Supreme Court of Tennessee
in Nashville

FREDDIE JONES, LUKE JONES, TRENNA JONES, RALPH JONES, LAVON JONES and JIMMY FREEMAN, as Surviving Children of ELNORA JONES, Deceased, Plaintiffs/Petitioners,	§	CASE # M2013-00769-SC-R23-CQ
v.	§	
ABBOTT LABORATORIES, Defendant/Respondent.	§	

On Certified Questions from the United States District Court for the Western District of Tennessee, Western Division Case # 2:07-cv-02120-WGY

BRIEF OF *AMICI CURIAE* TENNESSEE CHAMBER OF COMMERCE AND INDUSTRY, CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF DEFENDANT-RESPONDENT

Respectfully Submitted,

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INTEREST OF *AMICI CURIAE*

The Tennessee Chamber of Commerce and Industry, the Chamber of Commerce of the United States of America, and the Pharmaceutical Research and Manufacturers of America respectfully submit this brief as *amici curiae* pursuant to Rule 31 of the Tennessee Rules of Appellate Procedure.

The Tennessee Chamber of Commerce and Industry (the "Tennessee Chamber") is the state chamber of commerce and is the Tennessee Manufacturers' Association, representing all facets of business and industry across the State. Formed in 1912, it is one of Tennessee's oldest and most respected business organizations dedicated to ensuring a positive business and regulatory climate.

The Chamber of Commerce of the United States of America (the "U.S. Chamber") is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry, from every region of the country, including Tennessee. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. The Chamber thus regularly files amicus curiae briefs in cases raising issues of vital concern to the Nation's business community.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association that represents the country's leading pharmaceutical research and technology companies. PhRMA members are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. In 2012 alone, PhRMA members invested

roughly $48.5 billion in discovering and developing new medicines.[1] PhRMA members are the source of nearly all new medicines discovered throughout the world.

Members of the Tennessee Chamber, the U.S. Chamber, and PhRMA all have a critical interest in uniform and fair liability standards for lawsuits involving prescription medications. The Tennessee Supreme Court—like the courts of 47 other jurisdictions—has already held that, when a physician-patient relationship exists and a medicine can only be obtained through a physician, the learned intermediary doctrine applies and a company satisfies its duty to warn by properly warning that physician. The new liability standard Petitioners propose runs contrary to this uniform law and is equally contrary to public policy. The Tennessee Chamber, the U.S. Chamber, and PhRMA thus have a strong interest in the outcome of this case.

INTRODUCTION AND SUMMARY OF ARGUMENT

In 1994, in *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994), this Court joined the overwhelming majority of courts nationwide in adopting the learned intermediary doctrine. That doctrine holds that, because of the unique nature of prescription medications (which makes them only available to patients who receive medical care from a medical professional), pharmaceutical manufacturers meet their duty to warn by warning the prescribing physician of the risks of the medication.

Petitioners now seek to use Tennessee's process for certifying questions from a federal court to unseat this well-established doctrine. This an inappropriate use of the certification process, and Petitioners have not pointed to any changed circumstances that would justify this Court taking the extraordinary step of overturning its own precedent. To the contrary, the

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[1] *See* PhRMA, Pharmaceutical Industry Profile 2013, at 30 (2013), at http://phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf.

fundamental premise of the doctrine—that physicians are both the only means through which a patient can obtain prescription medications and the best source of individually tailored warnings about those medicines—remains unaltered. Developments since *Pittman* have, if anything, strengthened the patient-physician relationship and more deeply entrenched the learned intermediary doctrine as a vital element of the common law. Moreover, were the Court to adopt the rule Petitioners seeks, it would undermine public policy and patient well-being. For all these reasons, this Court should deny certification and affirm the continuing vitality of the learned intermediary doctrine in Tennessee law.

STATEMENT OF FACTS

Amici adopt Respondent's Statement of Facts to the extent necessary to support the arguments herein.

ARGUMENT

I. THIS COURT SHOULD DENY CERTIFICATION BECAUSE TENNESSEE ALREADY CONCLUSIVELY APPLIES THE LEARNED INTERMEDIARY DOCTRINE, AS DO THE OVERWHELMING MAJORITY OF JURISDICTIONS THROUGHOUT THE COUNTRY.

Less than 20 years ago, this Court joined the vast majority of jurisdictions nationwide in holding that the learned intermediary doctrine applies to prescription medications. *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994). Since then, the weight of authority in favor of the doctrine has only increased, and this Court itself has reiterated its adherence to the doctrine. *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686 (Tenn. 2011). Nonetheless, Petitioners ask this court to grant certification in order to abolish, or at least dilute, the learned intermediary doctrine in Tennessee. This request should be denied because it subverts the purpose of the certification process and would senselessly upset a well-established and well-founded doctrine.

Tennessee Supreme Court Rule 23 allows for the certification of questions from the federal court when "there is no controlling precedent in the decisions of the Supreme Court of Tennessee." In this case, Petitioners argue that the Court should grant certification in order to decide whether Tennessee should "reject [the learned intermediary] doctrine in its entirety." Petitioners' Br. at 5. This argument fails for the simple reason that "controlling precedent" of this Court has already decided that precise question.

In *Pittman v. Upjohn Co.*, 890 S.W.2d 425 (Tenn. 1994), this Court was asked to reject the learned intermediary doctrine in order to allow failure to warn claims against a pharmaceutical manufacturer. Instead, the Court followed "the majority of jurisdictions" by holding that the drug manufacturer's adequate "warnings and instructions to prescribing physicians were sufficient to discharge its duty to those persons to whom it owed a duty to warn." *Id.* at 429, 431. The Court explained that under the learned intermediary doctrine, "makers of unavoidably unsafe products . . . may reasonably rely on intermediaries to transmit their warnings and instructions." *Id.* at 429. "Physicians are such intermediaries because of the pivotal role they play in the unique system used to distribute prescription drugs." *Id.*

In the time since *Pittman*, courts nationwide have continued to apply the learned intermediary doctrine to prescription drugs. The doctrine has been adopted or applied by courts in 47 U.S. jurisdictions,[2] including Tennessee. Only one state (New Jersey) has adopted a direct-to-consumer exception; one other (West Virginia) has rejected the learned intermediary doctrine

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[2] Appendix A lists the 47 jurisdictions — state courts or statutes in 39 states, federal courts applying the law of an additional 6 states, and courts in the District of Columbia and Puerto Rico — that have endorsed the learned intermediary doctrine. Notably, each of these courts has done so without providing an exception for direct to consumer advertising or physician compensation, the two exceptions Petitioners ask the court to recognize if it does not abolish the doctrine entirely.

altogether.[3] This consistent legal precedent, standing on its own, demonstrates the continuing force of the *Pittman* decision, and provides a strong basis for denying certification.

Moreover, this Court itself reasserted the continuing vitality of *Pittman* less than two years ago in *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686 (Tenn. 2011). In that case, the Court reaffirmed that in Tennessee, "the learned intermediary doctrine is applicable in failure to warn suits where a physician is the intermediary between a defendant pharmaceutical or other medical product manufacturer and an injured patient." *Id.* at 701.

Given *Pittman* and *Nye*, there is no need for the Court to grant certification to decide whether the doctrine is part of Tennessee law: under this Court's "controlling precedent," it is. That fact alone should be sufficient to defeat Petitioners' request for certification. At the district court, however, Petitioners sought to evade this difficulty in part by claiming that this Court has not yet stated whether there is an applicable exception to the learned intermediary. As a result, the questions the district court actually certified (unlike the question Petitioners now ask the Court to answer) concern whether Tennessee recognizes an exception to the learned intermediary doctrine when there has been direct to consumer (DTC) advertising or when a physician has been compensated for prescribing a medication.

