Dear Doctor Letters As The Next Warning Frontier – Kapps Vs. Winter

Friday, October 28, 2011

Under the learned intermediary rule, for a warning claim to succeed, at a bare minimum the prescribing (or sometimes another) doctor **at least** has to read the allegedly defective warning. After all, there's a causation element to every warning claim – the defect (whatever's allegedly wrong with the warning) has to cause the injury. If the prescribing physician never even read the purportedly inadequate warning, none of those inadequacies could have affected his/her treatment of the patient. This common-sense notion, that a warning that's not read cannot be causal, has been bedrock law in prescription medical product liability litigation for decades:

Alabama

In re Trasylol Products Liability Litigation, 2011 WL 2117257, at *5 (S.D.Fla. May 23, 2011) (applying Alabama law) ("no record evidence indicating that [the prescriber] read the warning that Plaintiff claims was inadequate"); Emody v. Medtronic, Inc., 238 F. Supp.2d 1291, 1293, 1296 (N.D. Ala. 2003) (prescriber "did not even read the package insert"; thus he "he did not rely on [defendant's] warnings").

Arizona

Gebhardt v. Mentor Corp., 15 Fed. Appx. 540, 542 (9th Cir. 2001) ("evidence at trial showed that [the prescriber] did not read or rely upon the allegedly inadequate warnings of the [defendant's] device") (applying Arizona law).

California

Ramirez v. Plough, Inc., 863 P.2d 167, 177 (Cal. 1993) (where plaintiff "neither read nor obtained translation of the product labeling . . . there is no conceivable causal connection between the representations or omissions that accompanied the product") (over-the-counter drug case; plaintiff did not read warning); Conte v. Wyeth, Inc., 85 Cal. Rptr.3d 299, 308, 318-319 (Cal. App. 2008) ("[t]here can be no proximate cause where, as in this case, the prescribing physician did not read or rely upon the allegedly inadequate warnings promulgated by a defendant about a product"); Lord v. Sigueiros, 2006 WL 1510408, at *3-4 (Cal. Super. April 26, 2006) (prescriber "admits that he had not read the [drug's] label before prescribing it

to the decedent"), aff'd, 2007 WL 4418019, at *4 (Cal. App. Dec. 19, 2007) ("evidence does not raise an issue of material fact regarding causation because [the prescriber] testified that he did not read the warning label prior to or after prescribing [the drug] to [plaintiff]"); Motus v. Pfizer, Inc., 358 F.3d 659, 661 (9th Cir. 2004) ("the doctor who prescribed [the drug] . . . failed to read [the defendant's] published warnings before prescribing the drug. Because the doctor testified that he did not read the warning label that accompanied [the drug] or rely on information provided by [the manufacturer's] detail men before prescribing the drug to [plaintiff], the adequacy of [the] warnings is irrelevant") (applying California law); Latiolais v. Merck & Co., 2007 WL 5861354, at *3 (C.D. Cal. Feb. 6, 2007) (the "inserts played no role in his decision to prescribe" because "[the prescriber] could not recall if he ever read the package insert"), aff'd, 302 Fed. Appx. 756 (9th Cir. 2008).

Connecticut

Allen v. Mentor Corp., 2006 WL 861007, at *5, *7 (D. Conn. March 31, 2006) (prescriber "failed to inform himself with respect to the [device] by reading the [package insert], a source of which he was aware and failed to find and read"; "nothing to suggest that the warnings . . . affected [the prescriber's] conduct since he did not read them").

District of Columbia

Mampe v. Ayerst Laboratories, 548 A.2d 798, 802 (D.C. 1988) (prescriber "specifically stated on several occasions that he did not rely on the manufacturer's warnings as a source of information"; plaintiff "therefore could not prove that the alleged inadequacy in [defendant's] warning was a proximate cause of her injuries").

Florida

Rounds v. Genzyme Corp., 2011 WL 692218, at *3 (M.D. Fla. Feb. 18, 2011) (prescriber's "failing to read the warning" warranted dismissal); Fields v. Mylan Pharmaceuticals, Inc., 751 F. Supp.2d 1260, 1263 (N.D. Fla. 2009) ("[w]here a physician fails to review the warnings issued by the manufacturer, proximate cause cannot be established").

