COURT OF APPEALS OF WISCONSIN
PUBLISHED OPINION

Case No.: 03-0647

†Petition for Review filed

Complete Title of Case:

DONNA KURER, DYLAN F. KURER, AND DAWSON W. KURER,

PLAINTIFFS-APPELLANTS,†

V.

PARKE, DAVIS & COMPANY, AND WARNER-LAMBERT COMPANY,

DEFENDANTS-RESPONDENTS.

Opinion Filed:	March 30, 2004
Submitted on Briefs:	
Oral Argument:	January 6, 2004

JUDGES:	Fine, Schudson and Curley
Concurred:	
Dissented:	

Appellant ATTORNEYS:	On behalf of the plaintiffs-appellants, the cause was submitted on the briefs of *O. Thomas Armstrong* of *Quarles & Brady LLP*, of Milwaukee. There was oral Argument by *O. Thomas Armstrong*.
Respondent ATTORNEYS:	On behalf of the defendants-respondents, the cause was submitted on the brief of *Kenneth B. Ness* of *Terschan, Steinle & Ness*, of Milwaukee. There was oral argument by *Kenneth B. Ness*.

2004 WI App 74

COURT OF APPEALS
DECISION
DATED AND FILED

March 30, 2004

Cornelia G. Clark
Clerk of Court of Appeals

NOTICE

This opinion is subject to further editing. If published, the official version will appear in the bound volume of the Official Reports.

A party may file with the Supreme Court a petition to review an adverse decision by the Court of Appeals. *See* WIS. STAT. § 808.10 and RULE 809.62.

Appeal No. 03-0647 **Cir. Ct. No. 00 CV 001374**

STATE OF WISCONSIN **IN COURT OF APPEALS**

DONNA KURER, DYLAN F. KURER, AND DAWSON W. KURER,

PLAINTIFFS-APPELLANTS,

V.

PARKE, DAVIS & COMPANY, AND WARNER-LAMBERT COMPANY,

DEFENDANTS-RESPONDENTS.

APPEAL from an order of the circuit court for Milwaukee County: JEFFREY A. KREMERS, Judge. *Affirmed*.

Before Fine, Schudson and Curley, JJ.

¶1 SCHUDSON, J. Donna Kurer and her children, Dylan and Dawson ("Kurer"), appeal from the circuit court order granting summary judgment and dismissing their action against Parke, Davis & Company and Warner-Lambert Company (collectively, "Warner-Lambert"). Kurer argues that the court erred in concluding that her summary judgment submissions failed to establish that Warner-Lambert was negligent *per se* for failing to warn that her oral contraceptive, Loestrin®, was a possible cause of Stevens-Johnson Syndrome ("SJS"),[1] and for failing to inform her that Loestrin® could cause headaches and other symptoms of SJS, necessitating its discontinuance. Alternatively, Kurer argues that, at the very least, the submissions established a material factual issue of whether Warner-Lambert was negligent for failing to provide sufficiently clear and emphatic warnings that, she maintains, would have caused her to call her doctor and discontinue Loestrin®.

¶2 We conclude that the warnings accompanying Loestrin® were adequate as a matter of law and, therefore, that the circuit court correctly concluded that Warner-Lambert was not negligent *per se*. Additionally, we conclude that Kurer's summary judgment submissions failed to establish the requisite causal nexus between the alleged inadequate warnings and her injuries. Accordingly, without addressing any other issue,

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[1] Stevens-Johnson Syndrome is:

> a severe form of erythema multiforme … characterized by [bullous lesions] on the oral mucosa, pharynx, anogenital region, and conjunctiva; target-like lesions and fever. The patient may be unable to eat or properly close the mouth…. The eyes may become very painful[, and conjunctivitis with swelling and pus] may make it impossible for the patient to open them…. The conjunctival lesions may leave [residual corneal scarring]. The condition is occasionally fatal.

THE MERCK MANUAL OF DIAGNOSIS AND THERAPY 825 (17th ed. 1999).

see ***Gross v. Hoffman***, 227 Wis. 296, 300, 277 N.W. 663 (1938) (only dispositive issue need be addressed), we affirm.

I. BACKGROUND

¶3 In August 1996, shortly after giving birth, Kurer began using Loestrin®, an oral contraceptive. The Loestrin® package she received included a "Detailed Patient Package Insert"—an extensive, small-print description of the medication with numerous sections including, "Risks of Taking Oral Contraceptives," "Warning Signals," and "Side Effects of Oral Contraceptives." None referred to SJS. Two sections of the Detailed Patient Package Insert, however, provided information of importance to this appeal.