Granting certification to answer these more limited questions would also be inappropriate. They amount to little more than a request that this Court decide whether a well-

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[3] The West Virginia Supreme Court, in a 3-2 decision, rejected the doctrine in *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (2007). As the dissent observed, the majority reached its conclusion only by "downplay[ing] the continuing and vital role that a physician plays in the decision as to which prescription drugs are appropriate for a given patient based upon that particular individual's specific medical needs." *Id.* at 917 (Albright, J., dissenting). This Court has expressly rejected this central premise of the majority decision in *Karl*. As the *Pittman* Court explained, it is precisely this continuing "pivotal role" of the prescribing physician that forms the basis of the doctrine. 890 S.W.2d at 429.

established doctrine applies to the particular circumstances of this case. That is not the purpose of the certification process; if it was, every invocation of state law in a federal case would result in certification. Further, this Court's prior learned intermediary cases have given no indication that exceptions of the kind Petitioners propose would apply. Rather, *Nye* spoke of a general rule that "physicians . . . are the intermediaries relied on by manufacturers to give warnings to patients." 347 S.W.3d at 701.

Indeed, no state has recognized an exception to the learned intermediary doctrine on the grounds of physician compensation, and several courts have expressly found that the doctrine is unaffected by such compensation. *See, e.g.*, *In re Vioxx Cases*, No. JCCP 4247, 2006 WL 6305292 (Cal. Super. Ct. Dec. 19, 2006) ("payment to a physician, standing alone, does not deprive the physician of learned intermediary status) *aff'd sub nom.*, *In re Vioxx Class Cases*, 103 Cal. Rptr. 3d 83 (Cal. Ct. App. 2009); *Talley v. Danek Med., Inc.*, 179 F.3d 154, 157, 163-64 (4th Cir. 1999) (applying the doctrine in a case in which manufacturer paid doctor an annual consulting fee of $250,000, as well as 25,000 shares of stock). Petitioners claim *Murthy v. Abbott Laboratories*, 847 F. Supp. 2d 958 (S.D. Tex. 2012), a federal case from Texas, recognized such an exception. *Murthy*'s outcome, however, flowed from the federal court's erroneous prediction that the Texas Supreme Court would adopt exceptions to the learned intermediary doctrine in *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140 (Tex. 2012), a case under review when *Murthy* was decided. 847 F. Supp. 2d at 970. Instead, the Texas Supreme Court, after noting the vast precedent counseling against exceptions to the doctrine, declined to recognize any, thereby displacing the rationale for the *Murthy* holding. 372 S.W.3d at 161-162.

Only a single state, New Jersey, recognizes an exception to the learned intermediary doctrine for direct-to-consumer ("DTC") advertising, and even then the exception is severely

limited by New Jersey's general industry-protective laws.[4] In *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245 (N.J. 1999), the New Jersey Supreme Court recognized the DTC exception in the context of a state law that creates a presumption that prescription drug warnings approved by the FDA are sufficient. *Id.* at 1259-1260 (citing N.J.S.A. 2A:58C-4; 2A:58C-5(c)). Thus, the New Jersey court found that "compliance with FDA standards" for consumer warnings "should be virtually dispositive" of the majority of claims that fit within the DTC exception to the learned intermediary doctrine. In other words, even in New Jersey there are almost no circumstances in which the DTC exception will apply. *Id.; see also Kendall v. Hoffman-LaRoche, Inc.* 209 N.J. 173, 196 (N.J. 2012) (explaining that *Perez* created what amounts to a "super presumption" that compliance with FDA requirements would protect pharmaceutical manufacturers from liability for failure to directly warn consumers). And, in the years following *Perez*, at least six courts in other jurisdictions have considered and rejected the adoption of a DTC advertising exception. *See, e.g.*, *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376 (S.D.Fla. 2007) ("Since *Perez* was decided, no court . . . has recognized the DTC exception to the learned intermediary doctrine, and several courts have expressly rejected the DTC exception."); *DiBartolo v. Abbott Laboratories*, ---F. Supp.2d--- (S.D. N.Y. 2012) (holding that New York does not recognize a DTC exception); *Centocor*, 372 S.W.3d at 161 (collecting cases).

Nor should Petitioners' invocation of the Third Restatement of Torts §6(d) affect the analysis. That provision, which Tennessee has not adopted, sets out the traditional learned

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[4] Petitioners also cite *Rimbert v. Eli Lilly and Co.*, 577 F. Supp. 2d 1174 (D.N.M 2008), a New Mexico federal court case that predicted that the New Mexico Supreme Court would recognize the DTC exception, but the *Rimbert* court inexplicably ignored a New Mexico state court decision to the contrary. In *Serna v. Roche Labs., Div. of Hoffman-LaRoche, Inc.*, 684 P.2d 1187, 1189 (N.M.Ct. App. 1984), the New Mexico Court of Appeals held that the learned intermediary doctrine did apply. Further, *Rimbert* settled before the pharmaceutical company could challenge the decision.

intermediary doctrine, but then states that a manufacturer may have a duty to provide warnings to a patient "when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings." §6(d)(2). While, as Petitioners point out, two state Supreme Courts have adopted the learned intermediary doctrine as articulated in §6(d), neither they—nor any other Court—has found that this Restatement provision mandates an exception to the learned intermediary doctrine for either physician compensation or direct to consumer advertising. *See Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 770 (Ky. 2004) (adopting the learned intermediary doctrine as stated in §6(d) but refusing to decide which "if any" exceptions "should be adopted in Kentucky"); *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827, 842 (Neb. 2000) (adopting §6(d) and applying it to the case at bar, without adopting any specific exceptions). And for good reason. As the Restatement Comments explain, the limited exception found in §6(d)(2) was designed to cover situations—like the dispensation of vaccines in mass-inoculation clinics—where prescription drugs "are dispensed or administered to patients without the personal intervention or evaluation of a health care provider." Restatement Third, §6(d) Comments, at *e*.

Thus, contrary to Petitioners' suggestion, §6(d)(2) was not meant to create an exception to the doctrine in the traditional situation, like what occurred here, where the doctor and the patient discuss treatment options and reach a decision to use a particular medicine. *See DiBartolo v. Abbott Laboratories*, ---F. Supp.2d---, 79 U.C.C. Rep. Serv 2d (Callaghan) 305 (S.D. N.Y. 2012) (holding that because, as Abbott intended, treating physician met individually with patient before prescribing Humira, "[t]his is not a case" where §6(d)(2) applies). Even *Perez*, the lone case finding a direct to consumer exception, admitted that the Restatement "left unanswered" the question of whether such an exception should exist. 734 A.2d at 1253. In fact,

the Restatement Comments specifically note that while some have argued for a direct-to-consumer advertising exception to the learned intermediary doctrine, the Restatement "leaves to developing case law whether exceptions to the [doctrine] in th[at] or other situations should be recognized." Restatement Third, §6(d) Comments, at *f.*

The case law that has developed in the fifteen years since these Comments has almost universally rejected the sort of exceptions Petitioners request. There is no need for the Court to grant certification merely to reiterate what numerous courts have already found: the learned intermediary doctrine, adopted by the Court in *Pittman* and reiterated in *Nye*, applies to cases like this one where adequate warnings have been provided to a prescribing physician.

