

WEST VIRGINIA SUPREME COURT STRIKES DOWN LEARNED INTERMEDIARY RULE

By James M. Beck & Theodore H. Frank*

In 1999, the New Jersey Supreme Court created an unprecedented exception to the learned intermediary rule, holding that it did not apply where the manufacturer had engaged in direct-to-consumer advertising.¹ The decision was especially surprising because New Jersey was one of the few states where the legislature had explicitly written the learned intermediary doctrine into statutory law.² *Perez v. Wyeth Laboratories, Inc.* was not followed in other jurisdictions until 2007,³ when the West Virginia Supreme Court used the rationalization of direct-to-consumer advertising in *State ex rel. Johnson & Johnson Corp. v. Karl* (a case where there was none at issue) to hold that it would be the first state to disregard the learned intermediary doctrine.⁴

The learned intermediary doctrine has been adopted by state courts in thirty-nine states and by the District of Columbia—including thirty-four states where the decision was made by the highest court, and the highest court of the fourteen most populous states. Federal courts have made an *Erie* prediction in eight other states, and in Puerto Rico, that the state would adopt the learned intermediary rule.⁵ Thus, West Virginia's highest court has parted company with the forty-seven states that have judicially recognized this doctrine.

THE WEST VIRGINIA COURT'S DECISION

But in *Karl*, a 3-2 decision with four opinions, the West Virginia Supreme Court disagrees that virtually all states have adopted the learned intermediary doctrine. The lead opinion counts "decisions of only the highest state courts," and concludes that "a mere" twenty-one states have expressly adopted the doctrine.⁶ One reason for the discrepancy is the omission in *Karl* of cases involving prescription medical devices.

The majority goes on to reject all of the usual justifications for the doctrine. "At the outset," it notes, "the learned intermediary doctrine is not a modern doctrine. Rather, its origins may be traced as far back as 1925."⁷ This is a curious observation in a common law system governed by *stare decisis*; the doctrine has been on the books, and increasingly embraced, for more than eighty years. This casual approach to precedent is of concern to more than just pharmaceutical defendants;⁸ it potentially threatens other doctrines, such as product identification, remote causation, and even the burden of proof.

Criticizing the learned intermediary rule as "outdated" would hold if the rule was only rarely invoked, or if there were a general trend away from it. Neither is the case here. The rule is as routinely followed now as in prior years.⁹ Indeed, *Karl* cites not a single other opinion that outright rejects the rule. That is because no such opinion exists—until now. Remarkably, the *Karl* court relied on the absence of a ruling in the highest courts in twenty-two states (some of which are erroneously included) as "precedent" for rejecting the rule.¹⁰

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The majority opinion proceeds to attack direct-to-consumer (DTC) advertising. While there are certainly arguments that DTC advertising can be abused, there is also evidence that DTC advertising has been a substantial benefit to consumers and to health outcomes.¹¹ Nevertheless, the majority held that DTC advertising "obviates each of the premises upon which the [learned intermediary] doctrine rests."¹² In a world of DTC advertising, patients become active participants in their health care, and they ask for particular drugs by name. And the existence of DTC ads supposedly proves that it is possible to explain accurately the risks and benefits of drugs directly to patients.¹³ The majority therefore saw no benefit in adopting the learned intermediary doctrine. Manufacturers should simply warn patients directly of the risks associated with prescription drugs.

This reasoning is problematic, however. First, making decisions about the optimal level of direct-to-consumer advertising might seem a usurpation of legislative, executive, or administrative prerogative—particularly in a case in which the defendant did not, in fact, engage in this practice. Moreover, it is peculiar to respond to the supposed harm of DTC advertising by enacting a rule of law that forces manufacturers to do even more of it. By abrogating the learned intermediary rule altogether—supposedly based upon its critique of DTC advertising—*Karl* virtually forces every prescription medical product manufacturer to engage (even for drugs and devices that have not previously been the subject of DTC advertising) in precisely the DTC conduct about which the decision complains. How else is a company supposed to satisfy this new duty to convey warnings about prescription medical products directly to the general public, bypassing the doctor altogether?