Illinois

Tongate v. Wyeth Laboratories, 580 N.E.2d 1220, 1228 (Ill. App. 1991) ("that the physician failed to read the package inserts and the PDR negated any possible negligence on the part of the defendant and that the physician's negligence was the intervening, independent and sole proximate cause"); Ashman v. SK & F Lab Co., 702 F. Supp. 1401, 1405 (N.D. Ill. 1988) ("[p]laintiffs offer no evidence that [the prescriber] consulted the [drug's] label at the time he prescribed").

Indiana

Peters v. Judd Drugs, Inc., 602 N.E.2d 162, 165 (Ind. App. 1992) ("additional warnings would not have assisted [plaintiff] where the nurse [selecting the drug] did not read the label").

Kansas

Wright v. Abbott Laboratories, Inc., 259 F.3d 1226, 1235 (10th Cir. 2001) ([the prescribing nurse's] "failure to read the label - a basic task which she was trained to perform - was an efficient intervening cause of [plaintiff's] injury") (applying Kansas law).

Louisiana

Felice v. Valleylab, Inc., 520 So.2d 920, 927 (La. App. 1987) (in "[the prescriber's] own testimony she admitted that she had never read the warning label on the device itself, and that she had never read the manual. An adequate warning or instruction would have been futile"); Hall v. Elkins Sinn, Inc., 102 Fed. Appx. 846, 849 (5th Cir. 2004) (the prescriber "acknowledges that he never read the warning . . . therefore, [defendant's] warning (adequate or inadequate) played no role in the events leading to [plaintiff's] injury") (applying Louisiana law); Dykes v. Johnson & Johnson, 2011 WL 2003407, at *5 (E.D. La. May 20, 2011) (the prescriber "never read the warning, and thus the warning played no role in the events leading to plaintiff's injury").

Michigan

Dunn v. Lederele Laboratories, 328 N.W.2d 576, 583 (Mich. App. 1982) ("the doctor quit reading the inserts and PDR reprints. Thus, further notice by way of drug labels would not have altered the doctor's conduct"); Formella v. Ciba-Giegy Corp., 300 N.W.2d 356, 359 (Mich. App. 1981) (the "fact [the prescriber] failed to read the package inserts and PDR negates any possible negligence on the part of [the manufacturer] in not emphasizing the hazards in those publications"); Cronin v. Boots Pharmaceuticals, Inc., 1996 WL 149173, at *2 (Mich. App. Feb. 16, 1996) ("[g]iven the lack of evidence that [the prescriber] ever consulted or relied on defendants' package insert warnings in treating plaintiff, it cannot be said that those warnings played any role in the doctor's decision to prescribe"); William Beaumont Hospital v. Medtronic, Inc., 2010 WL 3998103, at *6 (E.D. Mich. Oct. 8, 2010 ("failure to heed clear warnings can be a superceding cause").

Minnesota

Kapps v. Biosense Webster, Inc., ___ F. Supp.2d ___, 2011 WL 4470701, at *23 (D. Minn. Sept. 27, 2011) ("doctors don't read instructions for use in great detail every time"; plaintiff conceded unread warnings not causal); Treuchel v. Eli Lilly & Co., 2009 WL 5216930, at *12 (E.D.N.Y. Dec. 21, 2009) ("[plaintiff's] prescriber did not rely on printed warnings. . . . [Plaintiff] cannot meet his burden. He failed to elicit any testimony from [any] prescriber suggesting that a different warning . . . would have changed the prescribers' decisions to continue prescribing [the drug] to [plaintiff]") (applying Minnesota law); Johnson v. Zimmer, Inc., 2004 WL 742038, at *9-10 (D. Minn. March 31, 2004) (no causation where surgeon "had never, in any context, seen the warnings").

Montana

Oakberg v. Zimmer, Inc., 211 Fed. Appx. 578, 581 (9th Cir. 2006) ("it is undisputed that neither [the prescriber nor plaintiff] read the [product's] package insert. Accordingly, even if the additional warning were printed in the package insert, they would not have been read") (applying Montana law).

New Hampshire

Bartlett v. Mutual Pharmaceutical Co., 731 F. Supp.2d 135, 146 (D.N.H. 2010) (the "[prescriber] made clear that he never reviewed [defendant's drug] label before treating [plaintiff] and that nothing about it influenced his decision to prescribe the drug"); Bartlett v. Mutual Pharmaceutical Co., 2010 WL 3659789, at *7 (D.N.H. Sept. 14, 2010) ("[plaintiff's] doctor did not read or rely upon [the drug's] label before prescribing the drug to her").

