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PUBLISHER LIABILITY

The Eastern District of Missouri ''got it wrong'' when it recently held that a publisher of medical reference material can be held liable for a monograph that allegedly failed to warn of the dangers of a drug, attorney Melissa J. Oretsky says in this BNA Insight. The author discusses applicable First Amendment principles, as well as case law that has otherwise uniformly rejected attempts to hold publishers liable for defects in the content of materials that they publish.

Medical Reference Materials Publisher Liability

BY MELISSA J. ORETSKY

In the realm of pharmaceutical product liability litigation, it is expected that plaintiffs will sue the pharmaceutical manufacturer. Sometimes plaintiffs may sue their prescribing physicians. They may even attempt to sue the pharmacy or the pharmacist that dispensed the medication. These defendants do not seem too far-fetched or unexpected. Far less common, and indeed far-fetched, is suing the *publisher* of medical reference materials (i.e., patient education fact sheets, patient education monographs, the Physician's Desk Reference) in such litigation.

How can a publisher of medical reference materials be held liable in such cases? Well, based on collective case law today, they cannot. Although plaintiffs have attempted to hold publishers liable for alleged defects in materials that they publish, courts across the country are rejecting such claims.

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Neeley v. Wolters Kluwer Health, Inc.

A recent case—indeed the only case—actually holding that a claim can be stated by publisher liability allegations is *Neeley v. Wolters Kluwer Health, Inc.*[1] Simply put, the court in *Neeley* got it wrong.

In *Neeley*, the plaintiffs alleged that the publishers of a prescription drug monograph failed to warn of the dangers of the drug when they published a monograph containing potential risk information.[2] Plaintiffs asserted that the publishers owed them a legal duty that arose out of public policy, foreseeability of harm, common law assumption of duty principles, and the volun-

[1] No. 4:11-CV-325JAR, 2013 BL 200607 (E.D. Mo. July 29, 2013).

[2] *Id.* at *10-11.

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tarily assumption of a duty of care to the plaintiff under the Restatement § 324A.[3]

Restatement (Second) of Torts § 324A (1965) provides:

> One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if (a) his failure to exercise reasonable care increases the risk of such harm, or (b) he has undertaken to perform a duty owed by the other to the third person, or (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

Despite being a Fed. R. Civ. P. 12(b)(6) motion to dismiss case, the court in *Neeley* relied on cases involving fraudulent joinder—a *different* standard of review than a 12(b)(6) motion—as ''persuasive authority for finding a viable claim'' against the publishers.[4] It found that despite the fact that the publishers lacked any direct relationship with the plaintiffs, the ''[p]laintiffs were foreseeable recipients of information provided by the [publishers].''[5]

The court held that the ''[p]laintiffs adequately allege that they were foreseeable third-party beneficiaries based upon the 'clear foreseeability of harm to Plaintiff' and because the [publishers] 'voluntarily assumed a duty of care to Plaintiff under the Restatement § 324 and common law assumption of duty principles.' ''[6] Additionally, the court rejected the publishers' claims of First Amendment protection on the basis of existing factual issues as to whether the publishers were authors or publishers.[7]

No Duty Owed to Plaintiffs

Neeley is an example of foreseeability run wild. Courts in jurisdictions across the country, *unlike Neeley*, have found a lack of a *duty* owed by medical reference materials publishers to plaintiffs. Notably, there is appellate authority rejecting claims that would hold a medical reference materials publisher liable based on drug information that it printed.

In California, ''there are clear judicial days on which a court can foresee forever . . . but none on which that foresight alone provides a socially and judicially acceptable limit on recovery of damages.''[8] Thus, in *Rivera v. First DataBank, Inc.*,[9] plaintiffs sued the publisher of a prescription drug monograph on theories of negligence and breach of contract for alleged flaws and inaccuracies in the monograph. However, the court found that:

> Plaintiffs failed to demonstrate defendant [publisher] owed them any duty. Defendant is neither the manufacturer of [the drug], which had the duty to publish the patient medication guide . . . in the language and form required by the FDA . . . , nor the pharmacy dispensing it. Plaintiffs did not show defendant was obligated to provide any information to them at all.[10]

Further, *Rivera* found that none of the information at issue in the monograph was a substitute for FDA-approved information that drug manufacturers were required to provide along with their drugs:

> Plaintiffs' criticism that [relevant] warnings were buried in fine print does not equate to negligence on defendant's part. Plaintiffs have not shown defendant had a duty to present the information in the monograph in any particular format or order . . . , the monograph is not government regulated. And again, the monograph was not a substitute for the patient medication guide. That [a pharmacist] failed to include that guide or the package insert or that plaintiffs overlooked them does not impose any duty on defendant to change the style, format, or contents of its monograph. As defendant points out, plaintiffs have not presented any evidence the monograph contained any information that was false.[11]

See also Hardin v. Palo Alto Medical Foundation, Inc.[12] In *Hardin*, the court followed *Rivera* and rejected the Plaintiffs' argument that a drug monograph publisher breached a duty of care to the plaintiff. It found as a matter of law that the plaintiffs could not establish that the publisher owed a duty to them.