Second, although there is a great deal of DTC advertising these days, there are plenty of drugs that are *not* advertised this way—such as the drug in *Karl*. Generally, only a relatively few blockbuster drugs are promoted with expensive ad campaigns; the \$2.38 billion/year spent on DTC advertising in 2001 is less than 2% of the annual cost of prescription drugs. Ordinary drugs, or drugs for rare conditions, do not merit the cost of DTC advertising. Why should the protections of the learned intermediary doctrine be removed from drugs that were (1) never advertised DTC, or (2) advertised DTC, but the plaintiff-patient who brought the case never saw or heard the ad? Even New Jersey applies the learned intermediary doctrine to non-DTC-advertised drugs, and appears to recognize causation as a defense.

Third, it is ordinarily impractical to warn patients directly about the risks associated with drugs. Every doctor has access to the *Physicians' Desk Reference* and can locate and understand prescription drug labeling. Patients are less able to find and read the package inserts, and less able to understand them. They will be even less likely to understand them if drug companies are forced to do additional disclosures for fear of liability. As it is, a 2002 FDA study found, only 16% of patients say they read "almost all" or "all" of even the brief summary disclosures

in DTC advertising, a problem that will surely be exacerbated when the disclosures become longer.¹⁴ Nor is it universal for pharmacies to distribute package inserts when they dispense prescriptions.

This leads us to the fourth point, which is that the opinion is unrealistic. Who, other than physicians and product liability lawyers, actually reads drug package inserts from cover to cover? The average patient surely does not. What purpose does it serve for courts to dictate the contents of documents that go unread?

Karl states that “only” four state supreme courts have adopted the learned intermediary rule since direct-to-consumer (“DTC”) drug advertising “proliferate[ed]” in 1997.¹⁵ However no court—other than that of *Karl*—rejected the rule during that (or any other) period. Nor does *Karl* acknowledge the additional seventeen high court opinions from twelve other states that reaffirmed the learned intermediary rule during this same period.¹⁶

THE LEARNED INTERMEDIARY DOCTRINE & PUBLIC POLICY

The learned intermediary rule fills an important role in the law, ensuring harmonious operation of state product liability law with the “unique system used to distribute prescription [products].”¹⁷

There are several reasons why no other jurisdiction shares the West Virginia view on display in *Karl*. First and foremost, the learned intermediary rule makes sense because it reflects common practice. Ever since the FDA started regulating prescription drugs in the 1930s, those drugs and (more recently) prescription medical devices have only been available to the public after doctors have decided that they are appropriate for the treatment of particular patients. Thus, the rule reflects how prescription drugs and medical devices are actually distributed. These mandatory federal restrictions on distribution are why prescription medical products are *not* the same as a “lawnmower,” the concurring opinion’s example.¹⁸ Anybody can go down to the hardware store and buy a lawnmower for any reason (or no reason) at all. That is not possible—legally—with prescription medical products.

Moreover, these FDA requirements are motivated by longstanding safety concerns. The FDA defines “[p]rescription drug” as “any drug (including any biological product...) required by Federal law... to be dispensed only by a prescription.”¹⁹ All drugs are presumed to be prescription drugs unless the FDA “finds such requirements unnecessary for the protection of the public health by reason of the drug’s toxicity or other potentiality for harmful effect.”²⁰ Similarly, a “prescription device” is “[a] device which, because of any potentiality for harmful effect... is not safe except under the supervision of a practitioner licensed by law to direct [its] use.”²¹

Federal limitations upon distribution of prescription medical products are thus explicitly based upon their inherent safety risks. Nobody is telling purchasers of lawnmowers that they cannot have them unless they first go to a government-licensed professional and obtain pre-certification that the purchase is necessary. Fundamentally, the learned intermediary rule is “based

on the principle that prescribing physicians act as ‘learned intermediaries’ between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient’s needs and assess the risks and benefits of a particular course of treatment.”²² “When the purchase of the product is recommended or prescribed by an intermediary who is a professional, the adequacy of the instructions must be judged in relationship to that professional.”²³ The rule is legal recognition of something that is as true today as ever: prescription medical products are not available to the public at large precisely because the FDA has determined that such products have inherent, unavoidable risks of sufficient gravity to require a doctor’s evaluation before anyone can use them.²⁴

