How the FDA Pre-Review Program Could Work

A Closer Look at Preemption in the Context of the Proposed Voluntary Pre-Review Program for DTC Television Advertising

By Arnold I. Friede and Robert N. Nicholas

Editor's note: This article was prepared after the recent appropriations legislation (Consolidated Appropriations Act, 2008, Pub. L. No. 110-161) that was signed by President Bush on Dec. 26, 2007. This legislation has an impact – perhaps both short term and long term – on the user fees funded voluntary DTC advisory review program that was established by FDAAA in September 2007. (For more background details, see "DTC User Fee Program Suspended By Congress: FDA Gets More Review Funds," The Pink Sheet, Jan. 7, 2008.) Indeed, as this article was going to press, FDA issued a Federal Register Notice announcing that the voluntary program will not be implemented for the time being due to certain intricacies in the appropriations legislation. (73 Federal Register, 2924, Jan. 16, 2008.)

However, the industry is studying the matter and may seek further legislation to reinstate the program. While this article addresses the specific preemptive effect of review of DTC television advertising by FDA under FDAAA, the thesis advanced here is largely applicable to FDA's existing program of voluntary DTC advertising review, which, according to the FDA's Jan. 16, 2008, notice, will be maintained.

Federal legislation approved in late 2007 set up a new framework – at least temporarily – for voluntary review of broadcast TV ads for prescription drugs.

Section 104 of the Food and Drug Administration Amendments Act of 2007 (FDAAA, Pub. L. No. 110-85) created a user-fee funded program for this voluntary advisory review of direct-to-consumer (DTC) television advertising by FDA. (See §736A of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §379h-1.)

The agency has secured sufficient funding commitments from industry to make the program operational, has established the specific fees payable by participants and has otherwise adopted a process for the submission and voluntary advisory review of proposed DTC television advertising by the Division of Drug Marketing, Advertising, and Communications (DDMAC) in the FDA Center for Drug Evaluation and Research (or, for products regulated as biologics, by the Advertising and Promotional Labeling Branch in the FDA Center for Biologics Evaluation and Research). See 72 Fed. Reg. 70334 (Dec. 11, 2007); 72 Fed. Reg. 60677 (Oct. 25, 2007). *See also generally DTC Television User Fee Program Documents, available at http://www.fda.gov/cder/ddmac/user_fees/default.htm.*[1]

1 Recent appropriations legislation (Consolidated Appropriations Act, 2008, Pub. L. No. 110-161) signed by President Bush on December 26, 2007 may have an impact, long term, on the user–fees funded voluntary DTC advisory review program established by FDAAA. See *"DTC User Fee Program Suspended By Congress: FDA Gets More Review Funds", The Pink Sheet*, January 7, 2008 at 22.

Creating resubmission opportunities

Under FDAAA's voluntary advisory review program, FDA is charged with "providing advisory comments on DTC advertisements regarding compliance of a proposed advertisement with the requirements of the [FDC] Act prior to its initial public dissemination." FDC Act, §736A(h)(1). The program includes an opportunity for a resubmission after initial comments by FDA, but the resubmission "may not introduce significant new concepts or creative themes into the television advertisement." *Id.* at §736A(h)(10).

Hence, the primary purpose of a resubmission is to gain FDA's express determination that the advertiser in fact has incorporated the agency's initial comments in a way that complies with the FDC Act, and, if not, to find out how to modify the advertisement even further so that it does. But even if an advertiser elects not to resubmit for final FDA concurrence (because, for example, of the additional broadcast delay this may entail), a DTC television advertisement that in fact incorporates FDA's advisory comments nevertheless would be in conformity with FDA's interpretation of the FDCA.

In either case[2], and at least until the agency notifies the advertiser later on that it has changed its mind about an advertisement based on changed circumstances, 21 U.S.C. 333(g)(4)(B), a DTC television advertisement that conforms with FDA's comments effectively carries an FDA *imprimatur* of compliance with the FDCA.