New Jersey

Perez v. Wyeth Laboratories Inc., 734 A.2d 1245, 1261 (N.J. 1999) ("a manufacturer who fails to warn the medical community of a particular risk may nonetheless be relieved of liability under the learned intermediary doctrine if the prescribing physician either did not read the warning at all"); Strumph v. Schering Corp., 606 A.2d 1140, 1148, 1150 (N.J. Super. App. Div. 1993) (the "[prescriber] testified that he had not even read the PDR entry"; "conclud[ing] that plaintiffs failed to present any evidence from which a jury could reasonably find that the alleged inadequacy of defendant's warnings regarding [the drug] affected the decision of plaintiff's doctors to prescribe the drug") (dissenting opinion), rev'd, 626 A.2d 1090 (N.J. 1993) (expressly adopting dissenting opinion as the opinion of the court); Appleby v. Glaxo Wellcome, Inc., 2005 WL 3440440, at *5-6 (D.N.J. Dec. 13, 2005) ("there is every indication that Plaintiff's doctor, . . . did not read package inserts").

New York

Mulhall v. Hannafin, 841 N.Y.S.2d 282, 287 (N.Y.A.D. 2007) ("to prove proximate cause, a plaintiff has the obligation to adduce proof that had a warning been provided, she would have read the warning and heeded it"; plaintiff "chose not to read the consent forms") (direct plaintiff warning claim); Banker v. Hoehn, 718 N.Y.S.2d 438, 441 (N.Y.A.D 2000) ("in the absence of reviewing any operating manuals for the [device]" by the prescriber, summary judgment granted on lack of proximate cause).

North Dakota

Harris v. McNeil Pharmaceutical, 2000 WL 33339657, at *4 (D.N.D. Sept. 5, 2000) ("[c]ase law supports the proposition that a physician's failure to read the warnings, including package inserts and the Physician Desk Reference, essentially negates any possible liability on the part of the manufacturer)."

Ohio

Oppenheimer v. Sterling Drug, Inc., 219 N.E.2d 54, 58-59 (Ohio App. 1964) (prescriber "specifically said – 'I don't recall specifically reading the precautions'"; "[i]t can hardly be said that he relied upon anything produced by the defendant").

Pennsylvania

Leibowitz v. Ortho Pharmaceutical Corp., 307 A.2d 449, 458 n.3 (Pa. Super. 1973) ("[e]ven if [the manufacturer] had failed to adequately warn of dangers, said reason is not actionable in the case of a prescription drug, where the prescribing physician did not rely on the package insert"); Nelson v. Wyeth, 2007 WL 4261046 (Pa. C.P. Phila. Co. Dec. 5, 2007) ("[defendant's] alleged failure to adequately warn could not have been the factual cause of [plaintiff's injuries] since the prescribing physician did not read nor rely upon any of [defendant's] warnings as contained in the label accompanying the prescription drug"), aff'd mem., 970 A.2d 489 (Pa. Super. 2009); Berry v. Wyeth, 2005 WL 1431742, at *5 (Pa. C.P. Phila. Co. June 13, 2005) ("[the prescriber] testified that he never read any warnings provided, thus any different warning (even a more adequate warning) would also have gone unread. Therefore, [plaintiff] was unable to establish that [defendant's] alleged failure to warn was the proximate cause"); Mazur v. Merck & Co., 767 F. Supp. 697, 712 (E.D. Pa. 1991) ("it is solely the responsibility of the learned intermediary to read [the package insert] and inform the patient of its meaning"; "[t]hat [the learned intermediary] may not have seen the package circular does not implicate [the drug company]"), aff'd, 964 F.2d 1348 (3d Cir. 1992).

Tennessee

Rodriguez v. Stryker Corp., 2011 WL 31462, at *11 (M.D. Tenn. Jan. 5, 2011) (prescriber "made the decision to use the pain pump entirely on his own"), reconsideration denied, 2011 WL 672555 (M.D. Tenn. Feb. 17, 2011).