Indeed, the warnings in the package insert are designed for doctors to read, not laypeople—containing jargon like “treatment-emergent hyperglycemia-related adverse events,” “mean (SD) pharmacokinetic parameters,” “agranulocytosis,” and “glomerular filtration rates.” Such warnings are “designed for the physician and not the patient.”²⁵

The rule further reflects reality by recognizing that doctors make most prescribing decisions for their patients in the context of a physician-patient relationship in which patients rely upon their doctors to explain treatment decisions, and do not rely upon their own reading of product labeling.²⁶ It would not just be burdensome, but dangerous, for the law to demand the dumbing-down of technical medical product information. Putting aside practicality, patients should follow doctors’ orders, and should not be conducting possibly ill-informed self-evaluations of their own prescribed medical treatments.²⁷

Further, this sort of scientific precision in labeling is almost certainly preferable, at least as long as prescription drugs are not freely available. Better to have doctors to break things down to their patients in one-on-one conversations, rather than having patients try to read package inserts themselves. At least until *Karl*, West Virginia recognized the doctrine of informed consent, which requires doctors to do just that.²⁸ Thus, at best, *Karl* has just created a regime of redundant and overlapping liability with the patients stuck in the middle—not knowing whom to believe if doctors and drug companies say different things.

Thus, “[i]t is... the duty of the physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug.”²⁹ “Education of the physician, on the one hand, and communication to the patient, on the other, are distinct processes, and the manufacturer’s duty involves only the former.”³⁰ If the product requires a doctor’s prescription—and a doctor, in fact, prescribed it—the rule properly applies.³¹

Conversely, a tort system that requires manufacturers to bypass doctors and warn patients directly would disrupt the physician-patient relationship. “[I]mposition of a generalized duty to warn would unnecessarily interfere with the relationship between physician and patient.”³² “When the physician-patient relationship does exist... we hesitate to encourage, much less require, a drug manufacturer to intervene in it.”³³

Doctors are highly trained, with their own professional and legal obligations to their patients. Among other things, they keep those patients from overreacting to the many warnings

(often directed to limited situations or patient populations) that the FDA requires product labeling to include.³⁴ Thus, the learned intermediary rule keeps doctors where they should be: front and center, as the primary source of patient information about medical treatment.

The rule ensures that, once a manufacturer has warned a doctor, it “may reasonably assume that the physician will exercise his informed judgment in the patient’s best interests.”³⁵ “[F]ailure [of medical personnel] to perform their duties from that point forward do[es] not operate to create, or to extend, a manufacturer’s duty to warn third-party family members, bystanders, or any persons other than the learned intermediary.”³⁶ Thus, manufacturers are not “advisors” to physicians during the informed consent process,³⁷ nor are they responsible for how physicians conduct their business.³⁸

An additional practicality consideration buttresses the rule. “[T]he treating physician is in a better position to warn the patient than the manufacturer.”³⁹ It is unrealistic to depend upon pharmacies to take up the slack, as they usually do not dispense prescription medical products to patients with full warnings.⁴⁰ Thus, it is frequently impractical, or even impossible, for manufacturers to provide direct warnings to unknown patients, particularly in a medical emergency.⁴¹

THE CONCURRENCE

Critics have charged that “West Virginia is now routinely called a ‘judicial hellhole’ with the ‘worst legal system in America.’”⁴² The state of jurisprudence in West Virginia is exhibited most starkly by the concurring opinion in *Karl* of two justices, which states:

Suppose Patient John Doe visits his *small-town West Virginia doctor*. Further suppose he is prescribed a drug by his doctor that causes him serious injury. Suppose that the drug is one that is heavily advertised. Patient Doe then sues his West Virginia doctor and the drug manufacturer for the injury caused by the drug. If this Court were to adopt the learned intermediary doctrine, the West Virginia doctor would remain in the lawsuit, but the drug manufacturer would not remain in the suit and would not be liable for damages if the drug manufacturer *could show that it warned the doctor of the risks* of injury associated with the drug. Thus, a *small-town West Virginia doctor* would become solely responsible for the injury to Patient Doe while an *out-of-state multi-million dollar drug manufacturer* is off the hook.... This result simply would be unfair.⁴³

The characterization of the result as “unfair” is strange. The “out-of-state multi-million dollar drug manufacturer” cannot make a prescription drug that has no significant risk of injury. If it did, the FDA would not have classified the product as a prescription drug to start with, and the learned intermediary rule would never come into play. So, it cannot be the fact that the product causes injury that makes anything unfair.

