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Tips For Keeping FDA Advisory Action Letters Out Of Court

By **Jaime Davis and Caitlyn Ozier** (June 20, 2018, 3:56 PM EDT)

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Regulatory compliance can be a moving target for pharmaceutical and medical device manufacturers, as they endeavor to stay up to date on the U.S. Food and Drug Administration's interpretation of applicable regulations and statutes and how they apply to a company's marketing and promotion of a drug or device.

Recognizing that, the FDA often exercises its option to give manufacturers notice of perceived violations by sending an "advisory action letter."[1] The FDA has clearly pronounced that it does not view these letters as final agency actions. Rather, the letters are intended to give manufacturers an opportunity to respond and correct the alleged violation voluntarily, before the agency initiates an enforcement action.

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While a manufacturer may vehemently disagree with the FDA's interpretation that its conduct violates applicable law, it may nevertheless decide it would be prudent to take corrective action to address the alleged violations.

The number of advisory action letters sent to manufacturers spiked after the FDA instituted new policies in 2009 that reduced oversight and review before issuance of the letters.[2] But since that uptick, the number of letters issued by the FDA has declined. In 2017, the FDA issued a record low number of letters to pharmaceutical and medical device manufacturers regarding advertising and promotional labeling of drugs and devices, perhaps in part due to the new Republican administration.

Despite this downtrend, drug and device manufacturers should continue to take care in creating their marketing materials. Receiving an advisory action letter can have long-lasting ramifications, as it leaves behind a public paper trail of perceived violations that plaintiffs counsel would love to show a jury should the company later face litigation.

Warning Letters Versus Untitled Letters

There are two types of FDA advisory action letters that often come up in product liability litigation: warning letters and untitled letters.

Warning letters are more significant, as the FDA only issues them for "violations of regulatory significance" that may lead to an enforcement action if not quickly and properly corrected.[3] Warning letters are designed to prompt the recipient manufacturer into voluntary compliance with applicable statutes or regulations. Despite the potentially serious nature of such a letter, the FDA has reiterated that it does not view warning letters as a form of final agency action.[4]

The FDA issues untitled letters for violations that it does not consider to be of regulatory significance.[5] The purpose of an untitled letter is to communicate certain concerns to the manufacturer and provide an opportunity for the manufacturer to respond and voluntarily take any corrective action. Because they address lesser violations, untitled letters are markedly different in content and format from warning letters — such as the absence of a title. Untitled letters also do not demand a response from the manufacturer, and do not threaten enforcement action should the manufacturer decide not to address the concerns raised in the letter.

Plaintiffs counsel (and the public at large) can access over a decade's worth of warning letters and untitled letters on the FDA's website. The FDA's general archive contains warning letters dating back to 2005, but pharmaceutical warning letters are available as far back as 1998.

Plaintiffs' Use of Warning Letters and Untitled Letters

Outside of the product liability context, many courts have recognized that warning letters and untitled letters are not final agency actions, based on the FDA's clear statements to that effect, and noted their highly prejudicial effect.[6] In spite of this, plaintiffs counsel often seek to admit warning letters and untitled letters as evidence in product liability cases.

The intention undoubtedly is to show evidence of alleged company misconduct, but plaintiffs can purport to offer the letters for a variety of other purposes, including as evidence that the company engaged in specific marketing tactics, to support allegations that a medical device was adulterated, to show notice of an alleged violation, to reveal or clarify the FDA's interpretation of the regulations or to support a claim for punitive damages. Additionally, in medical device cases, plaintiffs often rely on warning letters to assert parallel violations that they argue are not preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act.[7]

In considering admissibility, the key threshold question is whether the letter is relevant. Often this turns on whether the plaintiff can tie the letter to the specific product at issue, the relevant time period and his or her alleged injuries. Several courts have excluded warning letters and untitled letters in product liability cases based on the letters' irrelevance to the facts of that particular case.[8]

Grounds for exclusion include plaintiffs offering no evidence that their prescribers saw the marketing materials addressed by the letter,[9] or the fact that letters concerned a completely different product.[10] Timing is also important. For example, if a warning letter or untitled letter concerns advertising that aired after the plaintiff stopped taking the drug at issue, the letter should be irrelevant to plaintiffs' claims.[11]

Courts have recognized the risk of unfair prejudice to the defendant manufacturer should they allow the jury to consider such letters.[12] A smaller number of courts have excluded these letters on the grounds that they are inadmissible hearsay.[13]

Courts that have admitted warning letters — or least left the door open for admitting them at trial — found that the violations alleged in the letter were directly relevant to plaintiffs' specific claims, and that the letters fell under the public records exception to the hearsay rule.[14] A few courts have considered allowing plaintiffs to present the letters as part of their punitive damages case.[15]

Advice for Drug and Device Manufacturers and Their Counsel

The FDA remains vigilant. So far this year, the agency appears to be moving at a pace consistent with recent years in issuing advisory action letters related to advertising and promotion for prescription drugs and medical devices.

In February 2018, the FDA's Office of Prescription Drug Promotion issued an untitled letter to a pharmaceutical company for failing to display adequately the limitations of use or boxed warnings in the principal promotional panel at a conference exhibit booth. The same month, the FDA's Advertising and Promotional Labeling Branch, which regulates advertising and promotional materials for biological products such as vaccines, issued its first advisory action letter (also an untitled letter) since 2015. In April 2018, the agency issued a warning letter to a healthcare IT company based on statements made on a website and in a YouTube video regarding a device (imaging software).

Drug and device manufacturers and their counsel may find themselves in litigation where plaintiffs counsel seeks to admit warning letters or untitled letters. There are many ways to challenge admissibility through a motion in limine. In the motion, it is important to educate the court on what exactly these letters are — and are not.

The most successful argument tends to be where the manufacturer can show that the letters are not relevant to plaintiffs' specific claims. Manufacturers should also argue that the letters are inadmissible hearsay that do not fall within the public records exception because they do not represent "activities" of the FDA. At most, they demonstrate a tentative conclusion or advice issued by FDA employees, and the FDA itself makes clear that the letters are not final agency actions. Admitting warning letters or untitled letters also would be unfairly prejudicial, as a jury may put undue weight on such letters despite the agency's caveats.

Additionally, manufacturers should also seek to preclude evidence regarding such letters in plaintiffs' punitive damages case. The FDA specifically carves out "repeated or continual," "intentional," "flagrant" or "willful" violations or violations that present "a reasonable possibility of injury or death" as conduct where it is "not appropriate" for the FDA to issue a warning letter.[16] This is exactly the type of conduct usually required to sustain a claim for punitive damages. Accordingly, plaintiffs should not be permitted to use warning letters to persuade a jury to award punitive damages.

Manufacturers and their counsel have plenty of ammunition to try to prevent a jury from ever seeing warning letters and untitled letters. But that has never stopped plaintiffs from trying.

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