Legal Backgrounder

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# CONDITIONING FDA APPROVAL ON AGREEMENT NOT TO ADVERTISE VIOLATES LAW AND CONSTITUTION

by

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On March 16, 2005, the U.S. Food and Drug Administration (FDA) approved Amylin Pharmaceutical's new drug application (NDA) for SYMLIN® (pramlintide acetate) injection. SYMLIN® was approved subject to certain conditions, namely that Amylin agree to implement a Risk Minimization Action Plan (RMAP) due to concerns about the risk of hypoglycemia when pramlintide and insulin are administered concomitantly, as well as the potential for medication errors and off-label use. Amylin's RMAP states that Amylin agrees not to conduct any direct-to-consumer (DTC) advertising or journal advertising for one year, and assents to limited promotion restricted primarily to physicians who specialize in diabetes management who are supported by certified diabetes educators, among other things. Thus, it appears as if FDA has conditioned approval of SYMLIN®, in part, on Amylin's agreement not to advertise the drug product. As this LEGAL BACKGROUNDER argues, this agreement should be of concern to the drug industry. The paper makes the case that conditioning drug approval on an agreement not to advertise is without any statutory basis and violates the First Amendment.

***Statutory Authority***. FDA has no statutory authority to ban FDA-approved drugs from being advertised. The Federal Food, Drug, and Cosmetic Act ("FFDCA") grants FDA the authority to deny the introduction of new drugs into the market unless an application was filed and approved by the FDA. *See* 21 U.S.C. §355 (a). New drugs permitted on the marketplace must first go through a rigorous approval process, as well as strict labeling requirements. *See generally* 21 U.S.C. §§ 352, 355. Product approval means that the FDA has found the product to be safe and effective under its FDA-approved labeled conditions use.

Section 502(n) of the FFDCA also authorizes the FDA to regulate advertisements, including print and broadcast advertisements for prescription drug products. *See also*, 21 C.F.R.

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§ 202.1(l)(1). Though the statute requires prescription drug advertisements to contain a product's established name, formulation, and brief summary relating to the product's side effects, contraindications, and effectiveness, the statute expressly states that FDA cannot require pre-approval of advertisements except in "extraordinary circumstances." 21 U.S.C. § 352(n)(3)(A). Nothing in the FFDCA grants FDA the power to condition approval or to impose an outright ban on advertising of a drug product.

The FFDCA grants FDA power to approve a new drug with restrictions for drug products approved via Fast Track. *See* 21 U.S.C. § 356 et. seq.; 21 C.F.R. § 314.520. It permits FDA to require postmarketing restrictions for drugs approved in this manner if the Agency concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted. *Id*. Even in those instances, FDA can only impose one of two types of postmarketing restrictions: 1) restrict distribution to certain facilities or physicians with special training or experience, or 2) condition distribution on the performance of specified medical procedures. 21 C.F.R. § 314.520 (a)(1); 21 C.F.R. §314.520(a)(2). While promotional materials and advertisements for Fast Track-approved drug products must be submitted to FDA prior to dissemination, the FFDCA does not permit FDA to outright ban advertising of a drug product even for drug products approved via Fast Track. 21 U.S.C. § 356 (B)(2)(b); 21 C.F.R. § 314.550.

***First Amendment***. Even if FDA possessed statutory authority to ban advertising of an FDA-approved drug, such authority would violate the First Amendment. Drug advertising is commercial speech deserving First Amendment protection. *See Virginia State Bd. Of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976) (holding that even if the advertiser's interest is a purely economic one, that does not disqualify him from protection under the First Amendment).

*Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980) ("*Central Hudson*") is the landmark Supreme Court case governing commercial speech. In *Central Hudson*, the Court stated that a governmental restriction upon commercial speech is lawful only if the asserted governmental interest in the restriction is substantial, that the speech restriction directly advances the governmental interest asserted, and that the speech restriction is not more extensive than is necessary to serve the asserted governmental interest. *Id*. If the government cannot demonstrate that it meets all three prongs of the *Central Hudson* test, the speech restriction is unlawful. *Id*.

