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Ralph Tyler, Former Chief Counsel of the FDA, Joins Venable

Ralph S. Tyler, most recently Chief Counsel of the Food and Drug Administration and former Insurance Commissioner of the State of Maryland, has joined Venable as a partner. He will work out of Venable's Baltimore and Washington, DC offices.

Mr. Tyler, whose career spans more than thirty five years in the practice of law, will be part of the firm's Litigation and Regulatory Divisions. He is well known within the firm. "I look forward to the opportunity of practicing law with the lawyers at Venable, many of whom I have known and admired for years," Mr. Tyler said.

Mr. Tyler provides the following insight into a recent significant federal court decision regarding First Amendment free speech limitations on federal agency rule making.

R.J. Reynolds Tobacco Co. v. FDA

The November 7, 2011, decision of Judge Richard J. Leon of the United States District Court for the District of Columbia preliminarily enjoining FDA's final rule requiring cigarette companies to place graphic and textual warnings on cigarette packages (*R.J. Reynolds Tobacco Co. v. United States Food and Drug Administration*, Civil Case No. 11-1482 (D.D.C.)) confirms that regulated entities should scrutinize agency rules from the perspective of the free speech implications of the rules.

Background of the case

The 2009 Family Smoking Prevention and Tobacco Control Act directed FDA to issue regulations requiring cigarette manufacturers to display on cigarette packages "color graphics depicting the negative health consequences of smoking" and to place on the packages one of several textual warnings. Congress required the images to occupy 50% of the front and back of the package. Pursuant to this congressional directive, after notice and comment on a proposed rule, FDA issued a final rule. Several tobacco companies sued to challenge FDA's regulations, claiming violations of the First Amendment (freedom of speech) and the Administrative Procedure Act.

The graphic and textual warnings are a far cry from the long-running Surgeon General's warnings about the hazards of smoking. One image, for example, is of a man exhaling smoke through a tracheotomy tube and another is, as the district court described it, of "a bare-chested male cadaver lying on a table, and featuring what appears to be post-autopsy chest staples down the middle of his torso."

The textual warnings are equally blunt, e.g., "Warning: Cigarettes cause strokes and heart disease;" "Warning: Cigarettes cause fatal lung disease;" and "Warning: Smoking can kill you." FDA's rule also requires that cigarette packages display a telephone number ("1-800- QUIT-NOW") which interested persons could call to obtain smoking cessation information.

The court's decision

In granting the tobacco companies' motion for a preliminary injunction, the district court in *R.J. Reynolds* rejected the government's contention that FDA's rules were subject to a relaxed level of judicial scrutiny because the court found that the images were not "purely factual and uncontroversial disclosures." The court next concluded that the regulations were unlikely to withstand "strict judicial scrutiny" because the government was unlikely to be able to show that the regulations served a "compelling governmental interest" or that the rules were "narrowly tailored."

One may assume that the government will appeal Judge Leon's decision, whether that appeal is of the current preliminary injunction order or comes later and following a final (presumably adverse) judgment. Even without knowing the outcome of any appeal and potentially subsequent Supreme Court review of the regulations, the *R.J. Reynolds* case is noteworthy for the First Amendment focus which it brings to certain regulatory actions.

The broader relevance of the *R.J. Reynolds* decision

Despite the unique visual impact of the tobacco images and the associated textual warnings and “quit line” requirements, FDA’s tobacco warnings regulations are not so very different from many other regulations. Numerous regulations implicate speech, either compelling it or prohibiting it. Regulations requiring disclosures, for example, compel speech while other certain other regulations prohibit speech. The prohibition that drug companies not promote the off-label use of their drugs is a clear example of this latter type of a speech-related restriction.

In addition to the more familiar questions of whether an agency rule is lawful and was promulgated properly under the Administrative Procedure Act, the message of the *R.J. Reynolds* decision is that agency rules should be analyzed from a First Amendment perspective. If a regulation compels speech, for example, is the compelled material “factual and uncontroversial” or is it compelled advocacy of the government’s point of view? Does the regulation restrict speech? If so, can the government shoulder the heavy burden of showing that the regulation serves a compelling governmental interest? Is the regulation’s restriction on speech narrowly tailored or are there less speech restrictive alternatives?

The *R.J. Reynolds* decision confirms that agencies will have to answer these First Amendment questions to the satisfaction of the courts or the agencies will have their regulations invalidated.

Ralph Tyler and Venable’s **FDA Practice Group** are following this case very closely and can address questions.

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