Nor is the result “unfair” due to an inadequate warning. The hypothetical provides that the doctor was in fact properly warned. If the warning were inadequate, then the learned intermediary rule would not preclude liability of the manufacturer.⁴⁴ If the “out-of-state multi-million dollar drug manufacturer” adequately warned the “small-town West Virginia doctor” about the inherent risks of its product, then what wrong did it commit? “[T]he fact that a particular drug

might produce unfortunate side effects makes it ‘unavoidably unsafe’ but not ‘unreasonably dangerous’, and strict liability will not obtain if ‘proper warning is given, where the situation calls for it.’”⁴⁵

Suppose the “small-town West Virginia doctor” prescribed the hypothetical drug notwithstanding adequate warnings of the harm it caused his or her patient, or did so without telling the patient what could happen. Suppose there was malpractice, or perhaps a breach of that doctor’s informed consent duty. What business does the “out-of-state multi-million dollar drug manufacturer” have in the suit—except that it has deep pockets? The “unfairness” advanced as the basis for the concurrence’s hypothetical does not seem to be tied to any tort concept of fault, but rather wealth (“multi-million dollar company”) and residence (“out-of-state”).

But it is not a court’s job to impose what amounts to an extra-legislative tort tax in order to extract money (ultimately coming almost entirely from the pockets of other, out-of-state product users) for the benefit of local plaintiffs regardless of any concept of legal fault. Moreover, if West Virginia’s tort system allows what amounts to absolute liability on pharmaceutical manufacturers, manufacturers will inevitably re-consider whether the state’s (relatively small) market is worth serving.

Endnotes

- 1 *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999).
- 2 NJ Product Liability Act L. 1987, c. 197, § 4.
- 3 *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp.2d 795, 812 (E.D. Tex. 2002) (“New Jersey law is in direct conflict with the law of every other jurisdiction in the United States”); *see also*, *Colacicco v. Apotex, Inc.*, 432 F. Supp.2d 514, 547 n.30 (E.D. Pa. 2006); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp.2d 791, 812 n.19 (N.D. Ohio 2004), *aff’d*, 447 F.3d 861 (6th Cir. 2006); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 766 (Ky. 2004); *Eady v. Lansford*, 92 S.W.3d 57, 60-61 (Ark. 2002); *see* *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1148 (D. Or. 1989) (rejecting similar argument before *Perez* was decided).
- 4 *State ex rel. Johnson & Johnson Corp. v. Karl*, ___ S.E.2d ___, 2007 WL 1888777 (W. Va., 2007).
- 5 A full list of precedents is available at <<http://druganddevicelaw.blogspot.com/2007/07/headcount-whos-adopted-learned.html>>.
- 6 *Karl*, 2007 WL 1888777, at *8.
- 7 *Id.* at *10.
- 8 *Cf. State ex rel. Mobil Corp. v. Gaughan*, 211 W.Va. 106, 563 S.E.2d 419 (2002) (approving trial plan of over eight thousand asbestos plaintiffs against two hundred fifty defendants).
- 9 *E.g.*, *Ethicon Endo-Surgery, Inc. v. Meyer*, ___ S.W.3d ___, 2007 WL 1095552, at *2 (Tex. App. April 12, 2007); *Bodie v. Purdue Pharma LP*, ___ F.3d ___, 2007 WL 1577964, at *5-6, 11 (11th Cir. June 1, 2007) (applying Alabama law); *Stilwell v. Smith & Nephew, Inc.*, 482 F.3d 1187, 1194 (9th Cir. 2007) (applying Arizona law); *In re Zyprexa Prods. Liab. Litig. v. Eli Lilly & Co.*, ___ F. Supp. 2d ___, 2007 WL 1678078, at *28 (E.D.N.Y. June 11, 2007) (applying Pennsylvania, North Carolina and Florida law); *Soufflas v. Zimmer, Inc.*, 474 F. Supp.2d 737, 751 (E.D. Pa. 2007); *Madsen v. American Home Prods. Corp.*, 477 F. Supp.2d 1025, 1033 (E.D. Mo. 2007) (applying Iowa law); *Cowley v. Abbott Laboratories*, 476 F. Supp.2d 1053, 1060 (W.D. Wis. 2007) (applying North Carolina law); *Hill v. Wyeth, Inc.*, 2007 WL 674251, at *3-4 (E.D. Mo. Feb. 28, 2007); *Saroney v. Tap Pharm. Prods.*, 2007 WL 148845, at *6 (N.D. Ohio Jan. 16, 2007); *Paparo v. Ortho McNeil Pharm.*, 2007 WL 121149, at *3 (S.D. Fla. Jan. 10, 2007).