¶4 The "**WARNING SIGNALS**" section began by stating: "If any of these adverse effects occur [sic] while you are taking oral contraceptives, call your doctor immediately[.]" It then listed adverse effects, including "[s]udden severe headache," "dizziness," "[d]ifficulty in sleeping, weakness, lack of energy, fatigue, or change in mood (possibly indicating severe depression)."

¶5 The "**SIDE EFFECTS OF ORAL CONTRACEPTIVES**" section included a subsection titled, "**Other Side Effects**," which advised: "Other side effects may include change in appetite, headache, nervousness, depression, dizziness, loss of scalp hair, rash, and vaginal infections." Immediately thereafter, concluding the "**Other Side Effects**" section, the patient package insert warned: "If any of these side effects bother [sic] you, call your doctor or health care provider."

¶6 Also accompanying the Loestrin® package was a second, more extensive insert, often referred to as a "product package insert."[2] In that insert, under the

[2] For simplicity, this opinion will refer to the two types of inserts as the "patient insert" and the "product insert." Additionally, we note the existence of a third insert, the "Brief Summary Patient Package Insert." This third insert, however, has not become a factor in this appeal.

"**WARNINGS**" section, was a subsection, "**Headache**," which advised: "The onset or exacerbation of migraine or development of headache with a new pattern which is recurrent, persistent, or severe requires discontinuation of oral contraceptives and evaluation of the cause." The product insert also advised that other "adverse reactions have been reported in users of oral contraceptives and the association [between the contraceptives and the reactions] has been neither confirmed nor refuted." Among the listed reactions was "Erythema multiforme," a group of skin hypersensitivity disorders that, according to the summary judgment submissions, included SJS.

¶7 According to her deposition, Kurer started feeling "[d]izzy, light-headed, fainty" and started experiencing lethargy, sleepiness, and headaches after taking Loestrin® for four months. And, in December 1996, after two months of these symptoms, she read the entire patient insert, a copy of which had accompanied each of her six monthly doses, and all copies of which she had retained. After reading the warnings, however, Kurer did not immediately call her doctor; instead, she read material

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Typically, while the patient insert goes with the oral contraceptive to the patient, the product insert may be retained by the physician and/or may go to the patient, depending on the circumstances of the drug's distribution. In this case, however, whether Kurer had knowledge of the product insert is immaterial to her challenges to the adequacy of the warnings in the patient insert.

Nevertheless, because our discussion ultimately will also involve consideration of the contents of the product insert in this case, we note that the information in a product insert corresponds to that contained in the PHYSICIANS' DESK REFERENCE (PDR).

> The [PDR] is an annual publication compiling product information about pharmaceuticals. The information is provided by the drug manufacturers and is approved by the [Food and Drug Administration]. Each year the PDR and its supplements are sent free of charge to licensed physicians in the United States and abroad. A typical entry includes the trade name and chemical name of the drug, a description of the drug, indications and contraindications for its use, warnings, adverse reactions, administration and dosage, and information on managing and adjusting the dosage of the drug.

Garvey v. O'Donoghue, 530 A.2d 1141, 1144 n.4 (D.C. 1987).

about the first year of a baby's life, conferred with friends and family members, and concluded that her symptoms were postpartum and/or premenstrual. She explained: "So I guess I just dragged it on, not knowing anything worse would happen to me."

¶8 In February 1997, after new symptoms had developed and others had become more severe, Kurer was hospitalized and ultimately diagnosed with SJS from which she has suffered terrible consequences, including blindness. Kurer testified that had she been warned of the possible connection between her symptoms and SJS, she would have stopped taking Loestrin®. Consequently, Kurer brought claims based on Warner-Lambert's alleged failure to warn of the possible Loestrin®-SJS connection.[3]

¶9 Granting summary judgment, the circuit court concluded, in part, that: (1) the warnings accompanying Loestrin® were adequate as a matter of law; and (2) the submissions failed to establish that, had Kurer received any additional or different warnings, she would have discontinued her use of Loestrin®. We agree.

II. DISCUSSION

¶10 Summary judgment methodology is well known and need not be repeated here. *See* WIS. STAT. § 802.08(2); ***Grams v. Boss***, 97 Wis. 2d 332, 338-39, 294 N.W.2d 473 (1980). Although we value a circuit court's analysis, our review of its grant or denial of summary judgment is *de novo*. ***Green Spring Farms v. Kersten***, 136 Wis. 2d 304, 315-17, 401 N.W.2d 816 (1987). Here, on the issues we address, we conclude that the circuit court's analysis was sound and its conclusions were correct.

A. The Arguments

[3] We recognize, however, that while the summary judgment submissions suggest no dispute about Kurer's diagnosis or the tragic harm she suffered, they do refer to considerable dispute about whether Loestrin® causes SJS, or caused her SJS.