Texas

Pustejovsky v. Pliva, Inc., 623 F.3d 271, 277 (5th Cir. 2010) (prescriber "did not recall ever reading the package insert for the drug or consulting the Physician's Desk Reference. Her lack of memory, of course, does not preclude the possibility that she had read these materials, but neither can it sustain [plaintiff's] burden") (applying Texas law); Porterfield v. Ethicon, Inc., 183 F.3d 464, 468 (5th Cir. 1999) ("[plaintiff] has failed to present evidence that the failure to warn was a producing cause of her injury [because] . . . the surgeon who . . . us[ed] the [product], testified that at no time prior to [plaintiff's] surgery had he read [defendant's] package insert or any other [of its] literature") (applying Texas law).

Virginia

Stanback v. Parke, Davis & Co., 657 F.2d 642, 644, 645 (4th Cir. 1981) (prescriber's testimony "established that he had not read the package insert accompanying the vaccine"; "[w]hatever may be said about [the prescriber's] policies and . . ., it is clear that they precluded [defendant's] failure to warn from having any effect whatsoever on [plaintiff's] injury") (applying Virginia law); Rule v. Best Industries, Inc., 1997 WL 499937, at *2, 121 F.3d 700 (4th Cir. Aug. 25, 1997) ("[the prescriber] did not even read the materials provided by [the defendant]. . . . It would not have mattered what [defendant's] warnings said, and the alleged lack of warning was not a proximate cause of [plaintiff's] injury") (applying Virginia law).

Washington

Douglas v. Bussabarger, 438 P.2d 829, 831 (Wash. 1968) (no proximate cause where the prescriber "did not read the labeling which was on the container)".

West Virginia

Meade v. Parsley, 2010 WL 4909435, at *9 (S.D.W. Va. Nov. 24, 2010) ("[m]any courts have declined to find proximate causation in pharmaceutical failure-to-warn suits when the patient (or the prescribing physician if the learned intermediary doctrine is applicable) did not read the defendant manufacturer's allegedly inadequate warning") (plaintiff, since West Virginia does not recognize learned intermediary rule); In re Zyprexa Products Liability Litigation, 2009 WL 1514628, at *12 (E.D.N.Y. June 1, 2009) ("no evidence that [plaintiff] ever read any of defendant's warnings of possible risks") (plaintiff, since West Virginia does not recognize learned intermediary rule) (applying West Virginia law).

Wyoming

Thom v. Bristol-Myers Squibb Co., 353 F.3d 848, 856 (10th Cir. 2003) ("when a physician fails to read or rely on a drug manufacturer's warnings, such failure constitutes the intervening, independent and sole proximate cause of the plaintiff's injuries, even where the drug manufacturer's warnings were inadequate") (applying Wyoming law).

We can see a few justifiable exceptions – such as affirmative overpromotion. If a defendant's detailer said "don't bother reading the warnings" and the doctor didn't, then an obvious alternative means of causation presents itself. Ditto, if the doctor read something else that originated with the defendant. But the first seems vanishingly small (particularly nowadays), and the second is a reflection of changing media by which drug information is disseminated in the era of the Internet.

What we don't want to see is a trend – possibly driven by post-Mensing plaintiffs forced by preemption to make Dear-Doctor-letter (called "Dear Health Care Provider (DHCP) Letters" by the FDA) claims – that Dear Doctor letters are some sort of *deus ex machina* Superman that makes causation problems vanish in failure-to-read situations. It's not really an argument to say "defendant should have sent a Dear Doctor letter at just the right time and the prescriber would have read it."

So in that vein, we'll look at two recent cases that have dealt with Dear Doctor letter issues – one that we think ultimately got it right, and another that we think didn't delve nearly deeply enough into the nature of this sort of claim.

The first case – the good one – is the recent Kapps v. Biosense Webster, Inc., ___ F. Supp.2d ___, 2011 WL 4470701 (D. Minn. Sept. 27, 2011), decision that we overviewed here. Kapps was also a failure-to-read case (so we've cited it above), since the skilled tertiary care heart specialists who used the device weren't about to consult the package insert concerning a device that they had undoubtedly used many times before. Id. at at *23.

