

REDUCED LEGAL OVERSIGHT FOR FDA WARNING LETTERS AMPLIFIES COMPLIANCE AND LIABILITY RISKS

by

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Last summer, the Commissioner of the Food and Drug Administration (FDA) reversed existing, sound policy that required prior legal review of regulatory letters (Untitled and Warning Letters) by the Agency's Office of Chief Counsel (OCC). This reversal – eliminating review of regulatory letters for legal integrity except in cases of “significant legal issues”¹ – is one of several changes instituted by the Commissioner to increase enforcement activity and purportedly to limit enforcement delays. See Margaret Hamburg, M.D., *Remarks at the Food and Drug Law Institute* (Aug. 6, 2009).²

If enforcement activity is to be measured merely in terms of an increased number of Warning and Untitled Letters, then undoubtedly this policy change will amplify enforcement. And if regulatory delay occurred because lower level FDA employees without legal training thought twice about issuing regulatory letters based upon their own snap judgments about what the law allowed, then “delay” will surely be reduced. But the relevant question is, at what cost? Recently, a federal court of appeals reminded the FDA that “[i]t is a denial of due process of law to convict a person of a crime because he violated some bureaucrat's secret understanding of the law.” *United States v. Farinella*, 558 F.3d 695, 699 (7th Cir. 2009). In *Farinella*, an FDA employee testified under oath in open court as an “expert” witness, giving “improper” and “incoherent” testimony about the regulatory scheme he was supposedly enforcing. *Id.* at 700. How much more likely are these same bureaucrats to issue regulatory letters of the same ilk – with neither an oath, cross-examination, nor appellate review to restrain them? For good reason, the FDA had required that agency counsel review regulatory letters before they were sent.

Moreover, a significant percentage of FDA regulatory letters are issued in response to promotional pieces and marketing practices, presenting, among other things, important and sometimes subtle First

¹“Significance” is not defined, and is sufficiently vague as to allow almost unlimited discretion.

²Available at <http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm>.

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Amendment concerns beyond the ken of legally untrained FDA employees.³ Removal of the safety valve of prior trained counsel review risks the issuance of a larger number of letters infringing upon the speech and commercial rights of the recipients.

Indeed, even with prior counsel review, WLF identified through its “DDMAC⁴ Watch” program (which monitored FDA Warning Letters), more than 50 DDMAC Warning Letters to drug and device companies which were based upon legally deficient positions.

Background. On November 29, 2001, the Deputy Secretary of the Department of Health and Human Services directed the FDA to submit all Warning Letters and Untitled Letters to the OCC prior to their issuance to ensure “legal sufficiency and consistency with Agency policy.” FDA, *Regulatory Procedures Manual* at § 4-3 (Mar. 2009).⁵ By issuing only legally justified letters, the FDA hoped to “maintain credibility with the courts and win the litigation it chooses to pursue.” Food & Drug Law Institute’s 45th Annual Educational Conference Keynote Addresses, 57 FOOD & DRUG L.J. 227, 237 (2002) (hereinafter “2002 FDLI Speech”). There was concern, at the time, that the FDA was being viewed as a “paper tiger,”⁶ thus, better legal oversight would enhance Agency credibility and litigation outcomes – impressing upon courts and opposing litigants that every FDA regulatory letter “has undergone legal review, and that the agency is prepared to back it up by going to court if necessary.” GAO, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Its Limitations*, GAO-03-177, at 32 (Oct. 2002).⁷

In addition to these general goals, the FDA was also concerned that its advertising- and promotion-related regulatory letters might have been infringing upon the First Amendment rights of regulated companies. The FDA identified “commercial free speech” as one of its top legal priorities after the initial implementation of OCC review. 2002 FDLI Speech at 237. Thus, it seems reasonable to infer that First Amendment concerns at least partially motivated the implementation of OCC review.

Effect of OCC Review. The effect of OCC review has been studied, particularly with respect to direct-to-consumer (“DTC”) advertising. These studies revealed the following: *First*, the total volume of regulatory letters decreased, GAO, *Prescription Drugs: Trends in FDA’s Oversight of Direct-to-Consumer Advertising*, GAO-08-758T, at 3 (May 2008)⁸; *second*, the FDA spent more time reviewing proposed

³There is no assurance that regulatory letters responding to promotional pieces or practices, which present First Amendment commercial speech issues, will be considered as presenting “significant legal issues.” Some FDA officials, arguably contradicting their commissioner, recently suggested that Warning Letters will still be reviewed by OCC, but Untitled Letters will not. *FDLI Conference Part 4 – The Final Day*, Eye On FDA, Sept. 23, 2009, http://www.eyeonfda.com/eye_on_fda/2009/09/fdli-conference-part-4-the-final-day.html. These conflicting statements suggest that the wisdom of OCC review is acknowledged by some FDA personnel charged with enforcement.

⁴“DDMAC” stands for the FDA’s Division of Drug Marketing, Advertising, and Communications.

