Pharmaceuticals/Medical Devices

On a Learning Curve?

FDA Proposes Studies on Direct-to-Consumer Marketing of Prescription Drugs That May Impact the Current and Future State of the Learned Intermediary Doctrine

by Kim E. Moore and Meera U. Sossamon

Members of the New Orleans Bar practicing in the areas of pharmaceutical and medical device litigation may want to take note of recently proposed Food and Drug Administration[1] studies in the area of direct-to-consumer marketing of prescription drugs and medical devices. These study results may impact applicability of the learned intermediary doctrine for failure to warn claims.

In Louisiana, in order to prevail on a failure to warn claim against a manufacturer, a plaintiff must establish both: (1) inadequacy of the warning and (2) that the inadequate warning was the cause of his injuries.[2] And Louisiana, like many other jurisdictions, applies the learned intermediary doctrine to claims involving prescription drugs and medical devices under which the duty to warn of potential risks extends to the physician, not the patient.[3] To prove causation, the plaintiff must show that a proper warning would have changed the decision of the physician to prescribe the drug or device.[4]

In other jurisdictions, the advent of direct-to-consumer marketing of prescription drugs and medical devices has eroded applicability of the learned intermediary doctrine.[5] Courts in West Virginia and New Jersey, for example, have held that FDA requirements, which mandate that such ads contain a full disclosure of associated side effects, eliminates the need to rely on a "learned intermediary" to inform a patient of such risks.[6] Plaintiffs have urged courts applying Louisiana law to recognize a similar "direct-to-consumer" exception to the learned intermediary doctrine, although no Louisiana state or federal decision has done so yet.[7]

The FDA's recent announcement that it is studying the impact of the lengthy list of side effects recited at the end of television advertisements for prescription drugs could foreshadow a change in the content of direct-to-consumer ads.[8] Specifically, the FDA has become concerned that the length of the lists of warnings is inundating consumers such that they are unable to identify the more serious side effects of the drug, or in other cases, making a relatively innocuous drug or device appear dangerous.[9] Based on the results of the study, the FDA is considering limiting disclosures in consumer ads to only "major warnings" with a disclaimer that it is not an exhaustive list.[10] An FDA rule limiting the scope of warnings in consumer ads would seemingly revive the learned intermediary doctrine even in those jurisdictions that have accepted the "direct-to-consumer" exception as it would shift the burden to fully inform patients of risks back to the physician. On the other hand, if the FDA studies affirm the effectiveness of "direct-to-consumer" warnings and the more detailed consumer warnings are retained, the argument in favor of an exception to the learned intermediary doctrine could be strengthened.

New Orleans practitioners on both sides of the Bar will want to keep watch on the results of the FDA's study for its potential impact on the interplay between direct-to-consumer advertising of prescription drugs and medical devices and applicability of the learned intermediary doctrine.

FOOTNOTES

1. Anna Edney, "TV Drug Ads May Trim

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Lengthy Recitation of Side Effects," February 14, 2014, available at http://www.bloomberg.com/news/2014-02-14/tv-drug-ads-may-trim-lengthy-recitation-of-side-effects.html (hereinafter "Edney")

2. La. Rev. Stat. Ann. § 9:2800.52 (West 2014); see also *Stahl v. Novartis Pharm. Corp*., 283 F.3d 254, 261-62 (5th Cir. 2002)

3. *Allgood v. SmithKline Beecham Corp.*, 314 Fed. Appx. 701, 702 (5th Cir. 2009), *quoting Stahl v. Novartis Pharm. Corp*., 283 F.3d 254, 265 (5th Cir. 2002). ; *see also Mikell v. Hoffman–LaRoche, Inc.*, 649 So.2d 75, 80 (La. App.1994).

4. *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994); Eschete v. Roy, 554 F. Supp.2d 628, 634 (E.D. La. 2008); *Ferguson v. Proctor & Gamble Pharmaceuticals, Inc.*, 353 F. Supp.2d 674, 679 (E.D. La. 2004)

5. *See e.g. State ex rel. Johnson & Johnson Corp. v. Karl*, 220 W. Va. 463, 474, 647 S.E.2d 899, 910 (2007)

6. *Id.* The theory is that direct-to-consumer marketing of prescription drugs negates the need for the learned intermediary doctrine in three distinct ways: (1) it suggests that consumers themselves are capable of understanding complex medical warnings without the intermediary physician; (2) it suggests that consumers are active participants in making their own health care decisions, invalidating the idea that the weighing of risks and benefits of treatment rests solely with the physician; and (3) it encroaches on the patient-physician relationship by suggesting consumers ask their physicians about certain drugs, mooting any concerns about undermining the patient-physician relationship.

7. *Allgood v. GlaxoSmithKline PLC*, CIV.A. 06-3506, 2008 WL 483574 (E.D. La. Feb. 20, 2008) *aff'd* sub nom. *Allgood v. SmithKline Beecham Corp.*, 314 F. App'x 701 (5th Cir. 2009) (federal court declines to "redefine Louisiana's version of the [learned intermediary] doctrine to recognize an exception based on 'direct-to-consumer' advertising").

8. Tara Craig, "FDA Mulls Use of Side Effect Voiceover in TV Advertising: Agency Considers Updating How Drug Risks Are Communicated," February 20, 2014, available at http://www.pmlive.com/pharma_news/fda_mulls_use_of_side_effect_voiceover_in_tv_advertising_545027# (hereinafter "Craig")

9. *Id.* The FDA will survey 1,500 participants about their reactions to varying degrees of detailed voiceover warnings about potential side effects of prescription drugs, designed to assess perception and understanding of: product risks and benefits; disclosure about additional risks; and intention to seek more information about the product.

10. *See* Agency Information Collection Activities; Proposed Collection; Comment Request; Disclosure Regarding Additional Risks in Direct-to- Consumer Prescription Drug Television Advertisements, available at http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0168-0001

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