II. THE RATIONALE FOR THE LEARNED INTERMEDIARY DOCTRINE REMAINS STRONG.

Petitioners allege that the Court should abolish the learned intermediary doctrine because circumstances have changed since the Court adopted the doctrine in *Pittman*. Specifically, Petitioners allege that the rise of DTC advertising and compensation of physicians by pharmaceutical companies, as well as changes in the law, have undermined the rationales of the doctrine. This contention fails on multiple levels. First, as this Court stated in *Pittman*, the doctrine is fundamentally premised on the fact that:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

Pittman, 890 S.W. 2d at 431 (quoting *Stone v. Smith, Kline & French Laboratories*, 731 F.2d 1575, 1579-80 (1984)). As demonstrated by this Court's quotation of the exact same language less than two years ago in *Nye*, 347 S.W. 3d at 703, nothing in the years since *Pittman* has

altered this basic premise. Prescription drugs remain complex and doctors remain in a unique position to both understand these complexities and the individual needs of their patients. That is why it continues to be the case that patients may not obtain medications such as Humira without a prescription from an authorized medical professional, and that is why physicians are still the proper audience for warnings about a drug's effects. *See, e.g.*, 21 U.S.C. § 353(b)(1)(A) (defining prescription medications as those which cannot be used safely "except under supervision of a practitioner licensed by law").

Second, far from weakening the rationale for the learned intermediary doctrine, the "changed circumstances" Petitioners point to actually strengthen the doctrine. DTC advertising does not alter the physician's role in deciding whether and when to prescribe a medication to a patient, and such advertising has actually been shown to improve the pre-prescription conversation between doctors and patients. As to pharmaceutical companies' compensation of physicians, the practice existed when *Pittman* was decided, and recent changes in the regulation and administration of these financial interactions have worked to further ensure that the patient's well-being remains at the heart of every prescription decision. Finally, developments in the law only further demonstrate the vitality of the learned intermediary doctrine.

A. Physician's prescription decisions are not dictated by DTC advertising, which actually improves the quality of patient-physician interactions.

Petitioners' argument that DTC advertising undermines the learned intermediary doctrine amounts to an assertion that physicians no longer exercise medical judgment in prescribing medicines. It is, however, illogical to assume that consumers use advertisements as a substitute for their personal physicians, or that doctors abdicate their professional responsibility to "independently weigh relevant risks and benefits in prescribing [the] advertised drug." Richard B. Goetz & Karen R. Growdon, *A Defense of the Learned Intermediary Doctrine*, 63 Food &

Drug Law Journal 421, 432 (2008) (citing *Karl*, 647 S.E.2d at 917 (Albright, J., dissenting) ("To presume . . . that the mere presence of pharmaceutical advertising in our society relegates the physician to a mere dispensary of prescriptions is simply not true.")). Indeed, physicians who prescribe medications without considering the individual needs of their patients are subject to discipline by the Tennessee Board of Medical Examiners. *See, e.g.,* Rules of Tennessee Board of Medical Examiners, §0880-02-.14(2)(d) ("prescribing controlled substances in amounts or for durations not medically necessary, advisable, or justifiable is considered to be practicing beyond the scope of the professional practice"); *see also Centocor*, 372 S.W.3d at 162 n. 24 ("reasoning that the new era of DTC advertising relegates physicians to a mere dispensary role of prescriptions fails to consider the important professional and ethical standards the law requires of physicians").

The Food and Drug Administration itself has approved of DTC advertising, and an FDA study shows that, according to many physicians, DTC advertising leads patients to ask more thoughtful questions and makes time spent with patients more useful. Kathryn Aiken, *The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship*, Presentation at FDA-Sponsored Public Meeting on Direct to Consumer Advertising (Sept. 23, 2003), (*available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM213625.pdf). Further empirical evidence that DTC advertising of prescription medications has had an overall beneficial effect on the physician-patient relationship is provided by a 2004 joint report of the Federal Trade Commission and the U.S. Department of Justice. That report found that DTC advertising "provides consumers with useful information, stimulates productive discussions between doctors and patients, and encourages consumers to learn more about previously

undiagnosed conditions." FTC & US DOJ, *Improving Health Care: A Dose of Competition*, at Chapter 7, Part V, (*available at* http://usdoj.gov/atr/public/health_care/204694/chapter7.htm#1).

B. At the time of *Pittman*, at least one court had already rejected physician compensation as a rationale for abandoning the learned intermediary doctrine, and developments since have further reinforced the validity of this decision.

Petitioners also contend that the Court should abandon the doctrine it adopted in *Pittman* because drug companies compensate physicians for participation in research and clinical trials involving medications. Petitioners have provided no evidence of changes since *Pittman* that would warrant a retreat from the learned intermediary doctrine, or that the Court in *Pittman* was unaware that drug companies compensate physicians in certain circumstances. To the contrary, when this Court handed down *Pittman*, it did so fully cognizant of the practice of physician compensation. In 1991, three years before *Pittman*, the Ohio Supreme Court explicitly found that the learned intermediary doctrine applied despite plaintiffs' assertion that a doctor was operating as a paid investigator of the pharmaceutical company. *Tracy v. Merrell Dow Pharms, Inc.*, 569 N.E.2d 875, 879-80 (Ohio 1991). As the *Tracy* court explained, compensating the prescribing physician does not mean that the pharmaceutical company takes "control [of the doctor's] judgment, duties, and responsibilities." *Id.* at 879.

The *Tracy* court's reasoning still applies. Just last year, a district court rejected an argument that the learned intermediary doctrine should not apply because Abbott has compensated doctors who prescribe Humira, noting that compensated physicians retain "their duty to prescribe drugs to patients only when medically necessary." *DiBartolo*, --- F. Supp.2d at ---, 79 U.C.C. Rep. Serv 2d 305. The court found no clear evidence compensation would lead physicians to neglect this duty, and in fact there is evidence to the contrary. While Petitioners assert that physician compensation leads doctors to overprescribe medications, peer-reviewed

studies have shown that medicines used to treat many conditions are far more likely to be underused than overused. *See, e.g.*, J. T. Harrington, "Hip Fracture Patients Are Not Treated for Osteoporosis: A Call to Action," Arthritis & Rheumatism, 2002; and J. Ma, "National Trends in Statin Use by Coronary Heart Disease Risk Category," Public Library of Science-Medicine, May 2005. For elderly patients in particular, the failure to prescribe an indicated drug accounts for 50% of medication management errors, while the prescription of an inappropriate medication accounts for only 3% of such problems. T. Higashi et al., "The Quality of Pharmacologic Care for Vulnerable Elder Patients," Annals of Internal Medicine, May 4, 2004.

Since *Pittman*, the only changed circumstance with respect to physician compensation is the increase in regulation of the relationship between physicians and pharmaceutical companies. In 2002, PhRMA, on behalf of the numerous pharmaceutical companies it represents, issued a "Code on Interactions with Healthcare Professionals." That Code articulated guidelines designed to ensure that "a healthcare professional's care of patients" is based "solely on each patient's medical needs and the healthcare professional's medical knowledge and experience." PhRMA, Code on Interactions with Healthcare Professionals, Preamble (2002). In the same year that PhRMA issued its Code, the American Medical Association, the American College of Physicians, and the Accreditation Council for Continuing Medical Education all issued new or revised guidelines governing the relationship between doctors and pharmaceutical companies. *See* American Medical Association, Opinion of the Council on Ethical and Judicial Affairs, E-8.061; S. L. Coyle, "Physician-industry relations. 1. Individual physicians," *Annals of Internal Medicine*, Vol. 136, at 396-402 (2002); Accreditation Council for Continuing Medical Education, "Standards for commercial support of continuing medical education." A year later, the United States' Office of the Inspector General released its own guidelines in the area. *See*

Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, Fed. Reg. 68, 23731-23743 (2003).