¶11 Kurer's essential premise, as phrased in her brief to this court, is that by "failing to inform [her] about the association between SJS and oral contraceptives," Warner-Lambert "did not comply with governing FDA regulations." She anchors her arguments in regulations of the Federal Food, Drug and Cosmetic Act that mandate that the contents of the "patient package insert for an oral contraceptive drug product" warn of "risks … associated with the drug's use," 21 C.F.R. § 310.501(c)(2), of "the most serious side effects," § 310.501(c)(7), and of "other serious adverse reactions and potential safety hazards that may result from the use of oral contraceptives," § 310.501(c)(8). She contends, therefore, that the Loestrin® patient insert should have warned of SJS, and that its failure to do so constituted negligence *per se*. Alternatively, she contends that, "at the very least, whether Warner-Lambert was negligent in failing to warn [her] about SJS presents an issue of fact for the jury."

¶12 In a closely related argument, Kurer also addresses SJS symptoms, contending that under these same FDA regulations, Warner-Lambert was negligent *per se* "in failing to tell [her] to discontinue Loestrin® if she experienced recurrent and/or persistent headache[s]." And again, alternatively, she maintains that this at least presents a jury issue "particularly in view of the fact that Warner-Lambert told prescribing physicians, via the product package insert, that Loestrin® must be discontinued in such circumstances."

¶13 In support of her arguments, Kurer directs our attention to: (1) the difference between the warnings to consumers in the patient insert and to doctors in the product insert, and the latter's emphasis on recurrent headaches; and (2) the failure of either the patient insert or the product insert to specifically warn of SJS. Kurer maintains that had she been properly warned, she would have sought assistance from her physician promptly and, therefore, could have discontinued using Loestrin® and prevented the harm she suffered.

¶14 Warner-Lambert responds that "all of the necessary package inserts and warning labels had to be submitted [to] and approved" by the United States Food and Drug Administration, and that the FDA had not authorized any warning for SJS. Warner-Lambert explains that no such warning had been authorized because "prior to Kurer's case the FDA had never received an Adverse Event Report alleging that any oral contraceptive manufactured by any pharmaceutical company was possibly associated with SJS." Therefore, Warner-Lambert maintains, its warnings were not only adequate, but, as a matter of law, could not have warned of SJS except to the extent that the patient insert advised of certain symptoms, and to the extent that the product insert advised of the possible association of such symptoms with erythema multiforme.

¶15 On this legal point, as we will explain, Warner-Lambert is incorrect. Warner-Lambert also argues, however, that: (1) it *did* warn Kurer to call her doctor if she suffered symptoms, including bothersome or severe headaches; (2) it *did* advise her doctor of the possible association of such symptoms with erythema multiforme, which, Warner-Lambert maintains, included SJS; and (3) Kurer's submissions establish that an additional, specific warning of SJS would not have made any difference. On these critical *factual* points, Warner-Lambert is correct.

B. The Regulations and their Relationship to the Common Law

¶16 Drug labeling is part of a comprehensive regulatory scheme inextricably connected to drug approval. *See* ***Hurley v. Lederle Labs.***, 863 F.2d 1173, 1179 (5th Cir. 1988) (discussing 21 C.F.R. §§ 1, 201). An application for approval of a new drug must include "specimens of the labeling proposed to be used for such drug." 21 U.S.C. § 355(b)(1)(F). Grounds for refusing an application may include the failure to provide evidence supporting the "proposed labeling," § 355(d)(1), or the agency's "fair evaluation" that the proposed labeling is "false or misleading in any particular."

§ 355(d)(7). Approval, once granted, may be withdrawn based on "new information" leading to a "fair evaluation" that the labeling is "false or misleading in any particular." § 355(e)(3). The "content and format of labeling" is strictly prescribed. *See* 21 C.F.R. § 201.57 (detailing the requirements for prescription drugs and/or insulin).

¶17 Manufacturers of "oral contraceptive drug products" not only must satisfy the requirements for drug labeling generally, they also must inform consumers of "the benefits and the risks involved in their use" in the "patient package insert … required to be placed in or accompany each package dispensed to the patient." 21 C.F.R. § 310.501(a); *see also* 21 U.S.C. §§ 352, 355 (providing that the FDA regulates the labeling of oral contraceptives, including patient inserts).[4] The patient inserts must

[4] 21 C.F.R. § 310.501, provides in pertinent part:

> Patient package inserts for oral contraceptives.
>
> (a) Requirement for a patient package insert. The safe and effective use of oral contraceptive drug products requires that patients be fully informed of the benefits and the risks involved in their use. An oral contraceptive drug product that does not comply with the requirements of this section is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act. Each dispenser of an oral contraceptive drug product shall provide a patient package insert to each patient (or to an agent of the patient) to whom the product is dispensed, except that the dispenser may provide the insert to the parent or legal guardian of a legally incompetent patient (or to the agent of either). The patient package insert is required to be placed in or accompany each package dispensed to the patient.
>
> (b) Distribution requirements. (1) For oral contraceptive drug products, the manufacturer and distributor shall provide a patient package insert in or with each package of the drug product that the manufacturer or distributor intends to be dispensed to a patient.
>
> ….
>
> (c) Contents of patient package insert. A patient package insert for an oral contraceptive drug product is required to contain the following:
>
> ….

contain "[a] warning regarding the most serious side effects of oral contraceptives," 21 C.F.R. § 310.501(c)(7), "[a] statement of other serious adverse reactions and potential safety hazards that may result from the use of oral contraceptives," § 301.501(c)(8), and "[a] statement concerning common, but less serious side effects which may help the patient evaluate the benefits and risks from the use of oral contraceptives," § 301.501(c)(9).

¶18 Contrary to Warner-Lambert's argument, however, although the FDA has prescribed these standards, it has not foreclosed drug manufacturers from adding warnings. Drug manufactures can strengthen warnings or petition for additional warnings when new risk information arises. *See* 21 C.F.R. § 314.70(c)(2)(i); ***Motus v. Pfizer, Inc.***, 127 F. Supp. 2d 1085, 1093-94 (C.D. Cal. 2000); ***Caraker v. Sandoz Pharm. Corp.***, 172 F. Supp. 2d 1018, 1033-34 (S.D. Ill. 2001). Thus, even after approval, a drug manufacturer can add warnings without prior FDA approval. *See* ***Caraker***, 172 F. Supp. 2d at 1034. The FDA clarifies this in the preamble to its drug labeling regulations:

> The Commissioner ... advises that these labeling regulations do not prohibit a manufacturer, packer, relabeler, or distributor from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered.

> (2) A summary including a statement concerning the effectiveness of oral contraceptives in preventing pregnancy, the contraindications to the drug's use, and a statement of the risks and benefits associated with the drug's use.
>
> ….
>
> (7) A warning regarding the most serious side effects of oral contraceptives.
>
> (8) A statement of other serious adverse reactions and potential safety hazards that may result from the use of oral contraceptives.
>
> (9) A statement concerning common, but less serious side effects which may help the patient evaluate the benefits and risks from the use of oral contraceptives.

> The addition to labeling and advertising of additional warnings, as well as contraindications, adverse reactions, and precautions regarding the drug, or the issuance of letters directed to health care professionals (*e.g.,* 'Dear Doctor' letters containing such information) is not prohibited by these regulations.
>
> ….
>
> In considering these regulations in a product liability case, at least one court has held that an NDA [New Drug Application] holder may have a duty to add a warning before FDA approval of a supplemental application.

44 Fed. Reg. 37,434, 37,447 (1979) (citing ***McEwen v. Ortho Pharm. Corp.***, 528 P.2d 522 (Or. 1974)); *see also* 21 C.F.R. § 314.70(c)(2)(i) (2000); 44 Fed. Reg. 37,434, 37,447 (1979) (explaining that this regulation "permits the addition to the drug's labeling or advertising of information about a hazard without advance approval of the supplemental application by FDA").[5]

[5] We note that the preamble refers to "warning health care professionals" and, therefore, might not seem to apply to patient inserts. Indeed, at oral argument, Warner-Lambert maintained that the federal regulations precluded an oral contraceptive manufacturer from including any additional warning in its patient insert. Pressed to identify which regulations, however, Warner-Lambert conceded that it could not.

Our research reveals that on May 25, 1989, the FDA revoked the "guideline texts of professional and patient labeling for … oral contraceptive drug products," and did so in order "to enable manufacturers and others to receive the most current [medical] information available to the agency in the most timely manner possible." *See* 54 Fed. Reg. 22,585, 22,587 (1989), 54 Fed. Reg. 22,624, 22,624 (1989). In fact, 21 C.F.R. § 310.501(f) encourages manufactures to supplement approved applications. It provides:

> Requirement to supplement approved application. Holders of approved applications for oral contraceptive drug products that are subject to the requirements of this section are required to submit supplements under § 314.70(c)[, governing new drug approval,] of this chapter to provide for the labeling required by this section. *Such labeling may be put into use without advance approval by the Food and Drug Administration*.

¶19 Further, a drug manufacturer's compliance with the FDA's labeling standards does not preempt state-law claims.