⁵Available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf>.

⁶By 2002, the FDA had lost (or been forced to abandon) several high-profile cases. See *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002); *Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

⁷Available at <http://www.gao.gov/new.items/d03177.pdf>.

⁸Available at <http://www.gao.gov/new.items/d08758t.pdf>.

regulatory letters before they were issued, *id.*; and *third*, the regulatory letters that were issued dealt with more serious, complex issues. *Id.* at 12 (“Although the total number of regulatory letters FDA issued for violative DTC materials has decreased, the agency has issued in recent years proportionately more warning letters – which cite violations FDA considers to be more serious.”). It appears that OCC review produced quality over quantity – fewer overall regulatory letters more focused upon matters of arguably greater importance.

Conversely, the GAO’s study of the effects of *implementation* of OCC review raises questions whether *elimination* of that same review will result in more regulatory letters concerning alleged violations that are of less consequence to the users of FDA-regulated products.

Given the expected increase in regulatory letters, what are the risks to FDA-regulated entities and what can be done to minimize and manage these risks?

Managing Risks. The most obvious risk relates to the First Amendment implications of regulatory letters. Companies must be vigilant of the potential impact of regulatory action on protected commercial speech, and trade groups and associations should consider an *amicus curiae* role in cases raising this issue. In the future, a regulated entity confronted with an FDA regulatory letter should understand that, in all likelihood, the letter was written by a non-lawyer and not reviewed by an attorney prior to its issuance. Thus, going forward, there may well be more reasons to challenge such letters on legal grounds. Because advertisements and other promotional activity are protected commercial speech, regulated entities should keep in mind potential First Amendment challenges to these letters.

For instance, when imposing a restriction on commercial speech, the FDA must carry its burden with more than “mere speculation and conjecture.” *See Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993) (government “must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree”). Therefore, FDA regulatory letters should be evaluated for reliance solely upon conclusory agency statements as a basis for a claim that a regulatory violation has occurred.

In addition, many regulatory letters are deficient under the First Amendment due to a failure to demonstrate that anyone was actually misled by the information. *See Virginia State Bd. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 769, 773 (1976). A regulatory letter that appears to be predicated upon nothing more than a theoretical prospect of someone being misled should also raise a red flag.

Second, the issuance of a regulatory letter could potentially give rise to other forms of liability, such as under state “consumer protection” laws. FDA regulatory letters attract plaintiffs’ attorneys, both when representing private litigants and when acting increasingly often as state enforcers. That FDA letters frequently trigger civil litigation is one more reason for the Agency to exercise care that its legal reasoning is accurate and that its regulatory letters are directed to issues that really matter to consumers.

A case in point is *Johnson & Johnson v. State of West Virginia*, in which WLF recently filed an *amicus curiae* brief in the West Virginia Supreme Court, arguing against the imposition of civil liability based upon Warning Letters from the FDA.⁹ In the West Virginia case, Johnson & Johnson subsidiary Janssen Pharmaceutica received two DDMAC Warning Letters in 2003 concerning promotional mailings to physicians. *WLF Janssen Brief* at 3-4. A trial court in West Virginia, completely misunderstanding the

⁹*WLF Janssen Brief*, available at http://www.wlf.org/Upload/litigation/briefs/Johnson&JohnsonvWV_WLFAmicus.pdf.

tentative nature of Warning Letters,¹⁰ concluded as a matter of law that the advertising was “false or misleading” because the FDA’s Warning Letters seemingly said so. Based upon this conclusion, the Circuit Court ultimately assessed \$4.5 million in civil penalties. *Id.*

FDA’s elimination of OCC review of warning letters, and the resulting reduction of such letters’ legal accuracy, will increase civil litigation risks as exemplified by the *Johnson & Johnson* case. With FDA regulatory letters being written by non-lawyers, whose work is no longer being reviewed by lawyers, regulated companies must be particularly vigilant, both pre- and post-issuance, to protect themselves from legally deficient or ill-advised letters – and, if necessary be prepared to seek legal redress of their own. Policy at the FDA is generally imposed from the top down, so by understanding changes in the focus of the FDA’s enforcement efforts, particularly under the new administration, interested parties may have an opportunity to intervene legally where necessary and appropriate.

Conclusion. FDA regulated entities can expect an increase in the volume of regulatory letters now that OCC will no longer review regulatory letters which do not present “significant legal issues.” The likelihood that these letters will be legally deficient is also greater. Because even the mere issuance of a non-final, technically not binding, regulatory letter can have significant legal consequences, including civil litigation under state law, recipients of such letters will need to be increasingly active in protecting their rights. Once a regulatory letter has been issued, the entity receiving the letter should keep in mind that FDA counsel may have never reviewed it. Thus, legal defenses to the letters, including those based on the First Amendment, should be considered.

¹⁰*E.g.*, FDA Regulatory Procedures Manual at 4-2 (March 2009) (“A Warning Letter is informal and advisory. It communicates the agency’s position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action.”), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf>.