More recently, the Patient Protection and Affordable Care Act implemented a federal "Sunshine Law," under which pharmaceutical manufacturers must report certain physician payments to the Secretary of the U.S. Department of Health and Human Services. *See* Pub. L. No. 111-148, § 6002, 124 Stat. 119, 689 (codified as amended at 42 U.S.C. § 1320a-7h). PhRMA has also continued to revise its "Code on Interactions with Healthcare Professionals," reiterating the pharmaceutical industry's commitment to ensuring that its "interactions with healthcare professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine" PhRMA, Code on Interactions with Healthcare Professionals, Preamble (2009).

Thus, since *Pittman*, changes with respect to the financial relationship between pharmaceutical companies and doctors have worked only to improve the regulation of these interactions and to further ensure that the needs of the patient are at the heart of all prescription choices. *See DiBartolo*, --- F. Supp.2d at ---, 79 U.C.C. Rep. Serv 2d (Callaghan) 305 (S.D. N.Y. 2012) (rejecting plaintiffs' allegations that there is "any trend supporting an exception to [the learned intermediary doctrine] where drug manufacturers compensate physicians").

C. The evolving common law has embraced the learned intermediary doctrine.

Petitioners' final evidence of changed circumstances is "the evolving common law." Petitioners spend pages describing the history of the learned intermediary doctrine in the twenty-first century. In the end, though, all Petitioners' creative historiography cannot disguise the fact that while 47 jurisdictions have embraced the learned intermediary doctrine, only one state has

abolished it and only one state has recognized anything close to the exceptions Petitioners request.[5] Nor can Petitioners' account disguise the fact that both these states acted *before* this Court reaffirmed the vitality of the learned intermediary doctrine in its decision in *Nye*. Petitioners are right that the common law has evolved since the time of *Pittman*, but the evolution has only served to more firmly entrench the learned intermediary doctrine.

III. PETITIONERS' DESIRED HOLDING WOULD UNDERMINE PUBLIC POLICY BY UNFAIRLY INCREASING COMPANIES' LIABILITY WHILE DECREASING CONSUMER WELL-BEING.

The adoption of Petitioners' proposal would expose pharmaceutical and medical device companies to a wide range of new lawsuits alleging defects in the warnings provided directly to patients. This could create a perverse incentive for companies to flood patients with warnings more effectively conveyed through a physician who is able to understand the complex medical aspects of the treatment and provide personalized care to the patient. Further, the risk of liability may deter pharmaceutical and medical device companies from producing new drugs and other medical products, meaning that fewer innovative treatments will be available to those who need

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[5] Petitioners contend that a recent federal case from the Eastern District of Wisconsin suggests that the tide is turning against the doctrine. *See Maynard v. Abbott Laboratories*, 2013 WL 695817 (E.D. Wis. 2013), Appx. B. The *Maynard* court asserted that Wisconsin does not apply the learned intermediary doctrine, but it did so without any explanation and without mention of the prior federal court cases coming to exactly the opposite conclusion. *See, e.g.*, *Stupak v. Hoffman-La Roche, Inc.*, No. 8:05-CV-926T30TBM, 2007 WL 2350561 (M.D. Fla. 2007), *aff'd* 326 Fed.Appx. 553 (11th Cir. 2009), Appx. B (applying Wisconsin law and holding that "in the case of prescription drugs, the provision of proper warnings to a physician will satisfy the manufacturer's duty to warn since the patient cannot obtain the drug but through the physician" (internal quotation marks omitted)) . Moreover, the only Wisconsin *state* court case amicus is aware of that squarely addresses whether Wisconsin applies the doctrine is *Straub v. Berg*, Nos. 00-CV-2100 & 00-CV-0117 (Wis. Cir. Ct. Branch 16, Dane County, Jan. 6, 2003), attached as Appendix B. In that case the court adopted the doctrine and rejected plaintiffs' failure to warn claims against a pharmaceutical manufacturer because "plaintiffs have not met their burden of overcoming [defendant's] learned intermediary doctrine defense." Appx. B at 17.

them. Thus, Petitioners' proposed expansion of liability could end up harming the very patient well-being they profess to help.

A. Unnecessarily increasing the volume of warnings communicated to patients will decrease their efficacy.

An untrained patient provided with as much information as her physician may inappropriately overrate certain risks and underrate others, leading her to second-guess her doctor's prescription choices that would ultimately be most salutary to her health. For this reason, the FDA's current regulation of prescription drug warnings mandates one level of warnings for consumers and another for doctors. Thus, on the one hand, FDA requires that broadcast advertisements identify "major" side effects and contraindications, *see* 21 C.F.R. § 202.1(e)(1), and make "adequate provision [] for the dissemination of the approved or permitted package labeling." *Id.* For consumer-directed print advertisements, FDA requires a somewhat lengthier statement of a prescription medication's risks. *Id.* Manufacturers are encouraged to convey this information in simple and accessible language. *See* FDA, *Draft Guidance for Industry: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements* (Jan. 2004) at 2, (*available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory Information/Guidances/ucm069984.pdf).

By contrast, warnings to physicians about the risks associated with prescription medications necessarily involve more complex and extremely detailed scientific information. Pursuant to federal regulations, manufacturers convey such warnings to physicians through FDA-approved product labeling, which must include eighteen categories of safety information. *See* 21 C.F.R. § 201.57(c). Because of its volume and complexity, the FDA has recognized that this information, while of critical importance to the medical professional, is of "questionable"

value when provided directly to patients, and "relatively inaccessible to consumers." 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995).

The FDA's regime creates a sensible system in which patients receive the main warnings in a comprehensible manner from pharmaceutical companies, while the majority of the more complex information about a medication is imparted through a doctor who can individualize the explanations for each patient. Abolishing or limiting the learned intermediary doctrine as Petitioners propose would unseat this carefully constructed scheme by creating a system that might incentivize exhaustive listings on conceivable risk, no matter how technical or how remote. The FDA has recognized that such "defensive" warnings could "result in scientifically unsubstantiated warnings and underutilization of beneficial treatments," or, conversely, "cause meaningful risk information to lose its significance." 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) internal quotations and citations omitted).[6] Thus Petitioners' proposed rule would weaken the efficacy of the patient warning system they nominally seek to improve.

In a recent case concerning warnings on non-prescription medications, Judge Posner highlighted exactly this difficulty with overly detailed warning labels:

> The plaintiff argues that the label on the bottle of Children's Motrin should have added "rash" to the other allergic reactions warned against and should have mentioned SJS/TEN as one of the possible allergic reactions and (since virtually no consumer who was not a physician would have heard of the disease) recited its horrific consequences. But then the label would have had to describe as well every other serious disease that might, however infrequently, be caused, or even just arguably caused . . . by ibuprofen. And it would have to recite the symptoms of the disease

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[6] *See also* Jill Jacobson and David Feigal, M.D., *Red Sky in the Morning: Modifying Prescription Drug Labels as a Result of Postmarket Surveillance*, 62 Food & Drug Law Journal 529, 522-23 (2007) (explaining that prescription drug labels "are written for healthcare professionals, not patients," and that "communication of risks and benefits through product labeling is the cornerstone of risk management efforts for prescription drugs.").