Regular readers may recall – but may not, so we'll remind you – that the most unusual thing about Kapps was that the device had been reprocessed by someone (Ascent) unaffiliated in any way with the original manufacturer (Biosense), and the reprocessor had gone so far as to substitute its own name and labeling for the original manufacturer's. That led to the plaintiff's primary causation problem:

> "Ascent usurped one of Biosense's functions as a manufacturer – the function of providing instructions to customers – when Ascent replaced Biosense's instructions for use with Ascent's own. Thus, if [plaintiff's] claim depended on an argument that Biosense negligently failed to include certain warnings in its instructions for use, [that claim] would fail for lack of causation: [plaintiff's] damages could not have been caused by the omission of a warning from Biosense's instructions for use, because Ascent replaced Biosense's instructions with its own, and thus Biosense's instructions did not accompany the catheter that injured [plaintiff]."

2011 WL 4470701, at *23. That's actually a variant of the failure-to-read argument when you think about it, because the manufacturer's instructions weren't with the product any longer, and thus weren't available to be read by anyone.

The plaintiff in Kapps, aware of this problem, advanced a Dear Doctor letter claim to fix his causation problem. Such a "supplemental" warning, according to plaintiff, should have said "Dear Doctor, we have had a few reports of entrapment of this catheter in the mitral valve. Please be very careful with its use in the atrium, et cetera." 2011 WL 4470701, at *23. Of course, plaintiff's Superman-style letter would be sent to the medical community at just the right time to be read and heeded by the plaintiff's prescriber. Id. That's what Superman does – show up at just the right moment (usually to save somebody falling).

Well, the court in Kapps lets Superman leap over the first obstacle, "at least for the sake of argument" – the manufacturer's warnings not being with the product anymore didn't necessarily defeat a Dear Doctor letter claim:

"The fact that Ascent, in reprocessing the catheters, also became a manufacturer in some respects does not change the fact that Biosense was the catheters' original manufacturer and sold the catheters to doctors. The Court therefore finds – at least for the sake of argument – that Biosense had a duty to warn doctors of the risk of mitral-valve entrapment."

Kapps, 2011 WL 4470701, at *23.

So where's the kryptonite?

It might be in another argument – unfortunately not developed by the defendant – that the FDA might limit either the timing or substance of a Dear Doctor letter. The plaintiff's expert certainly didn't have any idea. 2011 WL 4470701, at *24. We don't claim to know for sure, either, since the only regulation we could find with reasonable effort was 21 C.F.R. §200.5, which discusses what Dear Doctor letters should look like, but shies away from the more important question of when they are required. This regulation just states "occasionally," which doesn't help very much.

There's also an FDA "draft guidance" about Dear Doctor letters – something utterly without binding legal effect – that states that the FDA "should" be "consulted" about whether to send a Dear Doctor letter and what it should say. Again, not all that helpful in litigation (other than as the basis for an expert opinion). But that draft does tell us this: Dear Doctor letters are for "important new information" – they're not for rehashing something that doctors already should know:

"[A] DHCP letter **is used to inform health care practitioners about important new information about a drug**. In most cases, the **new information** is about **an important new safety concern** that could affect the decision to use a drug or require some change in behavior by health care practitioners, patients, or caregivers **to reduce the potential for harm from a drug**. In some cases, the **new information** is about how to improve the effectiveness of a drug."

Draft guidance at 3 (emphasis added). New. New. New. New. Moreover, Dear Doctor letters should "avoid discussion of non-critical information that could obscure the more important information." Id. at 4. The only other FDA-recognized use for a Dear Doctor letter is "to correct misinformation in advertising or other types of prescription drug promotion." Id. at 3.

Because the defendant didn't have any regulatory argument developed, Superman got a free pass to leap over another obstacle:

> "[I] it seems reasonable to expect [plaintiff] to show that Biosense could have sent out the type of "Dear Doctor" letter that [plaintiff] calls for without violating those [unknown FDA] regulations. But neither party has discussed the regulations covering "Dear Doctor" letters. The Court therefore will assume, for the sake of argument, that Biosense could have issued the warning advocated by [plaintiff]."

Kapps, 2011 WL 4470701, at *24.

The court next identified, but passed by, another possible generalized causation argument, "also assum[ing], again for the sake of argument, that [plaintiff's physicians] would have paid closer attention to a "Dear Doctor" letter than to instructions that accompanied the [device]." Id. No kryptonite yet.

Still, the plaintiff lost in Kapps.

Why?

Causation on the most fundament level.

