



Tobacco Litigation Update

Legal Challenge to New Graphic Warning Labels for Cigarette Packages

R.J. Reynolds Tobacco Co. v. FDA

Background

On August 16, 2011, five tobacco companies (R.J. Reynolds, Lorillard, Commonwealth Brands, Liggett, and Santa Fe) filed a [Complaint](#) with the U.S. District Court for the District of Columbia, challenging the Food and Drug Administration's final rule announcing the graphic warning requirements scheduled to go into effect in September 2012. The plaintiffs argued that the final rule violates the First Amendment. They also argued that the FDA's rulemaking process was improper because the rule was not supported by the rulemaking record and the FDA failed to disclose methodologies, data, and assumptions underlying the rule. The industry asked the court to grant a preliminary injunction – an order from the court to put the requirements on hold until there is a final judgment on the merits of the claims.

Decision

On November 7, 2011, Judge Richard Leon [granted the motion](#) for a preliminary injunction. Judge Leon analyzed four factors when deciding to grant the injunction. First, he found a substantial likelihood that the industry would succeed with respect to the merits of its arguments. Judge Leon found that the graphic warnings are compelled disclosures that are not purely factual and uncontroversial and that they violate the “strict scrutiny” standard of review because the required warnings are not narrowly tailored to the government's goals (whether those goals are to inform or to change behavior), due to their size, placement, and content. Second, Judge Leon found that the industry would suffer irreparable harm if the injunction was not issued. Although the industry's estimated costs of compliance are insufficient to show that it would be irreparably harmed, Judge Leon found the industry's inability to recover damages from the government and harms flowing from having its First Amendment rights violated would result in an injury that could not be repaired. Judge Leon then weighed the third and fourth factors, finding that putting the law on hold would not substantially injure other parties (because the regulations already have a built-in 15-month delay) and that the

public interest (related to preserving First Amendment rights) would be furthered by granting the injunction.

Litigation Status

On November 29, the Department of Justice filed a notice of appeal with the U.S. Court of Appeals for the District of Columbia Circuit. The appeal will likely challenge Judge Leon's use of the "strict scrutiny" test instead of the "Zauderer" (or, alternatively, "Central Hudson") test, as well as his determinations about how the regulations are tied to the government's interests. (The tests mentioned above are discussed in the Consortium's First Amendment publications, located on our [website](#) in the section on [federal tobacco regulation](#)). An appeal at this stage – an interlocutory appeal – would determine whether the preliminary injunction was improperly granted. An appellate court is not required to defer to Judge Leon when analyzing the merits of the industry's claims. It is unclear how much guidance the appellate court – the D.C. Circuit Court of Appeals, which is currently reviewing remedies issues in the *U.S. v. Philip Morris* case concerning RICO violations and has heard arguments from the industry that the remedies ordered in that case are not necessary due to its new oversight by the FDA – will give Judge Leon to guide him if his decision is reversed or when he reviews the expected motions for summary judgment and makes a final determination concerning the case.

This [decision](#) is not in any way binding on the [case pending](#) in the U.S. Court of Appeals for the Second Circuit, related to New York City's point-of-sale warning requirements. (While it is possible that the Second Circuit could review this decision as it considers First Amendment issues related to the New York City case – issues that weren't decided by the lower court in the New York City case – it seems unlikely that the appellate court would find this interlocutory trial court decision to be very persuasive, since it is not a final decision on the merits and likely will be considered by the D.C. Circuit Court of Appeals before a final decision is made.) Oral arguments in the New York City case are scheduled for later this week. It is also important to note that this decision relates to the specific graphic warning requirements issued by the FDA to meet its obligations under the [Family Smoking Prevention and Tobacco Control Act](#), while the *Discount Tobacco City & Lottery Inc. v. U.S. et al.* case, pending at the U.S. Court of Appeals for the Sixth Circuit, includes a challenge to the graphic warning requirements, generally, found in the Tobacco Control Act.

Last updated November 2011