> if it was rare. *The resulting information overload would make label warnings worthless to consumers.*

Robinson v. McNeil Consumer Healthcare, 615 F.3d 861, 869-70 (7th Cir. 2010) (emphasis added). Judge Posner cited ample academic research establishing the problem of information overload that occurs when consumers are provided with voluminous warnings. *See id.* (citing Troy A. Paredes, *Information Overload and its Consequences for Securities Regulation*, 81 Wash. U.L.Q. 417, 440–43 (2003); Howard Latin, *'Good' Warnings, Bad Products, and Cognitive Limitations*, 41 UCLA L.Rev. 1193, 1211–15 (1994); *cf.* Richard Craswell, *Taking Information Seriously: Misrepresentation and Nondisclosure in Contract Law and Elsewhere*, 92 Va. L. Rev. 565, 583–85 (2006); Mark Geistfeld, *Inadequate Product Warnings and Causation*, 30 U. Mich. J.L. Reform 309, 322 (1997)).

Courts in other contexts have also discussed the potential hazards of liability regimes that encourage bombarding consumers with excessive warnings. For example, the California Supreme Court recently rejected an attempt to impose liability on a company for failing to warn consumers about the risks of another company's dangerous product. Petitioners had argued that such a warning was appropriate because the other product was frequently used in conjunction with defendant's own products. The California Supreme Court disagreed, holding that "such an expanded duty [to warn] could . . .undermine consumer safety by inundating users with excessive warnings." *O'Neil v. Crane Co.*, 53 Cal.4th 335, 363 (Cal. 2012). A New Jersey Court applied a similar rationale in declining to impose liability on a train storage container manufacturer for failure to warn of the dangers of the products that were periodically stored within it. *Andre v. Union Tank Car Co., Inc.*, 516 A.2d 277, 286 (N.J. Super. Ct. 1985). As that court elegantly put it, "[t]o warn of all potential dangers would warn of nothing." *Id.*

B. Abolishing the learned intermediary doctrine may deter companies from producing innovative new medicines.

Dispensing with the learned intermediary doctrine would also increase the likelihood that pharmaceutical companies will be unfairly held liable for gaps in a patients' knowledge that the companies are unable to control. As the FDA's current regime reflects, detailed warnings about complex prescription medications are—by their very nature— "relatively inaccessible to consumers." 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995). That is why doctors are necessary to act as intermediaries crafting the warnings to the particular needs of each patient. Yet under the patient's proposed rule, pharmaceutical companies could be held liable under a theory that they failed to draft general warnings that can clearly communicate all the risks of their products to any and every consumer. This increase in liability may deter some companies from introducing new products into the market.

Indeed, Justice O'Connor has noted that the current products liability regime already deters innovation:

> The threat of . . . enormous [damages] awards has a detrimental effect on the research and development of new products. Some manufacturers of prescription drugs, for example, have decided that it is better to avoid uncertain liability than to introduce a new pill or vaccine into the market.

Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc., 492 U.S. 257, 282 (1989) (O'Connor, J. concurring and dissenting); *see also* Cass R. Sunstein et al., *Assessing Punitive Damages (With Notes on Cognition and Valuation in Law*), 107 Yale L.J. 2071, 2077 (1998) (remarking, in the context of punitive damage, that "as a practical matter, a risk of extremely high awards is likely to produce excessive caution in risk-averse managers and companies. Hence unpredictable awards create . . . unfairness and . . . may overdeter desirable activity."). Adding more

unnecessary liability to the system by abolishing the learned intermediary doctrine can only aggravate the problem.

IV. THIS CASE DEMONSTRATES THE CONTINUED VITALITY OF THE LEARNED INTERMEDIARY DOCTRINE.

Petitioners ask this Court to take the exceptional step of granting certification of a question from a federal court in order to abolish the well-established learned intermediary doctrine, but this very case demonstrates the doctrine's continuing vitality. It is undisputed that the TNF-inhibitor Humira is a complex, highly technical medication designed to treat rheumatoid arthritis, a complex, highly painful disease. It is also undisputed that Ms. Jones was prescribed Humira by Dr. Adams, a physician who was expert in the disease and its treatment methods, and who had determined that Ms. Jones needed a TNF-inhibitor after more than a decade of treating her crippling rheumatoid arthritis through conventional means. In other words, Ms. Jones obtained Humira through a learned intermediary, an expert whose role was to provide the medication based on an individualized assessment of the strengths and weaknesses of the complex treatment and the nuances of his patient's condition. The law should not undermine this role.

CONCLUSION AND PRAYER

For the reasons stated above, the Tennessee Chamber, the U.S. Chamber, and PhRMA join Abbott in urging this Court to decline certification or to reaffirm the validity of the learned intermediary doctrine in this case.

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CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of May 2013, I caused true and correct copies of the foregoing **BRIEF OF *AMICI CURIAE* TENNESSEE CHAMBER OF COMMERCE AND INDUSTRY, CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITION FOR REVIEW** to be served on the following parties by overnight delivery, postage prepaid, to the following addresses:

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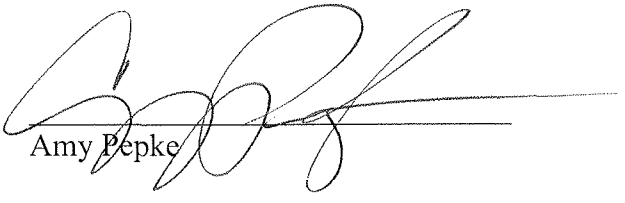

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APPENDIX A

APPENDIX A

United States Jurisdictions Endorsing the Learned Intermediary Doctrine

State/Territory	State or Federal Authority	Key Opinion(s) and Relevant Language
1. Alabama	State courts	• *Walls v. Alpharma USPD, Inc.*, 887 So.2d 881, 884-86 (Ala. 2004) ("'[W]here *prescription* drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use.'") (quoting *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304-05 (Ala. 1984)).
2. Alaska	State courts	• *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1194-95 & n.6 (Alaska 1992) ("A prescription drug's performance safety depends on many variables, including the nature of the drug itself, the patient's medical history, dosage, and combination with other medications, whose complex interplay is beyond the comprehension of the ordinary consumer. . . . In a sense, prescribing doctors are the consumers of prescription drugs. It is the doctor's evaluation of the patient's condition and consideration of the available treatment alternatives which leads to the choice of a specific prescription drug product.").
3. Arizona	State courts	• *Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. Ct. App. 1978) ("In the case of prescription drugs . . . the manufacturer's duty to warn is ordinarily satisfied if a proper warning is given to the prescribing physician.").
4. Arkansas	State courts	• *West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991) (stating that the Learned Intermediary Doctrine applies for three reasons: "First, a physician must prescribe the drug, the patient relies upon the physician's judgment in selecting the drug,

		and the patient relies upon the physician's advice in using the drug. That is to say that there is an independent medical decision by the learned intermediary that the drug is appropriate. Second, it is virtually impossible in many cases for a manufacturer to directly warn each patient. Third, imposition of a duty to warn the user directly would interfere with the relationship between the doctor and the patient.").
5. California	State courts	• *Brown v. Superior Ct.*, 44 Cal. 3d 1049, 1061-62 (Cal. 1988) ("The manufacturer cannot be held liable if it has provided appropriate warnings and the doctor fails in his duty to transmit these warnings to the patient.").
6. Colorado	State courts	• *Peterson v. Parke Davis & Co.*, 705 P.2d 1001, 1003 (Colo. Ct. App. 1985) ("Where, as here, an attending physician, in prescribing and in supervising the use of a drug, disregards the manufacturer's warnings and instructions, it is that conduct which renders the product unreasonably dangerous, and thus defective, and the adequacy of the warnings and instructions are not relevant."). • *Id.* at 1004 ("[T]he concern was with the warning given to the attending physician, and whether others were warned is irrelevant.").
7. Connecticut	State courts	• *Vitanza v. Upjohn Co.*, 778 A.2d 829, 836-38 (Conn. 2001) ("[P]rescribing 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.") (quotations omitted) (alteration in original). • *Id.* at 841 ("The learned intermediary doctrine stands for the proposition that, as a matter of law, the prescribing physician of a prescription drug is the person best able to take or recommend precautions against the harm.").