New York has rejected publisher liability claims on their merits for over 35 years. In *Demuth Development Corp. v. Merck & Co. Inc.*,[13] the court found ''no support'' for imposing a duty on publisher Merck concerning drugs and chemicals its materials described but that it did not sell. In doing so, it noted that a ''reasonable anticipation that [a] statement will be communicated to others whose identity is unknown . . . or even knowledge that the recipient intends to make some commercial use of it in dealing with unspecified third parties, is not sufficient to create a duty of care towards them.''[14]

Additionally, *Roman v. City of New York*,[15] found that the publisher of a procedure information pamphlet distributed at a hospital could not be held liable for an allegedly improperly performed procedure. The court noted that ''[o]ne who publishes a text cannot be said to assume liability for all 'misstatements,' said or unsaid, to a potentially unlimited public for a potentially unlimited period.''[16]

Likewise, courts in Pennsylvania have rejected publisher liability claims as recent as April of this year. In *A.B. vs. Ortho-McNeil-Janssen Pharmaceuticals*,[17] the plaintiffs asserted liability on the several theories, including the theory of ''negligent undertaking'' under Restatement § 324A.[18] They argued that the defendants,

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[3] *Id.* at *13.
[4] *Id.*
[5] *Id.*
[6] *Id.* at *13-14
[7] *Id.* at *14.
[8] *Thing v. La Chusa*, 771 P.2d 814, 830 (Cal. 1989).
[9] 115 Cal. Rptr. 3d 1 (Cal. App. 2010)
[10] *Id.* at 8.
[11] *Id.* at 8-9.
[12] No. RG11600291 (Cal. Super. July 3, 2012).
[13] 432 F. Supp. 990 (E.D.N.Y. 1977)
[14] *Id.* at 993 (citation and quotation marks omitted).
[15] 442 N.Y.S.2d 945, 947-48 (Sup. Ct. 1981).
[16] *Id.* at 948.
[17] No. 100100649 (Pa. C.P. April 5, 2013).
[18] Plaintiffs also asserted a claim for fraud; however, the court found that this claim failed as a matter of law because the publishers owed no duty of care to either plaintiffs or the prescribing physician. The same allegations were also made and dismissed in several separate identical opinions. *Banks v. Ortho-McNeil-Janssen Pharmaceuticals*, No. 100100618 (Pa. C.P. April 5, 2013); *Kreves v. Ortho-McNeil-Janssen Pharmaceuticals*, No. 100503671 (Pa. C.P. June 19, 2013); *S.B. v. Ortho-McNeil-Janssen Pharmaceuticals*, No. 100503629 (Pa. C.P. June 12, 2013). Plaintiffs filed appeals in Pennsylvania Superior Court pertaining to the dismissal of their publisher liability claims. However, notably, in September 2013, Plaintiffs withdrew their appeals.

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medical information publishers, ''fail[ed] to use reasonable care in their undertaking to provide accurate, up-to-date information about [the drugs].''[19] The court rejected the plaintiffs' argument. In order to recover under § 324A, plaintiff must prove the elements of a negligence cause of action (duty, breach of such duty, proximate cause, and damages).[20] The court noted that '' 'before a person may be subject to liability for failing to act in a given situation, it must be established that the person has a duty to act; if no care is due, it is meaningless to assert that a person failed to act with due care.' ''[21] The court found that the publishers did not assume any duty owed to the plaintiffs and plaintiffs failed to prove any of the prongs of Restatement § 324.[22]

Arkansas has also rejected publisher liability claims with respect to publishers of medical reference materials. In *Cheatham v. Teva Pharmaceuticals USA*,[23] the court refused to impose a duty owed by a drug monograph publisher to a plaintiff. In concluding that the publisher owed no legal duty to the plaintiff, the court found that:

> The undisputed facts do not permit a finding that [the publisher] owed any legal duty to warn or instruct [plaintiff] regarding [the drug]. [The publisher's] undertaking to provide patient drug education information to [the pharmacist] did not create such a duty. . . .[T]here is no basis for concluding that the monograph was intended to supplant either [plaintiff's] physician's warnings regarding the prescribed medication or the pharmacist's duties in connection with filling the prescription. [The publisher] did not deal directly with [plaintiff], but provided educational materials to [the pharmacist] to permit it to comply with its Pharmacy Board mandated patient counseling requirements. It would be contrary to existing legal principles to impose upon [the publisher] a duty greater than the pharmacy that filled the prescription and provided the monograph to [plaintiff].[24]

Maryland, Colorado, and New Jersey have also rejected the theory of a duty owed by publishers of medical reference materials to plaintiffs. *See Jones v. J.B. Lippincott Co.*[25]; *Bailey v. Huggins Diagnostic & Rehabilitation Center, Inc.*[26]; *Wilkow v. Drug Fair, Inc.*[27]

Thus, unlike the *Neeley* court, many courts have refused to find a duty owed by medical reference publishers to plaintiffs and have rejected plaintiffs' attempts to hold such publishers liable for alleged defects in the content of materials that they publish.