Would the hypothetical letter have done any good in the plaintiff's case? No. "[Plaintiff] cannot show that either [physician] would have done anything differently if Biosense had sent out the "Dear Doctor" letter proposed." 2011 WL 4470701, at *24. In short, the court found no evidence that Superman would have been able to save the day.

First, the plaintiff's Dear Doctor letter was garbage – or, as the opinion more gently puts it, "virtually content-free." 2011 WL 4470701, at *24. All it would have said was for surgeons "to be very careful" in light of "a few reports of entrapment of this catheter in the mitral valve." Id. So what? Doctors threading heart catheters are probably being "careful" anyway.

"Would a doctor who is manipulating a catheter inside a patient's heart near the mitral valve become more careful if he read a warning saying, "Be careful not to get this catheter trapped in the mitral valve"? Surely doctors know, based both on their training and on common sense, that they must be "very careful" when manipulating an instrument inside a human heart."

Id. Well, duh.

Second, plaintiff in Kapps had no evidence – in particular no affirmative statements from either doctor – what different actions a Dear Doctor letter of the sort being proposed would have prompted. One of the physicians wasn't even deposed. Thus as to him, "[t]here is not a shred of evidence in the record that, had [he] been warned that he should be careful about mitral-valve entrapment, he would have done anything differently." Id. at *25. As to the other physician, who was deposed, he "testified that in the time since [plaintiff's] procedure, [he] has not changed anything about how he uses [the device]." Id. If "direct personal knowledge" of a risk didn't change anything, plaintiff's vague Dear Doctor letter certainly wouldn't have. Id.

Third, not even a heeding presumption (not adopted in Minnesota) would have saved the claim. Assuming (the Kapps opinion made a lot of pro-plaintiff assumptions, before throwing out the case) that such a thing existed, it only presumes heeding, not causation:

"What is presumed under the heeding presumption is that the omitted warning would have been heeded, not that the heeding of the omitted warning would have prevented the plaintiff's injury. . . . Biosense is being faulted for not warning [the physician] to "be very careful" in manipulating the [using the device]. But there is no reason to believe that [he] was not being very careful. Put differently, there is no evidence that, if [he] had heeded the warning to be very careful, he would have done something differently – and thus there is no evidence that the absence of that warning caused [plaintiff's] injuries."

Kapps, 2011 WL 4470701, at *25 n.22.

Finally, we have some kryptonite to kill the Dear Doctor letter Superman.

Kapps thus gives defense counsel a decent roadmap of the types of arguments that can defeat Dear Doctor letter-based warning claims:

- Is a Dear Doctor letter within the scope of the defendant's duty to warn? If the prescription medical product is not the defendant's own product, unlike Kapps, where that was an important point, then probably not. That's why a Dear Doctor letter shouldn't help a generic-only plaintiff against the branded manufacturer. If the branded product isn't being sold anymore – generally, or to this particular physician, or to this particular patient's health plan – there shouldn't be any duty to send such a letter.

- Is the defendant allowed by FDA regulations to send a Dear Doctor letter concerning the risk at issue? From what little we've been able to discover in a few minutes on the FDA's website, we'd have to say that the kind of "reminder" letters, "consistent" with existing labels, mentioned in some of the generic cases aren't likely to pass muster.

- Is there evidence that Dear Doctor letters in general are likely to influence the plaintiff's prescriber's behavior? How many such letters does he get? Does s/he read them? What kind of information actually changes prescribing behavior? Examples? Here, it would really help if either the defendant or, even better, the prescriber, had software installed that kept track of the prescriber's receipt of and opening of Dear Doctor letters.

- Is there evidence that this particular proposed Dear Doctor letter would have changed the outcome of this particular case? Other causation evidence – failure to read warnings; prior knowledge of the risk; "I wouldn't do anything differently" testimony – will help here. So would information that the same physician received Dear Doctor letters about other, equally or more serious, risks and still uses those products in the same way. Again, software that keeps track of this kind of thing would be most useful.

So that's Kapps. On the other side of the ledger is Winter v. Novartis Pharmaceuticals Corp., 2011 WL 5008008, slip op. (W.D. Mo. Oct. 20, 2011). Winter let a Superman-type warning claim (maybe a Dear Doctor letter; maybe something else – the opinion isn't entirely clear) save the day for the plaintiff. Winter is a blatant failure-to-read case. The prescriber wasn't just ignorant – he was loudly ignorant. He testified that he didn't **ever** read any of the defendant's drug labeling because the lot of it was "useless":

"[The prescriber] cannot recall a patient with [cancer] to whom he did not prescribe [the drug] prior to that point. [The prescriber] has testified that he never read the package inserts for [drug] while practicing . . ., but that this was because [the defendant] produced them in a way that made them useless to a practitioner."