8. Delaware	State courts	• *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400 (Del. 1989) ("In the final analysis it is the physician who ultimately prescribes the drug or device. Thus, if the manufacturer of prescription products provides the physician with the legally appropriate information, it has satisfied its duty to warn.").
9. District of Columbia	State courts	• *Mampe v. Ayerst Labs.*, 548 A.2d 798, 801-02 n.6 (D.C. 1988) (the prescribing physician is "the user" of a prescription medication; "[w]hen 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.'") (quoting *Payne v. Soft Sheen Prods., Inc.*, 486 A.2d 712, 722 n.10 (D.C. 1985)).
10. Florida	State courts	• *Felix v. Hoffmann-LaRoche, Inc.*, 540 So.2d 102, 104 (Fla. 1989) ("[I]t is clear that the manufacturer's duty to warn of [the drug's] dangerous side effects was directed to the physician rather than the patient" because "the prescribing physician, acting as a 'learned intermediary' between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs.").
11. Georgia	State courts	• *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003) ("Under the learned intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer. The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication [or medical devices] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities.") (footnotes and quotations omitted) (alteration in original).

12. Hawaii	State courts	• *Craft v. Peebles*, 893 P.2d 138, 155 (Haw. 1995) (stating that the Learned Intermediary Doctrine applies to prescription pharmaceutical products because "physicians are in a better position [than manufacturers] to assess risks and determine when a particular patient reasonably should be informed about a risk," and applying the Learned Intermediary Doctrine to silicone breast implants) (quotations omitted).
13. Idaho	State courts	• *Sliman v. Aluminum Co. of Am.*, 731 P.2d 1267, 1270-71 (Idaho 1986) (endorsing general principle that warning an intermediary may satisfy duty to warn consumers in a case where the cap of a soda bottle caused an eye injury). • *Id.* at 1270-71 (citing with approval the principle that a drug manufacturer "fulfill[s] its duty to warn" if it "'properly warns a prescribing physician of the dangerous propensities of its product'" because "'[t]he doctor stands as a learned intermediary between the manufacturer and the ultimate consumer'" and "'[g]enerally, only the doctor could understand the propensities and dangers involved in the use of a given drug'") (quoting *Alm v. ALCOA*, 717 S.W.2d 588, 591-92 (Tex. 1986)).
14. Illinois	State courts	• *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 393 (Ill. 1987) ("The doctor, functioning as a learned intermediary between the prescription drug manufacturer and the patient, decides which available drug best fits the patient's needs and chooses which facts from the various warnings should be conveyed to the patient, and the extent of disclosure is a matter of medical judgment. As such, we believe the learned intermediary doctrine is applicable here and that there is no duty on the part of manufacturers of prescription drugs to directly warn patients.") (citations omitted).
15. Indiana	State courts	• *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 549, 553 (Ind. Ct. App. 1979) ("In the case of ethical drugs, the manufacturer's duty is discharged

		if adequate warning is given to doctors, who act as 'learned intermediaries' between the manufacturer and the ultimate user.").
16. Iowa	State courts	• *McCormick v. Nikkel & Associates, Inc.*, 819 N.W. 2d 368, 375 (Iowa 2012) (observing that "we recognize various 'no duty' rules in the warning area" and citing the "learned intermediary rule" as one such "no duty" rule the court recognizes)
17. Kansas	State courts	• *Humes v. Clinton*, 792 P.2d 1032, 1039-41 (Kan. 1990) (citations omitted) ("Since prescription drugs are available only to a physician, it is the physician's duty to inform himself or herself of the characteristics of the drugs prescribed and to exercise his or her judgment of which drug to administer in light of the drug's propensities and the patient's susceptibilities. . . . [W]e have adopted the learned intermediary rule, which relieves the manufacturers of the duty to warn consumers directly, in IUD cases.").
18. Kentucky	State courts	• *Larkin v. Pfizer*, 153 S.W.3d 758, 765, 770 (Ky. 2004) ("[P]roviding an adequate warning to the prescribing physician relieves the manufacturer of its duty to warn the patient regardless of how or if the physician warns the patient.").
19. Louisiana	State courts	• *Calhoun v. Hoffman-La Roche, Inc.*, 768 So.2d 57, 61 (La. Ct. App. 2000) ("'The manufacturer has no duty to warn the consumer directly of any risks or contraindications associated with the drug. The manufacturer of the drug has fulfilled its obligation when it has informed the prescribing and treating physicians of the risks of harm from the drug so that they may intelligently decide on its use and advise the patient.'") (quoting *Cobb v. Syntex Labs., Inc.*, 444 So.2d 203, 205 (La. Ct. App. 1983)).
20. Maine	State courts	• *Tardy v. Eli Lilly & Co.*, No. CV-03-538, 2004 WL 1925536, at *2-3 (Me. Super. Ct. Aug. 3, 2004) (holding that the Learned Intermediary Doctrine shields pharmacists from liability for failure to warn

		and noting that "[i]f the doctor is properly warned [by the manufacturer] of the possibility of a side effect in some patients, and is advised [by the manufacturer] of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided") (quotation omitted).
21. Massachusetts	State courts	• *Cottam v. CVS Pharm.*, 764 N.E.2d 814, 821 (Mass. 2002) ("Because the physician is the appropriate person to perform the duty of warning a patient of the possible side effects of prescription drugs, we now extend [the Learned Intermediary Doctrine] to pharmacies.").
22. Michigan	State courts	• *Smith v. E. R. Squibb & Sons, Inc.*, 273 N.W.2d 476, 479 (Mich. 1979) ("A manufacturer of a prescription drug has a legal duty to warn the medical profession, not the patient, of any risks inherent in the use of the drug which the manufacturer knows or should know to exist.").
23. Minnesota	State courts	• *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 n.1 (Minn. 1970) (citations omitted) ("The manufacturer has no duty to warn the lay public regarding prescription drugs.").
24. Mississippi	State courts	• *Janssen Pharmaceutica, Inc. v. Bailey*, 878 So.2d 31, 58 (Miss. 2004) ("When the product in question is a prescription drug, Mississippi follows the learned intermediary doctrine. Under this doctrine, the manufacturer's failure to warn the patient of the product's risks does not render the product defective or unreasonably dangerous so long as the manufacturer adequately warns the learned intermediary.").
25. Missouri	State courts	• *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 151-52 (Mo. 1967) ("[I]n this case we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of