First Amendment Protection

In addition to rejecting medical reference publisher liability claims because publishers owe no duty to plaintiffs, courts throughout the country have also held that the First Amendment precludes such claims.

Two such cases from New York discuss this First Amendment protection. In *Libertelli v. Hoffman-La Roche, Inc.*,[28] plaintiff filed a lawsuit against the publisher of the Physician's Desk Reference. The court found that ''the First Amendment blocks [plaintiff's] claim against the publisher.''[29] In *Demuth Development Corp.*,[30] the drug index publisher Merck was protected from liability for publishing allegedly incorrect information. The court found that ''Merck's right to publish free of fear of liability is guaranteed by the First Amendment.''[31]

Maryland also recognizes free speech principles with respect to medical reference publishers. In *Jones*,[32] the medical textbook publisher was not strictly liable for the content of the book it published as such liability ''could chill expression and publication which is inconsistent with fundamental free speech principles.''

Additionally, California also recognizes that medical publishers are entitled to free speech protection. *Vess v. Ciba-Geigy Corp. USA*,[33] a case applying the California anti-SLAPP statute,[34] found that defendant publisher's protected speech consisted of the publication of the Diagnostic and Statistical Manual of Mental Disorders.[35] *Rivera* also found that the publisher's prescription drug monograph was protected free speech.[36]

Colorado further stresses a publisher's fundamental right to free speech. In *Bailey*,[37] the court rejected publisher liability claims with respect to a book's allegedly

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[19] *Id.*

[20] *Id.*

[21] *Id.* (quoting *Wenrick v. Schloemann-Siemag Aktiengesellschaft*, 564 A.2d 1244, 1248 (Pa. 1989)).

[22] *Id.* Prior to the *A.B.* line of cases, a fraudulent joinder case in Pennsylvania federal court speculated (in the absence of contrary precedent) that there could conceivably be a publisher liability claim against a patient education monograph publisher. *Slater v. Hoffman-La Roche, Inc.*, 771 F. Supp. 2d 524 (E.D. Pa. 2011). *Slater* cited a single non-Pennsylvania case, holding that a pharmacist (not the publisher itself) who provided such materials in connection with selling a drug might be liable under an ''assumed duty'' rationale if the information provided was misrepresented as being ''complete'' when it was not.

[23] 726 F. Supp. 2d 1021 (E.D. Ark. 2010)

[24] *Id.* at 1024.

[25] 694 F. Supp. 1216, 1217 (D. Md. 1988) (the publisher of a medical textbook ''has no duty of care to plaintiff with respect to the content of the book and makes no warranty as to the contents'').

[26] 952 P.2d 768, 772-73 (Colo. App. 1997) (the publisher/author of book on dental procedures owed no duty of due care to plaintiff claiming injury from dental device).

[27] No. L-2137-98 (N.J. Super. Oct. 22, 1999) (no duty between the publisher of a patient information sheet and the plaintiff).

[28] No. 80Civ.5626, 1981 BL 165 (S.D.N.Y. Feb. 23, 1981).

[29] *Id.* at 3. The court also dismissed the claims against the publisher on the basis that the publisher's failure ''to perform independent tests'' on products did not amount to maliciousness, recklessness, or an intent to harm. *Id.* at 2. The court did not address whether the publisher had a duty to perform tests on drugs because other arguments made by the publisher were sufficient to defeat plaintiff's claims. *Id.* at 1.

[30] 432 F. Supp. at 993.

[31] *Id.*

[32] 694 F. Supp. at 1217-18.

[33] 317 F.3d 1097, 1110 (9th Cir. 2003).

[34] California's anti-''Strategic Lawsuit Against Public Participation'' (''SLAPP'') statute, Cal. Civ.Code § 425.16, allows for ''early dismissal of meritless first amendment cases aimed at chilling expression through costly, time-consuming litigation.'' 317 F.3d at 1109 (citation and quotation marks omitted). A defendant can move to strike plaintiff's complaint if it '' 'aris[es] from any act of that person in furtherance of the person's right of petition or free speech under the United States or California Constitution in connection with a public issue.' '' *Id.* (quoting the anti-SLAPP statute).