> Until 1965, the FDA regulations applicable to drugs prohibited companies from adding warnings or other information without prior approval. These regulations were amended in 1965, allowing labeling changes related to safety to be "placed into effect at the earliest possible time," the goal of which was for drug manufacturers "to enable prompt adoption of such changes." 30 Fed. Reg. 993 (1965). Liability, irrespective of the Food, Drug, and Cosmetic Act ("FDCA"), may attach if drug manufacturers do not at least request FDA approval of an additional warning as soon as new hazards or elevated risk associations are discovered. These options for conveying additional risk information are not prohibited but encouraged.
>
> Because there is no indication that Congress and the FDA have attempted to impede what the FDA has referred to as the "sophisticat[ed] and complex [ ] private tort litigation in the United States," this Court is right to interpret the FDA standards as minimum ones and to find that drug manufacturers still have a duty to timely disclose new known risks to learned intermediaries, especially because any other interpretation would run contrary to what appears to be an intent to preserve these tort remedies.
>
> In enacting the FDCA, Congress enacted no general preemption provision. While Congress did enact such a provision for things like medical devices, it chose not to with respect to prescription drugs. Thus, the normal practice Congress employs when it is attempting to carve out areas of preemption was specifically not done with respect to prescription drugs.

Caraker, 172 F. Supp. 2d at 1034-35 (citations, footnotes, and parentheticals omitted).

¶20 In Wisconsin, violations of FDA regulations may constitute negligence *per se*. *See* ***Lukaszewicz v. Ortho Pharm. Corp.***, 510 F. Supp. 961, 964 (E.D. Wis.),

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(Emphasis added.) Moreover, 21 C.F.R. § 314.70(c), which addresses "Supplements for changes that may be made before FDA approval," provides that "[c]hanges [to] labeling" may be made "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction." ***Id.*** None of these regulations is limited to warnings to health care providers alone; all apparently allow for additional warnings to patients. Thus, Warner-Lambert has pointed to nothing, and we have found nothing, that supports its contention that federal law prevents it from modifying labeling directed to patients in order to warn patients of potential hazards of oral contraceptives. Moreover, as we explain in the main body of this opinion, FDA approval of patient-directed warnings does not preempt state-law claims.

amended, 532 F. Supp. 211 (E.D. Wis. 1981). Further, it is a "well-established rule that the enactment of safety statutes or legislation giving a commission jurisdiction over a certain activity does not abolish the duty arising under common-law negligence." ***Kemp v. Wisconsin Elec. Power Co.,*** 44 Wis. 2d 571, 579, 172 N.W.2d 161 (1969) (citing ***Schulz v. Chicago, Milwaukee, St. Paul, & Pac. R.R. Co.,*** 260 Wis. 541, 51 N.W.2d 542 (1952)). Indeed, as our supreme court has explained:

> [A] safety statute merely establishes a minimum standard of care and the conduct, even though sanctioned or in conformity with the statute, is not thereby necessarily relieved of conforming to the common-law requirements of ordinary care. In any event the establishment of a statutory definition of negligence per se does not thereby result in a preemption of the entire negligence question. There remains the question of possible common-law negligence.

Hoffmann v. Wisconsin Elec. Power Co., 2003 WI 64, ¶12, 262 Wis. 2d 264, 664 N.W.2d 55 (quoted source omitted). Moreover, a "statute does not change the common law unless the legislative purpose to do so is clearly expressed in the language of the statute." ***Id.***, ¶13 (quoted source omitted); *see also* ***Fuchsgruber v. Custom Accessories, Inc.***, 2001 WI 81, ¶25, 244 Wis. 2d 758, 628 N.W.2d 833 ("To accomplish a change in the common law, the language of the statute must be clear, unambiguous, and peremptory.") (citations omitted).

¶21 As numerous courts have concluded, FDA regulations do not preempt the imposition of state common law liability for failure to warn claims. *See, e.g.*, ***Feldman v. Lederle Labs.***, 592 A.2d 1176, 1192 (N.J. 1991) ("[W]e find nothing in the federal scheme to support the assertion that manufacturers of prescription drugs and antibiotics who literally comply with [FDA regulations] must be immune from state tort liability for injuries caused by their products."); ***Mazur v. Merck & Co.***, 742 F. Supp. 239, 247 (E.D. Pa. 1990) ("[M]ere compliance with an FDA suggestion, or for that matter, regulation or order, does not mean that state tort law becomes irrelevant.... State tort law is intended to

supplement federal regulation ...."); *cf.* ***Medtronic, Inc. v. Lohr***, 518 U.S. 470, 486-87 (1996) (Stevens, J., writing for himself and Justices Anthony M. Kennedy, David H. Souter, and Ruth Bader Ginsburg) (negligence and strict liability claims for failure to warn about risks of a medical device were not preempted by federal regulations). "FDA approval is not a shield to liability. FDA regulations are generally minimal standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area." ***Hill v. Searle Labs.***, 884 F.2d 1064, 1068 (8th Cir. 1989) (citations omitted). "An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes." ***Wells v. Ortho Pharm. Corp.***, 788 F.2d 741, 746 (11th Cir. 1986).[6]

