolidated briefing schedule would best suit the needs of the instant case and the Court:

> October 18, 2011 (60 days from the date of the motions): Government's consolidated response to plaintiffs' preliminary injunction and summary judgment motions, and government's dispositive motion and administrative record to be filed
>
> November 18, 2011: Plaintiffs' consolidated reply in support of their motions and opposition to government's dispositive motion
>
> December 19, 2011: Government reply in support of its dispositive motion

Counsel for the parties have conferred on the government's proposed October 18 consolidated response date, and plaintiffs' counsel would not agree to that date. Plaintiffs' counsel indicated that they would like to have the preliminary injunction briefing complete by late September, briefing on their summary-judgment motion complete in October, and a decision from the Court on the preliminary-injunction motion by the end of October. *See* Preliminary Injunction Motion at 7.

The government's proposed schedule would have all aspects of the case fully briefed and ready for decision on the merits by December 19, nine months before the effective date of the regulation. The government's schedule should be adopted for the following reasons:

Plaintiffs' delay undercuts their desire for immediate relief: Plaintiffs filed their complaint and motions nearly 60 days after promulgation of the final regulation. However, the objections plaintiffs raise in this lawsuit are essentially the same as those they submitted to the FDA in January 2011, in response to the FDA's November 2010 proposed regulation – meaning that plaintiffs have had over nine months to formulate the arguments presented here. Plaintiffs' delay in seeking a preliminary injunction until they had a 45-page summary-judgment motion ready to file undercuts any assertion that they need immediate relief to avoid spending money in anticipation of a regulation that does not take effect for thirteen months.

The government's schedule is more efficient: Plaintiffs' 21-page preliminary-injunction motion relies upon nearly the entirety of their 45-page summary-judgment motion (all but pages 1-6, 16, and 42-45), meaning that it will be far more efficient for the Court to order a consolidated briefing schedule on both motions (and the government's dispositive motion), and to decide all motions together. In addition, the administrative record is not yet compiled, and will be submitted with the government's dispositive motion. Under the government's schedule, the entire case would be fully briefed and ready for decision nine months before the regulation takes effect. Even assuming that plaintiffs need to plan in advance of the effective date of the regulation, the government's schedule allows for a significant amount of time for the Court to issue a well-considered decision with the benefit of a single set of well-developed briefs.

A proposed order is attached.

Respectfully submitted,

Dated: August 22, 2011

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