[35] Additionally, the court affirmed the dismissal of plaintiff's state law fraud claim against the publisher because the plaintiff failed to properly plead averments of fraud. *Id.* at 1108.

[36] 115 Cal. Rptr. 3d at 5-6.

[37] 952 P.2d at 773.

false statements about dental amalgam safety noting that ''[t]he expression of opinions upon matters of public concern is the core value protected by the First Amendment.''[38]

Conclusion

As evidenced by the rulings of numerous courts in jurisdictions throughout the country, publisher liability claims—specifically claims against publishers of medical reference materials—have been rejected for various reasons, including a lack of duty owed to plaintiffs and for fundamental, constitutional free speech concerns.

Case law primarily reveals that plaintiffs have yet to devise any valid, persuasive arguments to support such liability claims.

Does the recent *Neeley* case represent a break with past precedent? Although its rationale seems unconvincing, only time will tell.

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[38] *Id.* Numerous courts throughout the country have also held that the First Amendment precludes various other types of publishers from being held liable for alleged informational defects. *Winter v. G.P. Putnam's Sons*, 938 F.2d 1033, 1036-38 (9th Cir. 1991) (publisher of encyclopedia of mushrooms not liable for erroneous description of mushroom as edible); *Stutzman v. Armstrong*, No. 2:13-CV-00116-MCE-KJN, 2013 BL 240978, at *17 (E.D. Cal. Sept. 10, 2013) (authors and publishers of books containing allegedly false statements protected by First Amendment; at most book was ''mixed'' speech entitled to full protection); *Gorran v. Atkins Nutritionals, Inc.*, 464 F. Supp. 2d 315, 326-27 (S.D.N.Y. 2006) (diet book case); *First Equity Corp. v. Standard & Poor's Corp.*, 690 F. Supp. 256, 258-59 (S.D.N.Y. 1988) (publisher of corporate records), *aff'd on other grounds*, 869 F.2d 175 (2d Cir. 1989); *Fowler v. Thomas Nelson Publications*, No. 08-12572, 2009 BL 46345 (E.D. Mich. March 6, 2009) (Bible publisher not liable for Bible's negative portrayal of homosexuality); *Lewin v. McCreight*, 655 F. Supp. 282, 284, n.2 (E.D. Mich. 1987) (publisher not liable for ''defective'' formula in book); *Rosenberg v. Harwood*, No. 100916536, 2011 BL 333199 (Utah Dist. May 27, 2011) (plaintiff could not sue Google maps for negligent directions); *Ginsburg v. Agora*, Inc., 915 F. Supp. 733, 739 (D. Md. 1995) (subscription newsletter publisher not liable for advertisements); *Barden v. HarperCollins Publishers, Inc.*, 863 F. Supp. 41, 45 (D. Mass. 1994) (publisher did not vouch for qualifications of author); *Pittman v. Dow Jones & Co.*, 662 F. Supp. 921, 923 (E.D. La. 1987) (newspaper publisher not liable for advertisements), *aff'd,* 834 F.2d 1171 (5th Cir. 1987); *Gutter v. Dow Jones, Inc.*, 490 N.E. 2d 898, 901 (Ohio 1986) (investment newspaper); *Birmingham v. Fodor's Travel Publications, Inc.*, 833 P. 2d 70, 75-76 (Haw. 1992) (travel guide not required to warn about dangerous swimming conditions); *Lacoff v. Buena Vista Publishing, Inc.*, 705 N.Y.S. 2d 183, 187-88 (N.Y. Sup. N.Y. Co. 2000) (investment ''how to'' book); *Daniel v. Dow Jones & Co.*, 520 N.Y.S. 2d 334, 339-40 (N.Y. Sup. 1987) (computerized news service not liable for allegedly false story); *Walter v. Bauer*, 439 N.Y.S. 2d 821, 822 (N.Y. Sup. 1981) (book of science experiments not liable for injuries caused by explosion*), mod. on other grounds*, 451 N.Y.S. 2d 533 (App. Div. 1982); *Smith v. Linn*, 563 A.2d 123, 125-126 (Pa. Super. 1989) (publisher not liable for negligence in publishing a book pertaining to dieting); *Walters v. Seventeen Magazine*, 241 Cal. Rptr. 101, 103 (App. 1987) (no liability for errors in advertisement); *Alm v. Van Nostrand Reinhold Co.*, 480 N.E. 2d 1263, 1267 (Ill. App. 1985) (''how to'' book publisher); *Reynolds v. Murphy*, 188 S.W. 3d 252, 266-67 (Tex. App. 2006) (information in subscription newsletter); *Orozco v. Dallas Morning News, Inc.*, 975 S.W. 2d 392, 396 (Tex. App. 1998) (newspaper reporting of criminal activity).

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