Id. at *1.

Here's the first point where Winter sluffs off an issue. Exactly how were the warnings "useless"? The opinion doesn't say. We think that could be plenty important. The format, almost entirely, as well as a lot of the content, of drug warnings is prescribed by FDA regulations. Is this doctor saying that the FDA-mandated aspects of the label are why he finds it "useless." Does the doctor not read any drug labeling at all? That would make causation impossible to prove, since such aspects of the label would be impossible for the manufacturer to change. Winter, however, passes by this issue entirely.

Anyway, for whatever reason, the doctor in Winter proclaimed his failure to read the relevant warnings. Under the abundant precedent cited above, that should lead to a no-causation summary judgment ruling.

But here comes Superman (called "communications") to the rescue. Dear Doctor letters? Sure. In fact, one was apparently sent to onr non-reader prescriber in Winter. But here comes an issue of fact – the same doctor who didn't bother with package inserts, may not have bothered with Dear Doctor letters either, only we can't be sure:

> "[Defendant] highlighted these latest changes in a Dear Doctor letter dated September 24, 2004, but the parties dispute whether [the prescriber] ever received this letter."

Winter, 2011 WL 5008008, at *1. The same doctors who don't read drug labels, probably don't read anything else either – but when caught, they plead ignorance, and ta-da, that's a "dispute." Here's another example of a problem needing a technological fix. Paper Dear Doctor letters leave no paper trail, unfortunately. Software does. Sending Dear Doctor letters by email means that a doctor who, as in Winter "ma[kes] himself ignorant," id. at *2, won't be able to hide behind that ignorance any longer.

Get modern - win cases.

Rather than actually grapple with (or at least mention) the causation questions, as Kapps did, the opinion in Winter contented itself with vague generalities:

"But even assuming [defendant's] claims are true, [plaintiff] has still shown that genuine issues of material fact exist as to causation on her claims. First, [the prescriber] has testified that he did not read the package inserts for [the drug] medication because [defendant] produced these inserts in a way that made them useless to practitioners."

2011 WL 5008008, at *2. Okay, but there's not a scrap of affirmative evidence of causation in that statement. How could anything different in an insert that's "useless" change this doctor's treatment? No idea. And if it's inherent in how the FDA requires inserts to be drafted, then it would be afirmatively impossible.

Next.

"Further, [plaintiff] has argued that [defendant] had a duty to reflect the known side effects of its medication in articles and communications through sales representatives, both of which could have reached [the prescriber] and changed the course of events despite his not reading package inserts."

Id. There's Superman. Something, who knows what, saying exactly the right thing at exactly the right time. What "communications"? Could it be a Superman Dear Doctor letters – timed, of course, just right so that Superman can save the day? Stay tuned.

But to us this sort of rank "could have" speculation doesn't cut it – not where the plaintiff has the burden of showing causation. There's no mention of any evidence that this doctor – who didn't read drug warnings, and couldn't say if he'd even received Dear Doctor letters – read articles, let alone changed his practice in reliance on them. Nor is there evidence that this doctor ever did anything in reliance on "communications," either via Dear Doctor letters or in person via sales representatives. If such evidence existed, we'd expect to see some mention of it in the Winter opinion, but we're left scratching our heads.

Superman causation arguments – be they Dear Doctor letters, articles, or some sort of "underpromotion" by sales representatives, should require affirmative proof. If a Dear Doctor letter is postulated, there needs to be evidence that the same doctor reacted positively to other similar letters involving comparable risks. If an article (or a Dear Doctor letter) is postulated, there must be some basis that a proper basis for such an article (or letter) in fact existed at the "just in time" moment that the plaintiff's Superman swoops in. The kind of mushy non-evidentiary, non-analysis in Winter makes a mockery of the burden of proof.

Not too long ago we took to task a pro-plaintiff law review article that whined about "evidence based medicine." Right now, we'd be happy just to have evidence-based litigation., instead of the Winter of our discontent.