C. Application of the Law to the Facts of this Case

¶22 Although compliance with FDA standards generally will foreclose negligence *per se*, *see* ***Lukaszewicz***, 510 F. Supp. at 964; *see also* ***Mazur***, 742 F. Supp. at

[6] *See also* ***Caraker v. Sandoz Pharm. Corp.***, 172 F. Supp. 2d 1018, 1033 (S.D. Ill. 2001) ("FDA's drug labeling decisions impose only 'minimum' standards that are open to supplementation by state law through a jury's verdict enforcing a manufacturer's common law duty to warn.... Because there is no evidence that either Congress or the FDA intended on scrapping state products liability claims based on a failure to warn ..., it is reasonable to find that the FDA has imposed a minimum—as opposed to conclusive—standard of safety."); ***Mazur v. Merck & Co.***, 742 F. Supp. 239, 247 (E.D. Pa. 1990) ("[M]ere compliance with an FDA suggestion, or for that matter, regulation or order, does not mean that state tort law becomes irrelevant. First, compliance with an FDA regulation may establish that the manufacturer met the appropriate minimum standards of due care, but compliance does not necessarily absolve the manufacturer of all liability. Manufacturers must meet state safety requirements, whether codified or embodied in the common law, in addition to satisfying the initial FDA requirements.") (citation omitted); ***Kociemba v. G.D. Searle & Co.***, 680 F. Supp. 1293, 1299 (D. Minn. 1988) ("The mere fact that the [drug] received FDA approval does not, by itself, indicate that Congress impliedly intended to preclude state tort actions against prescription drug manufacturers. This is especially true in light of the widely held view that FDA regulation of prescription drugs establishes *minimum* standards, both as to design and warning."); ***Edwards v. Basel Pharm.***, 933 P.2d 298, 302 (Okla. 1997) ("It is the widely held view that the FDA sets minimum standards for drug manufacturers as to design and warnings. We conclude that compliance with these minimum standards does not necessarily complete the manufacturer's duty.") (citation omitted); ***Savina v. Sterling Drug, Inc.***, 795 P.2d 915, 931 (Kan. 1990) ("[R]egulations imposed by the FDA are minimal standards. A drug company is not prohibited from providing additional warnings and additional information that is not required by the FDA.").

257-58, such compliance, as we have explained, does not preclude a finding of negligence. And although negligence *per se* and negligence are distinguishable, in this case our analyses of them eventually merge because Kurer is specifically arguing that the patient insert warnings were not clear and emphatic enough to satisfy the FDA requirements for a patient insert for an oral contraceptive. *See* ¶17, above.

¶23 To support her claim of negligence *per se*, Kurer must establish that Warner-Lambert failed to warn in a manner that complied with the FDA standards. She has failed to do so. The submissions do not establish that Warner-Lambert knew that Loestrin® could cause SJS. Without any actual or constructive knowledge of this alleged adverse effect, Warner-Lambert cannot be said to have violated FDA regulations by failing to add an SJS warning. Unquestionably, therefore, the submissions established that Warner-Lambert's warnings complied by stating the dangers that were known or reasonably knowable at the time.

¶24 To support her claim of negligence, Kurer must establish that Warner-Lambert breached its duty to warn, and that the breach caused her injuries. *See* ***Gracyalny v. Westinghouse Elec. Corp.,*** 723 F.2d 1311, 1316-17 (7th Cir. 1983) (claim of negligence, unlike claim of strict liability, requires plaintiff to prove specific acts of causal negligence); ***Dippel v. Sciano***, 37 Wis. 2d 443, 459-60, 155 N.W.2d 55 (1967). With respect to the adequacy of a warning, the initial inquiry under both strict liability and negligence analyses is the scope of the manufacturer's duty to provide a warning. ***Gracyalny***, 723 F.2d at 1318. Although the adequacy of a warning often presents a factual issue for a jury, that is not always so. *Compare* ***id.*** at 1321, *with* ***Alvarado v. Sersch***, 2003 WI 55, ¶29, 262 Wis. 2d 74, 662 N.W.2d 350 (summary judgment in negligence is proper where no reasonable jury, properly instructed, could find defendant was negligent). We, like the trial court, conclude that Kurer failed to establish either any

inadequacy in the warnings or any causal link between an alleged inadequacy and her injuries.