In *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), the Supreme Court applied the *Central Hudson* test and ruled that the statutory ban on advertising of compounded drugs violated commercial speech rights. The issue in this case was a section of the Food and Drug Modernization Act of 1997, which exempted pharmacy compounders from FDA's drug approval requirements provided that the compounders "not advertise or promote the compounding of any particular drug, class of drug or type of drug." The Court, utilizing the *Central Hudson* test, held that the government cannot ban truthful advertising of a lawful activity. Furthermore, the Court stated that one of the government's main concerns — that advertising compounded drugs would place people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway — would fail to justify the



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restrictions. *Id*. at 374. The Court said that "this concern rests on the questionable assumption that doctors would prescribe unnecessary medications and amounts to a fear that people would make bad decisions if given truthful information, a notion that the Court has rejected as a justification for an advertising ban." *Id*.

Applying the *Central Hudson* and *Western States* analyses to FDA's requirement that Amylin not advertise SYMLIN®, it is clear that FDA has not met its First Amendment burden. FDA would likely assert that by banning advertising of SYMLIN® it is protecting public health by limiting information about the availability of the drug only to the small subset of diabetics that will receive a benefit from taking SYMLIN®, thereby protecting those diabetics in which its use is contraindicated. There is little doubt that FDA has an interest in protecting the public health and safety and that such an interest is substantial. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995). However, the Supreme Court in *Western States* clearly 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 such information. *Western States*, 535 US at 374. Thus, FDA cannot meet the first prong of the *Central Hudson* test.

While debatable, it is likely that banning advertising of SYMLIN® also directly advances FDA's interest of ensuring that SYMLIN® is only prescribed to the narrow subset of diabetics that would benefit, thus satisfying the second prong of the *Central Hudson* test.

The advertising ban, however, clearly fails the third prong of the *Central Hudson* test because the ban is far more extensive than necessary to serve the asserted governmental interest. Even if the government interest in public safety is substantial and restricting advertising may help protect safety and health, a complete ban on direct-to-consumer advertising is much more extensive than necessary to serve that interest. There are numerous, less onerous restrictions that FDA could have placed on Amylin that could achieve the same results. For example, instead of providing less information by banning advertising, FDA could have mandated that more information be provided to ensure that the drug is prescribed to the correct patient population and administered correctly. When approving the labeling for SYMLIN®, FDA could have required more information about the appropriate patient population and the dangers of prescribing the drug to those that do not fit within that population be included in any direct-to-consumer advertising.

SYMLIN® is either safe and effective under its labeled conditions of use, or it is not. Since FDA has already found SYMLIN® to be safe and effective under its labeled conditions of use, regardless of whether someone advertises or remains silent, the fact that SYMLIN® is safe and effective under its labeled conditions of use does not change. FDA's advertising ban is nothing more than an effort that seeks to keep people in the dark for what the government perceives to be their own good — a concept the Supreme Court has warned courts to view with skepticism.

Furthermore, FDA's outright ban on advertising SYMLIN® as a means to minimize risk is contrary to the Agency's own guidance. In March 2005, FDA issued a document titled "Guidance for Industry Development and Use of Risk Minimization Action Plans." The

Guidance includes recommendations for how to reduce "risk" associated with the use of certain drugs. One example the Guidance gives as a tool to use in a risk minimization plan is "promotional techniques such as direct-to-consumer advertising highlighting appropriate patient use or product risks." This is exactly what the FDA banned in its approval letter. Therefore, not only is the ban on direct-to-consumer advertising without statutory authority and a constitutional violation, it is also in direct conflict with FDA's own guidance.

***Conclusion***. The FDA's complete restriction on direct-to-consumer advertising is outside its authority and is an unconstitutional violation of the First Amendment.

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