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When In Doubt, Write Your Doctor A Letter

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James Huston, Ellen Adler, and Joanna Simon

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Article

Law360, New York (June 07, 2013, 11:48 AM ET) -- "Dear Doctor" letters were front and center in the recently tried case of Tietz v. Abbott Laboratories Inc., et al., No. 12-L-002715. On Thursday, May 9, 2013, a Chicago jury returned a $2.2 million verdict in favor of the plaintiff who alleged his wife was injured by Abbott's failure to adequately warn of risks related to its arthritis drug, Humira.

The verdict has significant implications for the future of failure-to-warn litigation involving prescription drugs. Tietz has opened the door to the argument that a drug manufacturer has a duty to send a "Dear Doctor" letter to provide new drug warnings before the letter is approved by the U.S. Food and Drug Administration, despite regulations and guidance that arguably require such approval.

Background

Tietz accused Abbot Laboratories and AbbVie Inc. of failing to adequately warn doctors about Humira's infection risks. Tietz alleged that as a result of taking Humira, his wife was hospitalized and nearly died of a widespread histoplasmosis infection that doctors struggled to diagnose in early May 2010. If Abbott had adequately warned of the risk of developing unrecognized histoplasmosis through a quickly distributed "Dear Doctor" letter on Humira, argued Tietz, doctors could have diagnosed his wife's infection faster.

Abbott did distribute a "Dear Doctor" letter warning of this exact risk on May 17, 2010 — "Abbott would like the inform you … [of] the risk of developing unrecognized histoplasmosis" — but Tietz argued that Abbott knew of the risk at least 20 months earlier as evidenced by an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) concerning Humira.

The REMS was instituted in September 2008 when the FDA told Abbott it would need to complete the REMS in order to ensure that Humira's benefits outweighed its risks. According to Abbott, it met all FDA-imposed deadlines relating to the REMS, including timely providing a "Dear Doctor" letter concerning histoplasmosis to the FDA for its approval.

Abbott presented testimony that it could not send out a "Dear Doctor" letter sooner than it did. Senior director of regulatory affairs, Raymond Votzmeyer, testified that Abbott could not have sent out the "Dear Doctor" letter before May 2010 because the letter needed FDA approval, which was not given until April 2010.

Votzmeyer maintained that Abbott met all FDA deadlines relating to the issuance of a "Dear Doctor" letter and that it was the FDA's delayed approval that prevented an earlier distribution date. Votzmeyer admitted, however, that providing full information on Humira was ultimately Abbott's responsibility — not the FDA's.

In closing argument, Tietz argued that Abbott's unreasonable delay in sending a "Dear Doctor" letter contributed to

his wife's injuries. Tietz's attorney asked for $5.8 million in damages, and the jury returned a verdict in favor of Tietz for $2.2 million.

Analysis

Whether Abbott should have (or even could have) distributed a "Dear Doctor" letter to warn physicians about the risks of histoplasmosis was a central issue in this hard-fought trial. But we question whether the jury should have been permitted to make the determination that Abbott's alleged delay in sending the "Dear Doctor" letter amounted to negligence.

"Dear Doctor" letters are governed by a single federal regulation (21 C.F.R. § 200.5) and are the subject of several FDA guidance documents. The regulation itself is short, straightforward and very specific about things such as typeface and font size, but it poses some ambiguities for pharmaceutical manufacturers, such as whether "Dear Doctor" letters are to be sent by the manufacturer or the FDA. 21 C.F.R. § 200.5 ("Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care").

Despite these ambiguities, most courts — and the FDA — regard "Dear Doctor" letters to be part of a drug's label. See, e.g., Christopher v. Cutter Labs., 53 F.3d 1184, 1187 n.3 (11th Cir. 1995); 21 C.F.R § 321(m). Changes to a drug's label to add or strengthen a warning require FDA approval (through the "changes being effected" process or otherwise). See 21 C.F.R. § 314.70(c)(6) (2012); Pliva v. Mensing, 131 S. Ct. 2567, 2576 (2011).

Although not all label changes require the preapproval of the FDA, the 11th Circuit has noted, "FDA approval must be sought prior to issuing such a ["Dear Doctor"] letter, as it is considered a change in package labeling." Christopher, 53 F.3d at 1187 n.3. Yet, the court in Tietz, despite evidence that Abbott distributed the May 2010 "Dear Doctor" letter soon after it received FDA approval, allowed the jury to consider Abbott's failure to send the letter sooner as evidence of negligence.

The court's decision in this regard is also contrary to the FDA's guidance, which encourages manufacturers and distributors to contact the agency to determine whether sending a "Dear Doctor" letter is the appropriate mechanism to convey the new information.[1] The FDA suggests that it can help determine how "to present the new information in the letter" and the "target audience for the information in the letter."

The FDA indicates that consulting with it before distributing the letter will "avoid the need to send a corrective letter in the event that the FDA determines," after a "Dear Doctor" letter has been sent, "that the content of the letter was somehow false or misleading" or "lacking in fair balance."

Lessons from Tietz

The Tietz case serves as a reminder to drug manufacturers that they must weigh the risks, benefits and timing of sending a "Dear Doctor" letter to physicians when they are aware of specific additional instructions or warnings missing from a drug's label. Manufacturers are not permitted to sit on information that may affect physician prescribing decisions.

Tietz makes clear that manufacturer compliance with FDA-imposed deadlines is not sufficient to avoid liability, even though compliance with such deadlines is arguably the industry standard.[2] Tietz also demonstrates the requisite care that a manufacturer should take when drafting a "Dear Doctor" letter because the letter may end up in front of a jury. We expect, in the wake of the Tietz, to see more pharmaceutical products liability cases focus on an alleged failure to timely send a "Dear Doctor" letter.

--By James W. Huston, Ellen N. Adler and Joanna L. Simon, Morrison & Foerster LLP

James Huston is a partner, and Ellen Adler and Joanna Simon are associates in the firm's San Diego office.

not intended to be and should not be taken as legal advice.

[1] See Guidance for Industry and FDA Staff: Dear Health Care Provider Letters: Improving Communication of Important Safety Information 2 (2010), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM233769.pdf

[2] Compliance with an industry standard, although evidence of non-negligence, is not alone sufficient to avoid liability. See The T.J. Hooper, 60 F.2d 737 (2d Cir. 1932) ("Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.")