10 2007 WL 1888777, at *21. For example, *Karl* erroneously lists the District of Columbia, when its highest court acknowledged the learned intermediary rule in *Mampe v. Ayerst Labs.*, 548 A.2d 798, 802 n.6 (D.C. 1988).

11 See generally NATIONAL HEALTH COUNCIL, DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING: OVERVIEW & RECOMMENDATIONS (January 2002).

12 State ex rel. Johnson & Johnson Corp. v. Karl, ___ S.E.2d ___, 2007 WL 1888777, *17 (W. Va. 2007).

13 *Id.* at *19.

14 K.J. Aikin, “The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship,” Presentation at FDA public meeting, Washington, D.C. (22–23 September 2003). www.fda.gov/cder/ddmac/aikin/index.htm (13 April 2004).

15 *Karl*, 2007 WL 1888777 at *35.

16 Hurley v. Heart Physicians, P.C., 898 A.2d 777, 783-84 (Conn. 2006); Rite Aid Corp. v. Levy-Gray, 894 A.2d 563, 577 (Md. 2006); Walls v. Alpharma USPD, 887 So.2d 881, 883 (Ala. 2004); Janssen Pharmaceutica, Inc. v. Bailey, 878 So.2d 31, 57 (Miss. 2004); Howland v. Purdue Pharma, L.P., 821 N.E.2d 141, 146 (Ohio 2004); Morguson v. 3M Corp., 857 So.2d 796, 801-02 (Ala. 2003); Schaerrer v. Stewart’s Plaza Pharmacy, Inc., 79 P.3d 922, 928-29 (Utah 2003); Happel v. Wal-Mart Stores, Inc., 766 N.E.2d 1118, 1127 (Ill. 2002); Hansen v. Baxter Healthcare Corp., 764 N.E.2d 35, 42 (Ill. 2002); Cottam v. CVS Pharmacy, 764 N.E.2d 814, 820 (Mass. 2002); Moore v. Memorial Hospital, 825 So.2d 658, 664 (Miss. 2002); Bennett v. Madakasira, 821 So.2d 794, 804 (Miss. 2002); Vaccariello v. Smith & Nephew Richards, Inc., 763 N.E.2d 160, 164 (Ohio 2002); Perez, 734 A.2d at 1257; Spensieri v. Lasky, 723 N.E.2d 544, 549 (N.Y. 1999); E.R. Squibb & Sons, Inc. v. Farnes, 697 So.2d 825, 827 (Fla. 1997); Edwards v. Basel Pharmaceuticals, 933 P.2d 298, 300-01 (Okla. 1997).

17 Pittman v. Upjohn Co., 890 S.W.2d 425, 429 (Tenn. 1994).

18 *Karl*, 2007 WL 1888777, *59 (Maynard, J. concurring).

19 21 C.F.R. §203.3(y).

20 21 C.F.R. §310.200(b).

21 21 C.F.R. §801.109.