		the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.") (quotation omitted).
26. Montana	State courts	• *Hill v. Squibb & Sons, E. R.*, 592 P.2d 1383, 1387-88 (Mont. 1979) ("As a general rule, the duty of a drug manufacturer to warn of the dangers inherent in a prescription drug is satisfied if adequate warning is given to the physician who prescribes it.").
27. Nebraska	State courts	• *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827, 841-42 (Neb. 2000) ("Pharmaceutical products have historically been treated differently in regard to a duty to warn. . . . [I]n cases involving prescription drugs, it is widely held that the duty to warn extends only to members of the medical profession and not to the consumer. This concept, known as the learned intermediary doctrine, is based upon the premise that, as a medical expert, a patient's prescribing or treating physician is in the best position to evaluate the often complex information provided by the manufacturer concerning the risks and benefits of its drug or product and to make an individualized medical judgment, based on the patient's particular needs and susceptibilities, as to whether the patient should use the product. . . . We adopt § 6(d) of the Third Restatement.") (quotations omitted).
28. Nevada	State courts	• *Allison v. Merck & Co., Inc.*, 878 P.2d 948, 958 n.16 (Nev. 1994) (stating, in response to the dissent's reliance on "the so-called 'learned intermediary doctrine," that "the mass immunization exception [to the Learned Intermediary Doctrine] does apply to this case" because the measles, mumps, and rubella vaccine at issue was administered without "the type of individualized medical judgment contemplated by the learned intermediary defense," without endorsing the Learned Intermediary Doctrine or

		considering whether it might apply to prescription medications).
29. New Hampshire	Federal courts	• *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 656 (1st Cir. 1981) (citations omitted) ("In cases involving ethical drugs, the manufacturer must warn the physician, not the patient."). • *Nelson v. Dalkon Shield Claimants Trust*, No. 84-276-SD, 1994 WL 255392, at *4 (D.N.H. June 8, 1994) ("'[I]t is generally accepted that in a case involving medical products prescribed or used by a physician or trained medical personnel, the warning runs to the physician not the patient.'") (quoting *Knowlton v. Deseret Med., Inc.*, 930 F.2d 116, 120 n. 2 (1st Cir. 1991)).
30. New Mexico	State courts	• *Serna v. Roche Labs., Div. of Hoffman-LaRoche, Inc.*, 684 P.2d 1187, 1189 (N.M. Ct. App. 1984) ("Where the product is a prescription drug, the manufacturer's duty to warn is fulfilled if it warns the physician, not the patient.").
31. New York	State courts	• *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993) ("Warnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects. The physician acts as an 'informed intermediary' between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient.") (citations omitted).
32. North Carolina	State statute	• N.C.G.S.A §99B-5(c) ("no manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the

		claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product")
33. North Dakota	Federal courts	• *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004) ("[P]rescribing 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 risks and benefits of a particular course of treatment.") (quotations omitted).
34. Ohio	State statute	• R.C. §2307.76(c) ("An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it")
35. Oklahoma	State courts	• *McKee v. Moore*, 648 P.2d 21, 24 (Okla. 1982) ("In the absence of FDA regulations to the contrary, the manufacturer has no obligation to warn a consumer if the prescribing physician has been adequately warned of any adverse side effects. The manufacturer's duty is to warn the physician, who acts as a learned intermediary between the manufacturer and the consumer, because he is in the best position to evaluate the patient's needs, assess the benefits and risks of a particular therapy, and to supervise its use.").
36. Oregon	State courts (but it applies only to causes of action based on negligence,	• *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 528-29 (Or. 1974) (stating, in a case where the plaintiff's "sole theory of recovery" was "the alleged failure of defendants to adequately warn the medical profession" and where the plaintiff thus did not assert that the manufacturer had a duty to warn her directly, that "the duty of the ethical drug manufacturer is to warn the doctor, rather than the

	not to causes of action based on Oregon's strict liability statute, Or. Rev. Stat. § 30.920).	patient"). • *Oksenholt v. Lederle Labs.*, 625 P.2d 1357, 1362 (Or. Ct. App. 1981) (stating, in a case where a physician sued a manufacturer for misrepresenting the risks of a drug that he prescribed, that "[a] drug manufacturer's duty, as described in *McEwen*, is a duty to adequately inform doctors of the harm associated with prescription drugs"). • *Griffith v. Blatt*, 51 P.3d 1256, 1261-62 (Or. 2002) (holding that Or. Rev. Stat. § 30.920 "does not create a defense to strict liability based on the learned intermediary doctrine," in a case where a pharmacist placed in a generically labeled bottle a lotion that could be used no more than twice and had to be washed off within 12 hours, and the plaintiff suffered severe injury as a result).
37. Pennsylvania	State courts	• *Coyle ex rel. Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1385 (Pa. 1991) ("[W]hen a drug 'is available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor.' . . . We formulated this rule with reference to comment k and the policies expressed therein.") (quoting *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971)).
38. Puerto Rico	Federal courts	• *Guevara v. Dorsey Labs.*, 845 F.2d 364, 366 (1st Cir. 1988) ("It is generally accepted, and the parties do not contest, that a prescription drug manufacturer has a duty to adequately warn prescribing physicians of the hazards posed by the use of its drugs. The warning is directed not to the ultimate user but to the doctor prescribing the drug, who must then take into account the propensities of the drug and the susceptibilities of the patient and make an informed decision regarding the advisability of its use.") (citation and quotations omitted).
39. South Carolina	Federal courts	• *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) ("Under [the Learned Intermediary

		Doctrine], the manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device.").
40. South Dakota	Federal courts	• *McElhaney v. Eli Lilly & Co.*, 575 F. Supp. 228, 231 (D.S.D. 1983) ("In cases involving prescription drugs 'the manufacturer must warn the physician, not the patient.' The prescribing physician acts as a learned intermediary between the patient and manufacturer.") (quoting *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 656 (1st Cir. 1981)).
41. Tennessee	State courts	• *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) ("Under the 'learned intermediary doctrine,' makers of unavoidably unsafe products who have a duty to give warnings may reasonably rely on intermediaries to transmit their warnings and instructions. Physicians are such intermediaries because of the pivotal role they play in the unique system used to distribute prescription drugs. . . . [T]he manufacturer of an unavoidably unsafe prescription drug can discharge its duty to warn by providing the physician with adequate warnings of the risks associated with the use of its drug.") (citations omitted).
42. Texas	State courts	• *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157 (Tex. 2012) ("we hold that a prescription drug manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, it has no further duty to warn the end users directly").
43. Utah	State courts	• *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003) (holding that "[u]nder [the Learned Intermediary Doctrine], manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient," and thus pharmacist had no duty to warn patient about prescription medication's risks).

