First Amendment Reservation of Rights

The Tobacco Control Act's ("TCA's") modified risk tobacco product ("MRTP") provisions have serious First Amendment problems that prior litigation about the provisions does not allay.

The MTRP provisions restrict protected speech—namely tobacco manufacturers' communications to adult consumers about lawful tobacco products. Those provisions, moreover, discriminate based on both the content of such protected speech and the identity of the speaker. As to content-based discrimination, manufacturers can freely convey other messages about their products, but cannot make a modified risk claim without the Food and Drug Administration's ("FDA's") permission.[1] And as to speaker-based discrimination, doctors, insurers, government officials, and almost anyone else can speak freely regarding the risks of tobacco products without prior FDA approval, but manufacturers cannot. In *Sorrell v. IMS Health Inc.*, the Supreme Court held that speech restrictions based on content and speaker are subject to "heightened judicial scrutiny" under the First Amendment, a burden the Court described as ordinarily "all but dispositive."[2]

The MRTP provisions, though, would have difficulty meeting even the less stringent test set forth in *Central Hudson Gas & Electric Corp. v.Public Service Comm. of New York,* for reviewing restrictions on truthful and non-misleading commercial speech.[3] Under *Central Hudson*, FDA must show that the speech restriction directly advances a substantial government interest and is not more extensive than necessary to do so.[4] Preventing adult consumers from receiving truthful, non-misleading information about tobacco products is not a legitimate, much less a substantial, government interest. The Supreme Court has long "rejected the notion that the Government has an interest in preventing dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."[5] Yet that is precisely what the MRTP provisions, as interpreted by FDA, seek to do.

The TCA requires applicants to demonstrate that marketing a modified risk product would "benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."[6]

The FDA has indicated that it will assess the likelihood that existing users of tobacco products who would otherwise stop using such products will instead switch to the modified risk product, and that non-users would start using it.[7] To that end, FDA's *Draft Guidance for Industry: Modified Risk Tobacco Product Applications* recommends that MRTP applications include "human studies regarding actual use of the product and consumer perception of the product, including its labeling, marketing and advertising," so that FDA can ascertain the MRTP's "effect

[1] FDCA § 911(b)(2)(A)(i) (21 U.S.C. § 387k(b)(2)(A)(i)).
[2] *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 565, 571 (2011).
[3] *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980).
[4] *Id.* at 564.
[5] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002).
[6] FDCA § 911(g)(1)(B) (21 U.S.C. § 387k(g)(1)(B)).
[7] FDCA § 911(g)(4)(B), (C) (21 U.S.C. § 387k(g)(4)(B), (C)).

on behavior among current tobacco users."[8] These provisions make clear that a key basis of FDA's decision whether to allow a truthful, non-misleading health claim about a tobacco product is how the claim will affect adult consumers' decisions. The First Amendment bars this paternalistic approach. Adult tobacco users have the right to make their own decisions about tobacco products. FDA cannot properly seek to constrain, dictate, or influence those decisions by censoring the information that consumers receive.

Discount Tobacco City & Lottery, Inc. v. United States, offers FDA no refuge from this prohibition, even in the 6th Circuit where the case was decided, much less in other circuits more in line with the Supreme Court's increasingly robust protection of commercial speech.[9] While *Discount Tobacco* rejected a First Amendment challenge to the MRTP provisions, the Court treated the case as a facial attack, requiring the plaintiffs to show that "no set of circumstances exists under which [the statute] would be valid."[10] Here, where FDA has the opportunity to shape its regulation on a prospective basis, the inquiry is exactly the opposite—how to avoid any situation in which the MRTP provisions, as FDA interprets them, will cause constitutional harm.

[8] FDA, *Draft Guidance for Industry: Modified Risk Tobacco Product Applications* (Mar. 2012) at 19, *available at* http://tinyurl.com/ycsv9eho..
[9] *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012).
[10] *Id.* at 522 (quoting *United States v. Stevens*, 559 U.S. 460, 472 (2010)).