Legal Opinion Letter

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BILL DENYING TAX DEDUCTION FOR DRUG ADS UNCONSTITUTIONAL

by
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On June 21, 2007, U.S. Representative Pete Stark introduced a Bill titled the "Fair Balance Prescription Drug Advertisement Act of 2007." H.R. 2823 (110th Cong., 1st Sess.). If enacted, the Bill would deny a tax deduction for any expenses associated with a direct-to-consumer ("DTC") advertisement for a new prescription drug for the first two years after approval. Section 4 of H.R. 2823 (proposing to add new § 280J to the Internal Revenue Code of 1986). The Bill would also eliminate the tax deduction for any expenses associated with any direct-to-consumer ("DTC") advertisement that FDA determines misbrands the drug because it violates the "brief summary" requirements in section 502(n) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 352(n), by failing to include a true statement relating to side effects, contraindications, and effectiveness. Section 3 of H.R. 2823 (proposing to add new § 311(1) to the Act). Additionally, the Bill would require FDA to promulgate new regulations that substitute a "*perfect* balance" disclosure standard for risk vs. effectiveness claims for the agency's current "*fair* balance" rules (*see* 21 CFR § 202.1(5)(ii)) and tax deductibility would be automatically denied for any expense associated with any DTC advertisement that FDA determines fails to meet this new perfect balance standard. Section 3 of H.R. 2823 (proposing to add new § 311(2) to the Act, providing that the portion of the advertisement devoted to describing "side effects, contraindications, or any lack of effectiveness" *shall not be "less than* the portion of the advertisement devoted to describing the benefits of the drug taking into account [a variety of contextual factors]" (emphasis supplied)).

The Stark Bill is starkly unconstitutional under the First Amendment. Several separate and distinct lines of constitutional reasoning support this conclusion, three of which are detailed here. First, the intent of this bill is to ban or suppress advertising through the tax code. By attempting to eliminate the tax deductibility of DTC advertising expenses for any new drug for the first two years after approval, the Bill is a blatant attempt to suppress DTC advertising totally during that period, even when the advertising is entirely truthful and not misleading. The central intent is not to raise tax revenues; it is censorship, plain and simple. As the Supreme Court taught us long ago in *Grosjean vs. Am. Press Co.*, 297 U.S. 233 (1936), regulating speech under the "guise" of taxation is a particularly "odious method[]" of regulation. 297 U.S. at 249. "It is bad because . . . it is . . . a deliberate and calculated device in the guise of a tax to limit the circulation of information to which the public is entitled in virtue of the constitutional guarantees [in the First Amendment]." 297 U.S. at 250.

Further, an intended ban on effective advertising that is truthful and not misleading (even when disfavored by the Legislature), likely fails the threshold "substantial government interest" test under *Cent'l Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 564 (1980), for sustaining a governmental restriction on commercial speech. *See IMS Health Inc. v. Ayotte*, 490 F.

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Supp. 2d 163, 181 (D.N.H. 2007), *appeal docketed*, No. 07-01945, 1st Cir., (July 6, 2007). ("As the Supreme Court has recently explained, however, '[w]e have previously 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.' *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002) [additional quotes and citations omitted]").

Moreover, although some may construe a two year ban on deducting expenses for DTC advertising for newly approved drugs as an incidental or indirect limit on speech, its effect in suppressing speech is precisely the same, making it subject to constitutional analysis under the First Amendment as if it was a direct prohibition on speech for the first two years after approval of a new drug. Such an outright speech ban, even if clothed as an indirect prohibition on deducting advertising-related expenses, plainly violates the First Amendment. Indeed, the Congress itself has implicitly acknowledged the unconstitutionality of a two year post-approval moratorium on DTC advertising of newly approved drugs in recently rejecting, for First Amendment reasons, legislation that would have imposed a direct ban on post-approval advertising for a period of two years or three years.

Second, the "perfect balance" provisions of the Stark Bill that would eliminate tax deductibility for expenses for DTC advertising under § 502(n) of the Act have serious due process problems that compound the underlying First Amendment concerns. Clearly, under *Central Hudson* the government can prohibit advertising that is false or inherently misleading. *See Washington Legal Foundation vs. Friedman*, 13 F. Supp. 2d 51, 66-67 (D.D.C. 1998). But, under the "perfect balance" provisions, the FDA could make a unilateral decision that has the effect of banning speech in advertising that is otherwise truthful and not misleading. This would violate the constitutional protections of due process of law. When significant First Amendment issues are implicated, the government cannot impose such a Draconian punishment (i.e. denial of tax deductibility) *ex parte* without the opportunity for an evidentiary hearing. Assuming, for analysis sake, that Congress could deny a tax deduction for ads that the FDA determines violate the new perfect balance regulations, the FDA cannot impose such a penalty based on unilateral agency action. Indeed, Congress has again recognized as much by providing for substantial hearing rights before civil monetary penalties may be imposed for drug advertising violations under legislation that recently passed in the House and the Senate.

Third, there is an extremely serious question whether a violation of § 502(n) of the Act or any new "perfect balance" regulations promulgated by FDA could be characterized as false or inherently misleading and thereby obviate the government's burden to prove the remaining prongs of the *Central Hudson* balancing test. There is no affirmative falsity in any such violations. Moreover, there is a substantial basis to argue that violation of §502(n) or any new perfect balance regulations is not "*inherently* misleading" for *Central Hudson* purposes. *Central Hudson* defined such "inherently misleading" speech as speech "more likely to deceive the public than to inform it." 447 U.S. at 563. But just because the Stark Bill would trigger denial of tax deductibility on account of a unilateral FDA determination of a statutory or regulatory violation does not make speech that fails to meet the regulatory requirement "*inherently* misleading." *Compare Washington Legal Foundation*, 13 F. Supp. 2d at 67 ("FDA exaggerates its overall place in the universe . . . [by arguing that a claim is] 'inherently misleading' merely because the FDA has not yet had the opportunity to evaluate the claim.") Indeed, if there was such "inherent" deception in these statutory and regulatory violations, then there would have been no need for the statute and regulations to have prescribed the contours of the mandated disclosures in such painstaking detail. They would have already been apparent from the Act's general prohibition on false and misleading representations. For these reasons, a congressional determination that an advertisement is misleading if it fails to include specific information is not the foundation for a determination of "inherent misleadingness" under *Central Hudson*.

In sum, Representative Stark's attempt to impose pharmaceutical advertising bans under the cloak of tax code is unconstitutional under at least three distinct lines of reasoning discussed here. Just as the Members of the Senate and House did when they rejected similar attempts to ban pharmaceutical advertising in this Session of Congress, they must seriously consider these constitutional infirmities when debating the Stark Bill

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