¶25 A plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury. ***Mazur***, 742 F. Supp. at 262; *see also* ***Staymates v. ITT Holub Indus.***, 527 A.2d 140, 147 (Pa. Super. Ct. 1987) (evidence must support a reasonable inference that the existence of an adequate warning may have prevented the injury). Even in the event that a warning is inadequate, proximate cause is not presumed. ***Mazur***, 742 F. Supp. at 262. Absent proof that a more complete or explicit warning would have prevented Kurer's use of Loestrin®, she cannot establish that Warner-Lambert's alleged failure to warn was the proximate cause of her injuries.

¶26 Kurer stated that she had never heard of anyone having SJS before her own case. And Kurer's expert explained that in order for a warning to make a difference, it must be easily and readily understood. Kurer ultimately admitted that, *at the time she suffered her symptoms*, she had "no clue" whether additional warnings would have led her to call her physician and stop taking Loestrin®. At her deposition, she testified:

> Q [I]n December, [you read] the warning label.
> A Yes.
> Q And it talked about heart attacks, strokes, embolisms, blood clots, and other things that could lead to death or other very severe consequences. And in December you knew those things could be a possible consequence for continuing to use the Loestrin, correct?
> A Correct.
> Q And knowing these possible severe consequences which could lead to death, paralysis[,] blindness, things like that, you still elected to take—continue taking the Loestrin, correct?
> A Correct.
> Q Do you have any idea on a percentage basis how much more likely it is to have any of these things that we just talked about occur as a result of using oral contraceptive[s] versus the

probability of or possibility of having a situation where you did with SJS?

A No clue.

Q So you don't know it's more likely, less likely, anything like that?

A No.

Q Okay. Did it concern you that you could have a heart attack, blood clot, embolism, a stroke while using the Loestrin?

A I never heard of anyone having it.

Q Okay. You never heard of anyone having SJS before, correct?

A Exactly.

Q And if SJS had been placed on the package insert, would that have necessarily stopped you from continuing to take that Loestrin?

A With the symptoms? Yes. I would have stopped.

Q Okay. Why would that have prevented you from taking it more?

A Because when I had this rash, and had my ringing in the ears, if I would have read that on the birth control pills, I would have pertained it to it, and I would have stopped taking it.

Q If we could go back to what your knowledge was, at that time, from December to February. I believe, before, you said that you never heard of SJS before, erythema multiforme before, erythema multiforme major before, or TENS [Toxic Epidermal Necrolysis] before you went in the hospital at St. Luke's. Correct?

A Correct.

Q Okay. So if you never heard of these things, and even if the SJS had been mentioned on the package insert, that really wouldn't have changed your thought process or decision to keep on using the Loestrin, would it?

[Plaintiff's counsel]: I'm going to object to that question because she testified to just the opposite before. She indicated if she'd seen any symptoms, or read about them, she would have stopped taking it immediately. I thought she just said that …. Unless I'm misunderstanding your question.

[Defense counsel]: No. I appreciate that. That's why I had the preface there that I wanted to go back to your knowledge at the time.

[Plaintiff's counsel]: You mean December.

[Defense counsel]: Yes.

[Donna Kurer]:

A You can't ask me that now. I have no clue. If you're asking me that now, I'm going to say no, I wouldn't have took [sic] it.

[Defense counsel]:

Q Okay. But, at the time, you did not know what SJS was, correct?
A No.
Q And you wouldn't have known what any of the symptoms of SJS –
A No.
Q Okay. And if you never heard of anyone else having SJS, and not knowing what it was, if that had been on the package insert, is it fair to assume that you would have kept on taking the Loestrin?
A I have no clue.

¶27 Although Kurer now insists that she would have called her doctor, her submissions provide no support. After all, it is undisputed that she had many of the symptoms listed on the patient insert, including headaches that bothered her, but that she did not call her doctor as the patient insert instructed.

¶28 Still, maintaining that the warnings fell short, Kurer attempts to attach significance to the differences in the patient insert warnings between: (1) "sudden severe headache" and merely bothersome headaches; and between (2) the advice to call a doctor "immediately" and the less emphatic advice to merely call. *See* ¶¶4-5, above. Her attempt fails. Under the exact warnings, only if a patient suffers no headache at all, or no bothersome headaches, does the patient insert fail to advise a call to the doctor. Clearly and repeatedly, the patient insert warns patients to call their doctors in the event of headaches, whether severe or merely bothersome.

¶29 Moreover, Kurer's attempt fails to account for the patient insert's equally clear warnings to call doctors about other symptoms she suffered, including some associated with erythema multiforme, which, according to the submissions, included SJS. The report of Rodney Richmond of the Institute for Pharmaceutical Care, on which Kurer heavily relies, does not alter the analysis. While detailed and impressive, and while maintaining that "[b]ased upon a clinical consensus statement published in 1993, SJS is a

skin reaction that is discreetly different from erythema multiforme," and "[t]herefore … should be treated as such with respect to characterizing potential drug-induced adverse events," the report cannot counter the critical, undisputed understandings of Kurer's doctors.