Indeed, while doing so is beyond the scope of this article, one could argue that a DTC television advertisement that has run this FDA gauntlet can properly be identified as having been "reviewed and approved by FDA" or something similar. Cf. §421 of the Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, *repealing* 21 U.S.C. §331(l) (prohibiting labeling and advertising of products approved by FDA as "FDA Approved")

FDA preemption issues

Given FDA's comprehensive involvement in the entire process, and the review and effective approval by the agency of submitted DTC television advertising modified in conformity with FDA's advisory comments, there are compelling reasons to conclude that state-law claims based on allegations that the advertising is false, misleading, lacking in fair balance, or otherwise legally problematic should be preempted.

The question of when FDA's actions preempt state-law claims is the subject of current judicial consideration in a variety of contexts. The U.S. Supreme Court has already granted review in this term in two cases that raise important

2 Indeed, even some lesser form of FDA action or inaction may also be entitled to preemption depending on the circumstances.

The primary purpose of a resubmission is to gain FDA's express determination that the advertiser in fact has incorporated the agency's initial comments in a way that complies with the FDC Act, and, if not, to find out how to modify the advertisement even further so that it does.

FDA preemption issues[3] and is considering reviewing a third.[4] FDA, through the Department of Justice, has filed *amicus curiae* briefs strongly supporting preemption in those three cases.[5] At least two other significant cases have already reached a United States Court of Appeals.[6]

Academics likewise are contributing to the discussion.[7] But whatever the outcome of the pending cases, it seems clear that a finding of preemption is warranted in circumstances like those present in the voluntary DTC television advertising advisory review program under FDAAA described above.

One of the primary reasons for finding federal preemption, but by no means its only justification in this context, is to avoid courts' second-guessing FDA under state law and thereby interfering with and eroding FDA's regulatory authority over the conduct in question. In this respect, then, FDA's action on a matter, or its purposeful inaction, is deemed to create both a compliance "floor" and a compliance "ceiling".[8]

Once FDA provides its comments on a DTC television advertisement, and subject possibly to a subsequent changed

3 *Riegel v. Medtronic, Inc.* 451 F. 3d 104 (2d Cir. 2006), *cert. granted*, 76 USLW 3017 (June 25, 2007) (No. 06-179); *Desiano v. Warner-Lambert Co., LLC.*, 467 F.3d 85 (2d Cir. 2006), *cert. granted sub. nom., Warner-Lambert Co., LLC v. Kent*, 76 USLW 3020 (Sept. 25, 2007) (No. 06-1498).

4 *Levine v. Wyeth*, ___ A.2d ___, 2006 WL 3041078 (2006), *petition for cert. filed*, 75 USLW 3500 (March 12, 2007) (No. 06-1249).

5 *See generally* Brief of the United States as Amicus Curiae, *Wyeth v. Levine*, No. 06-1249, *available at* http://www.usdoj.gov/osg/briefs/2007/2pet/6invit/2006-1249.pet.ami.inv.html; Brief of the United Sates as Amicus Curiae Supporting Respondent, *Riegel v. Medtronic, Inc.*, No. 06-179, *available at* http://www.usdoj.gov/osg/briefs/2007/3mer/1ami/2006-0179.mer.ami.html; Brief of the United States as Amicus Curiae Supporting Petitioners, No. 06-1498, available at http://www.usdoj.gov/osg/briefs/2007/3mer/1ami/2006-1498.mer.ami.html

6 *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006), *appeal pending*, No.06-3107 (3d Cir.); *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, 2005 WL 3752269 (D.N.J. 2005), *motion to vacate denied and interlocutory appeal certified*, 2006 WL 2819046 (D.N.J. 2006), *appeal pending*, No. 06-5148 (3d Cir).