22 *Vitanza*, 778 A.2d at 836-37.

23 *Mampe*, 548 A.2d at 802 n.6.

24 See also, e.g., Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1387 (Pa. 1991); Larkin v. Pfizer, Inc., 153 S.W.3d 758, 763 (Ky. 2004); Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1287 (11th Cir. 2002) (applying Georgia law); Fane v. Zimmer, Inc., 927 F.2d 124, 129 (2d Cir. 1991) (applying New York law); Phelps v. Sherwood Medical Industries, 836 F.2d 296, 298-99 (7th Cir. 1987) (applying Indiana law).

25 Oksenholt v. Lederle Laboratories, 656 P.2d 293, 297 (Or. 1982). See also, e.g., Martin v. Hacker, 628 N.E.2d 1308, 1311 (N.Y. 1993); Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir. 1974) (applying Texas law); Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 841-42 (Neb. 2000).

26 See, e.g., West v. Searle & Co., 806 S.W.2d 608, 613 (Ark. 1991); Humes v. Clinton, 792 P.2d 1032, 1039 (Kan. 1990); Williams v. American Medical Systems, 548 S.E.2d 371, 375 (Ga. App. 2001); Reaves v. Ortho Pharmaceutical Corp., 765 F. Supp. 1287, 1289 (E.D. Mich. 1991).

27 Perez., 734 A.2d at 1254; Dyer v. Best Pharmacal, 577 P.2d 1084, 1088 (Ariz. App. 1978); *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp.2d 795, 815 (E.D. Tex. 2002).

28 E.g., Cross v. Trapp, 294 S.E.2d 446, 454-56 (W. Va. 1982).

29 584 A.2d at 1385.

30 Harwell v. American Medical Systems, Inc., 803 F. Supp. 1287, 1299 (M.D. Tenn. 1992).

31 Ellis, 311 F.3d at 1282.

32 Morgan v. Wal-Mart Stores, Inc., 30 S.W.3d 455, 467 (Tex. App. 2000).

33 Swayze v. McNeil Laboratories, Inc., 807 F.2d 464, 471 (5th Cir. 1987)

(applying Mississippi law).

34 *Larkin*, 153 S.W.3d at 764; see also “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,” 71 Fed. Reg. 3922 (Jan. 24, 2006) (to be codified at 21 CFR Parts 201, 314, and 601) (acknowledging danger of overwarning).

35 Tracy v. Merrell Dow Pharmaceuticals, Inc., 569 N.E.2d 875, 876 (Ohio 1991).

36 Ellis, 311 F.3d at 1283. See also Brooks v. Medtronic, Inc., 750 F.2d 1227, 1232 (4th Cir. 1984) (applying South Carolina law).

37 Polley v. Ciba-Geigy Corp., 658 F. Supp. 420, 421 (D. Alaska 1987).

38 Ellis, 311 F.3d at 1283; Prohaska v. Sofamor, S.N.C., 138 F. Supp.2d 422, 444 (W.D.N.Y. 2001).

39 McCombs v. Synthes, 587 S.E.2d 594, 595 (Ga. 2003).

40 Tracy, 569 N.E.2d at 880.

41 West, 806 S.W.2d at 613; Cunningham v. Charles Pfizer & Co., 532 P.2d 1377, 1381 (Okla. 1974); Talley v. Danek Medical, Inc., 179 F.3d 154, 163 (4th Cir. 1999) (applying Virginia law).

42 Strahin v. Sullivan, ___ S.E.2d ___, 2007 WL 1891551, at *1 (W. Va. Feb. 21, 2007) (Starcher, J. dissenting).

43 *Karl*, 2007 WL 1888777, at *55-56 (emphasis added) (Maynard, J. concurring).

44 E.g., Proctor v. Davis, 682 N.E.2d 1203, 1211, 1213 (Ill. App. 1997) (“the failure of the prescribing and treating physicians to learn of the risks of a drug from other sources does not relieve the manufacturer of liability for harm resulting from its own failure to adequately warn”).

45 *Larkin*, 153 S.W.3d at 761 (quoting Restatement (Second) of Torts §402A, comment k (1965)).