¶30 Roger Lalich, M.D., the obstetrician/gynecologist who prescribed Loestrin® for Kurer, did not clarify whether he understood the relationship between erythema multiforme and SJS at the time he prescribed the contraceptive. However, based on what he had reviewed in preparation for the August 14, 2002 deposition in this case, he had come to understand that SJS "was part of that [erythema multiforme] syndrome." And Charles Brummitt, M.D., Kurer's treating physician, considered erythema multiforme to "come in major and minor forms," the more serious of which was "the Stevens-Johnson's form." Therefore, regardless of whether the FDA or Warner-Lambert should have embraced scientific information such as that forming the basis for Richmond's opinion, and regardless of whether, as a result, the Loestrin® warnings should have distinguished SJS from erythema multiforme and warned of both, the undisputed fact remains: when Kurer suffered her symptoms, her patient insert advised her to call her doctor, and the product insert, in turn, connected such symptoms to erythema multiforme, thus effectively warning of SJS *as her doctors then understood it*.

¶31 We reject Kurer's assertion, articulated in her reply brief, that "Warner-Lambert asks the Court to immunize it from any liability for failing to warn [her] about recurrent and persistent headache, as well as SJS, because it allegedly provided adequate warnings to [her] prescribing physician, Dr. Lalich." That is not what Warner-Lambert has asked, and that is not what this court has done. If the patient insert in this case had

said nothing about the very symptoms Kurer suffered, and instead simply placed all the warnings in her doctor's hands, this could have been a very different case.[7]

[7] Information and advice to a patient contained in a patient insert, in combination with more specific information and advice to a doctor contained in a product insert, may achieve the best balance between telling patients so little as to leave them unwarned and so much as to leave them overwhelmed. *See* Catherine A. Paytash, Note, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug-Related Injury*, 51 STAN. L. REV. 1343, 1368-71 (1999) (advocating such a hybrid-model as the best approach to promoting safe and effective prescription drug therapy). As Warner-Lambert suggests:

> The FDA's intent, via all of these labeling regulations and restrictions, is to make the labeling a realistic reflection of what is needed in order to make intelligent decisions. The ultimate objective is meaningful summarization of responsible data, while avoiding sensory overload. With this objective in mind, the FDA has not authorized any oral contraceptive manufacturer to specifically warn about SJS.

To put this in practical terms, consider the inserts in this case. The patient insert consists of two very long, small-print pages with numerous sections. The product insert, with a similar format and font, is three times as long. It is reasonable to surmise, therefore, that the FDA's regulatory scheme anticipates a patient-physician partnership—that is, a warning system alerting patients to symptoms and leading them to contact their doctors who, better informed, take appropriate action. This, in fact, was the circuit court's view. Granting summary judgment, the court observed:

> I believe that the hybrid approach that I think is appropriate here is one that says, ["]Look, with respect to the physicians, you have to advise them of certain things that include even more rare conditions that maybe are specifically appropriate to your patient, maybe aren't[,] and we are going to rely on you to decide how much of that information you should pass on to your patient.["] …
>
> But there is another set of information that we know should go directly to the patient perhaps … more general information to put them on notice that, ["L]ook, there [are] some things you should watch out for, some primary symptoms to be aware of that you might want to talk to your health care provider about and we are going to require you do that.["]

This hybrid approach, however, has not been accepted by those courts embracing the "learned intermediary doctrine." They focus on the product insert—the warnings provided to doctors, not patients—to determine whether compliance with FDA standards shields a drug manufacturer from liability for failure to warn. *See, e.g.*, ***Taurino v. Ellen***, 579 A.2d 925, 928-29 (Pa. Super. Ct. 1990).

Other courts, however, explain why such absolute adherence to the learned intermediary doctrine may be particularly inappropriate for oral contraceptives. Often dispensed through clinics, and often prescribed for extended time periods, oral contraceptives often come with little patient-physician

¶32 Clearly, therefore, while Kurer's circumstances are tragic, Warner-Lambert's warnings were adequate as a matter of law, and the summary judgment submissions failed to establish that Kurer would have heeded a different warning. The circuit court correctly granted summary judgment.

By the Court.—Order affirmed.

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interaction. Thus, these courts observe, warnings to doctors in product inserts may provide little if any meaningful warning to the consumer. *See*, *e.g.*, ***MacDonald v. Ortho Pharm. Corp.***, 475 N.E.2d 65, 69-71 (Mass. 1985).

Although the parties debate how the learned intermediary doctrine affects this appeal, we need not make that determination given the bases on which we have resolved this case.