7 *See e.g.* Sharkey, Catherine M., *"Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State versus Federal Courts"* . Brooklyn Journal of Law and Policy, Vol. 15, No. 3, 2007 available at SSRN: http://ssrn.com/abstract=1020709

8 *See material cited in* fn. 5, supra.

determination by the agency based on new information or changed circumstances, 21 U.S.C. §333(g)(4)(B), a finding by a court that a DTC television advertisement consistent with FDA's comments still violates state law would amount, among other things, to the kind of second-guessing that the preemption doctrine is intended to foreclose. The decision in *Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc.,* 499 F. 3d 239 (3d Cir. 2007), *petition for cert. filed,* No. 07-822 (Dec. 18, 2007), illustrates the point.

Preemption case – Nexium vs. Prilosec

In that case, a purported nationwide class of third-party insurance payors and others alleged that advertising for Nexium made misleading implied claims of superiority versus its predecessor product, Prilosec, and hence violated the consumer fraud statutes of Delaware and other jurisdictions. In response, Zeneca argued that inasmuch as the advertising claims for Nexium were based on labeling that FDA had expressly approved, the plaintiffs' state law claims were preempted by the FDCA under the doctrine of implied conflict preemption. Because:

(1) FDA's regulation of prescription drug advertising is "extensive and specific,"

(2) there is an "essential affinity" between labeling and advertising where "the rules that govern labeling form the basis for the advertising regulations," and

(3) there is a "high level of specificity in federal law and regulations" where "both the FDCA and FDA regulations provide specific requirements for prescription drug advertising,"

The two-judge Third Circuit majority found that "the purpose of protecting prescription drug users in the FDCA would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the veracity of statements approved by the FDA." 499 F. 3d at 251-252.

Accordingly, it held the plaintiffs' claims to be preempted by the FDCA. *Id.* Judge Cowen, in dissent, took issue with much of the majority's analysis. But one of his primary arguments was that it was "undisputed that the FDA has not approved the veracity of the particular advertisements in question." *Id.* at 255. Largely "because the FDA has not approved or disapproved the veracity of the advertising statements"

The FDA's action on a matter, or its purposeful inaction, is deemed to create both a compliance floor and a compliance ceiling.

It seems evident that a DTC television advertisement that is consistent with the comments received from FDA under the FDAAA voluntary advisory review program is protected under the doctrine of federal preemption from attack under state law.

comparing Nexium with Prilosec[9], Judge Cowen declined to find any irreconcilable conflict between the plaintiffs' state law claims and the FDCA regime. Id. at 256.

Ads consistent with FDA comments are safe

So, whether one adopts the Zeneca majority's preemptive reasoning or Judge Cowen's narrower approach in dissent (which apparently would have resulted in preemption if FDA had approved the specific advertisements in question or if the advertising had been modified to incorporate FDA's specific comments[10]), it seems evident that a DTC television advertisement that is consistent with the comments received from FDA under the FDAAA voluntary advisory review program is protected under the doctrine of federal preemption from attack under state law.[11]

This is a sound, and even common-sense, result. Otherwise, the entire voluntary advisory review program that Congress established for DTC television advertising would be eroded because advertisers would lack any assurance that an advertisement satisfactory to, and expressly or effectively approved by, FDA would not be subject to attack later under state law. ■

Arnold I. Friede is a counsel at McDermott, Will & Emery in Washington, D.C. He is a former FDA associate chief counsel and also has served as a senior corporate counsel at Pfizer Inc., where one of his areas of concentration has been DTC advertising, including the extent to which it is subject to protection under the First Amendment. Robert N. Nicholas is a partner and chair of the FDA practice group at McDermott, Will & Emery in Washington, D.C. The views expressed in this article are solely those of the authors and not of any entity by which the authors are employed or with which they are associated.

9 Nor had the advertisements been modified to accommodate specific FDA comments in the course of an official agency-administered advertising review process.

10 *Id.*

11 *See also e.g. In re Bextra and Celebrex Marketing and Sales Practices Litigation,* 2006 WL 2374742 (N.D. Cal. 2006) (FDA's conclusions about proper warnings in advertising preempt state law claims seeking additional or different warnings).