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S. 1082, Enhancing Drug Safety and Innovation Act of 2007

Two-Year Moratorium on Drug Advertising Raises Constitutional Red Flags

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A bill that is soon to be considered by the U.S. Senate threatens to impose significant restrictions on the dissemination of truthful information about prescription drugs. S. 1082 (the Food and Drug Administration Revitalization Act) entitled the “Enhancing Drug Safety and Innovation Act of 2007” would give the FDA the authority to impose a “temporary moratorium” prohibiting direct-to-consumer advertising for up to two years after a drug is approved. This would vastly expand the FDA’s authority to restrict truthful, direct-to-consumer drug advertising and it is clearly inconsistent with First Amendment principles that protect commercial speech.

Well-settled First Amendment protections for commercial speech were articulated by the courts in response to regulations much like that proposed in S. 1082. More than three decades ago, the United States Supreme Court struck down a state ban on prescription drug advertising in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976). In doing so, the Court held for the first time that speech that does no more than propose a commercial transaction is protected by the First Amendment.

The Court observed that “[a]s to the particular consumer’s interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day’s most urgent political debate,” adding that “[t]hose whom the suppression of prescription drug price information hits

the hardest are the poor, the sick, and particularly the aged.” *Id.* at 763. It further pointed out that “society also may have a strong interest in the free flow of commercial information,” calling it “indispensable.” *Id.* at 764, 765. *See Washington Legal Foundation v. Henney*, 202 F.3d 331, 333-334 (D.C. Cir. 2000) (“First Amendment protections extend both to distribution and receipt of commercial speech.”).

In the years since the Court first articulated its commercial speech doctrine, constitutional protections for advertising have become even more firmly established. For example, in the Supreme Court’s most recent commercial speech decision, it struck down statutory provisions under which the FDA prohibited advertising and promotion of certain compounded drugs. *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002). In doing so, it highlighted the basic principle that “[i]f the First Amendment means anything, it means that regulating speech must be a last – not first – resort,” and that the government bears a significant burden of justifying any speech restriction. *Id.* at 372-373.

The Court also emphatically “rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.” *Id.* at 374. Thus, whatever latitude the government may have to regulate commercial speech, it does not include the ability to fashion rules based on the assumption that “the public will respond ‘irrationally’ to the truth.” *Id.* at 375 (quoting *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 501, 507 (1996)). The Court is “especially skeptical” of such regulations. *Id.*

In light of this background of constitutional jurisprudence, the speech restrictions proposed in S. 1082 are particularly suspect. Applicable case law holds that the type of restriction on drug advertising set forth in the bill must overcome a high hurdle to survive judicial review. A potential two-year “temporary moratorium” on drug advertising proposed in Section 505(o)(5)(F) of the bill is a classic prior restraint on speech – the type of restriction most likely to be overturned by reviewing courts. As the Supreme Court has emphasized repeatedly, “[a]ny system of prior restraints of expression comes to

this Court bearing a heavy presumption against its constitutional validity.” *New York Times v. United States*, 403 U.S. 713, 714 (1971). *See Near v. Minnesota*, 283 U.S. 697, 713 (1931) (“it has been generally, if not universally, considered that it is the chief purpose of the [First Amendment] to prevent previous restraints upon publication”).

Courts have invalidated even brief delays on publication when imposed by government, and have imposed strict procedural protections in the limited situations in which any delay may be tolerated. *E.g.*, *Freedman v. Maryland*, 380 U.S. 51, 58 (1965). In S. 1082, however, the proposed two-year “temporary moratorium” is anything but “brief,” and there are no procedural safeguards and no right to immediate judicial review, as the Constitution requires. Consequently, it is difficult to imagine that this provision could survive judicial scrutiny.

In the context of prescription drug advertising, any delay in publication can have a particularly harmful impact on the public, as the Court anticipated in *Virginia State Board of Pharmacy*. Prescription medications require a doctor’s approval, and the available evidence suggests that advertising prompts consumers to ask their physicians important health-related questions. Because of this heightened awareness resulting from commercial messages, 30 million Americans in 2004 asked a doctor for the first time about a new medical condition.¹ In addition, a survey of 3,000 patients by the Harvard Medical School and Business School faculty found that, counting patients who discussed a prescription drug advertisement during a doctor’s appointment and who received a new diagnosis as a result, 43 percent were diagnosed with “high priority” conditions such as hypertension, diabetes, depression, and high cholesterol.²

Even if Section 505(o)(5)(F) could overcome the heavy presumption against prior restraints, such a broad restriction on speech is not “narrowly tailored” as is required for any limitations on commercial speech. The Supreme Court has emphasized “if the Government could achieve its interests

¹ “Consumer Reactions to DTC Advertising: 7th Annual Survey,” *Prevention Magazine and Men’s Health* (2004).

² Joel Weissman, David Blumenthal, *et al.*, “Consumers’ Reports on the Health Effects of Direct-To-Consumer Drug Advertising,” *Health Affairs*, W3 (2003), pp. 82-93.

in a manner that does not restrict speech, or that restricts less speech, the Government *must do so.*” *Western States Medical Center*, 535 U.S. at 371 (emphasis added). Nevertheless, proposed Section 505(o)(5) (F) would empower the FDA to impose an extended moratorium on advertising rather than to use alternatives that do not require censorship. In this regard, it is not sufficient that the government might find it more convenient, or consistent with its goals, to employ the more restrictive tool of an advertising ban. *Id.* at 371-373. Where other, less censorious measures can be used to ensure the public is protected, the government must use those alternatives. *E.g., Rubin v. Coors Brewing Co.*, 514 U.S. 476, 490-491 (1995).

S. 1082 proposes the most restrictive and least constitutionally sensitive tool in the government’s regulatory arsenal – a prior restraint on truthful, non-misleading speech. Such an approach is unlikely to survive judicial review.

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