44. Virginia	State courts	• *Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 44 (Va. 1980) ("[I]n the case of prescription drugs, it is the general rule that the duty of the drug manufacturer is to warn the physician who prescribes the drug in question.") (quotations omitted).
45. Washington	State courts	• *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978) ("Where a product is available only on prescription or through the services of a physician, the physician acts as a 'learned intermediary' between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.") (footnote omitted).
46. Wisconsin	Federal courts	• *Stupak v. Hoffman-La Roche, Inc.*, No. 8:05-CV-926T30TBM, 2007 WL 2350561 (M.D. Fla. 2007), *aff'd* 326 Fed.Appx. 553 (11th Cir. 2009) (applying Wisconsin law and holding that "in the case of prescription drugs, the provision of proper warnings to a physician will satisfy the manufacturer's duty to warn since the patient cannot obtain the drug but through the physician" (internal quotation marks omitted)). • *Monson v. Acromed Corp.*, No. 96-C-1336, 1999 WL 1133273, at *20 (E.D. Wis. May 12, 1999) (manufacturer had no duty to warn plaintiff because "[t]he general rule regarding medical devices is that

		the manufacturer must warn the physician – the so-called 'learned intermediary' – and not the patient directly"). • *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (stating, in a case governed by Wisconsin law, that "under the Learned Intermediary Doctrine, manufacturers of prescription medical products have a duty only to warn physicians, rather than patients, of the risks associated with the use of the product"). • *But see Maynard v. Abbott Laboratories*, 2013 WL 695817 (E.D. Wis. 2013) (asserting, without citation or explanation, and without reference to prior precedent to the contrary, that "Wisconsin does not apply the learned intermediary doctrine").
47. Wyoming	State courts	• *Rohde v. Smiths Medical*, 165 P.3d 433, 442 & n.7 (Wyo. 2007) (holding that medical device manufacturer was not liable for failure to warn because plaintiff did not point to any evidence that "the warnings provided by [the manufacturer] to Dr. Poole were inadequate" and referring to Dr. Poole as the "learned intermediary").

APPENDIX B

STATE OF WISCONSIN | CIRCUIT COURT BRANCH 16 | DANE COUNTY

THOMAS STRAUB, personally and As Special Administrator of the ESTATE OF SAMUEL STRAUB, and SUSAN STRAUB,
Plaintiffs,
vs.
ERIC BERG, M.D., THE MEDICAL PROTECTIVE COMPANY, and WISCONSIN PATIENTS COMPENSATION FUND,
Defendants,

AND

THOMAS STRAUB, personally and As Special Administrator of the ESTATE OF SAMUEL STRAUB, and SUSAN STRAUB,
Plaintiffs,
vs.
HOFFMANN-LAROCHE, INC., ERIC BERG, M.D., and WISCONSIN PATIENTS COMPENSATION FUND,
Defendants.

Decision and Order – Summary Judgment

Case Nos. 00-CV-2100
00-CV-0117

This matter is before the court on two summary judgment motions. Defendant Hoffmann-LaRoche (Roche) seeks summary judgment dismissing wrongful death claims 2, 4, 5, and 6. Roche maintains that under Wisconsin law, the intentional act of suicide is a superceding and intervening act that breaks the causation chain and defeats those claims. Claim 3, of the Amended Complaint, a survival claim, alleges that Roche's negligence caused Samuel Straub's depression prior to his death. Roche contends that claim 3 must be dismissed as a matter of law because under the learned intermediary doctrine, Roche satisfied any duty owed to warn of the risk of depression caused by the use of the acne drug Accutane by warning Samuel's physician,

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1/6/3

Dr. Eric Berg, of that very risk. Because this court concludes that Roche has failed to establish a *prima facie* defense that defeats plaintiffs' claims 2, 4, 5, and 6, Roche's summary judgment motion is denied as to those claims. Because this court concludes that Roche has established a defense that defeats plaintiffs' claim 3, Roche's summary judgment motion is granted as to claim 3.

Defendants Dr. Eric Berg and his insurer (collectively Berg) seek summary judgment dismissing all claims against them on the ground that the intentional act of suicide is a superceding intervening act that breaks the causation chain and therefore defeats those claims. Because this court concludes that Dr. Berg has failed to establish a *prima facie* defense that defeats plaintiffs' claims, Dr. Berg's motion for summary judgment is denied.

FACTUAL BACKGROUND

This action involves two consolidated lawsuits arising out of Samuel Straub's death. On January 16, 1997, Samuel committed suicide by hanging himself at home. Samuel was sixteen years old at the time of his death. The plaintiffs in this action are Samuel's parents and his estate. The principal defendants are Roche, the drug company that manufactures a prescription medication called Accutane, and Dr. Eric Berg, the dermatologist who prescribed Accutane to Samuel for treatment of his acne. Plaintiffs maintain that the Accutane caused Samuel to become depressed and to ultimately commit suicide.

Samuel suffered from severe acne. He began to receive treatment for that condition beginning in 1993 and was prescribed a variety of remedies that included antibiotics, topical creams/gels, and medicated soaps. Accutane had been recommended by another physician between 1993 and 1995 but was not prescribed because the Straubs' health insurance did not cover the prescription and the cost was prohibitive. Samuel began to see Dr. Berg in February

1995. At that time, Dr. Berg noted that Samuel's acne condition was not improving and could have been worsening. There were concerns expressed about scarring. Dr. Berg's assessment, recorded in the office visit medical record, states:

I think he is a good candidate for Accutane. Mother has talked about this with Dr. Falk in the past and has read the handouts more than once. I discussed the significant risks versus benefits, treatment options, etc. I recommend Accutane treatment. Will plan on starting Accutane. Will check labs first including CBC, chemistry panel and urinalysis. Once Accutane is started, they know he needs to stop all other acne treatment, whether topical or internal. He should also avoid vitamin A supplementation. Moisturizers advised. Recheck about one month after starting Accutane treatment.

Upon Samuel's return one month later for a recheck, it was apparent that some improvement had taken place. The medical note indicates that Samuel had some skin dryness on his face and that Samuel denied any significant side effects, except for slightly chapped lips. The note states that Dr. Berg ordered further lab work and if the lab results were satisfactory, he would call in a refill. Upon determining that the lab work was satisfactory, Dr. Berg ordered a five-week refill.

Samuel returned a month later (April 1995) for a recheck. Again, the medical note indicated improvement in the acne coupled with dry skin side effects. Lab results indicated an elevated "Trg" (triglyceride) level. The Accutane therapy was continued. In May 1995, Samuel returned for the one-month re-check. The only major side effect noted was dry skin but the acne lesions appeared to be healing. Lab work results were satisfactory and the triglyceride level had improved. Dr. Berg prescribed a refill for the Accutane.

In June 1995, Samuel returned for the one-month recheck. His acne was improved and his skin was reported as slightly dry. Lab work indicated slightly elevated triglycerides and liver levels. Samuel completed his course of Accutane therapy with the June 1995 refill.

In September 1995, Dr. Berg's office recommended further lab work because of the previous elevated levels in Samuel's lab results. Samuel's mother reported that Samuel had expressed concern about a recent acne flare-up. Dr. Berg prescribed a soap and a topical antibiotic solution. That therapy was continued through 1995 and into 1996. In February 1996, Samuel returned for an acne recheck. His acne seemed to be controlled and the soap and topical application regimen was continued.

In May 1996, Samuel's mother called Dr. Berg's office to ask if Samuel could return to oral antibiotic therapy because they noticed some small pits of scarring and they did not want them to become worse. Dr. Berg prescribed an oral antibiotic. Samuel returned to Dr. Berg's office for a checkup in July 1996. The oral antibiotic did not help and Samuel's acne had been flaring significantly. Accutane treatment was advised and discussed. Lab work was completed and the results were satisfactory.

Samuel began a second course of Accutane therapy at the end of July. At the beginning of September, lab work remained satisfactory and Samuel was prescribed an Accutane refill. The October recheck noted only slight improvement of Samuel's acne. Samuel did not report any significant side effects other than skin dryness and rare occurrences of bloody noses. Lab tests continued to be unremarkable. The October 1996 medical note states:

I prescribed Accutane 40 mg #75 1 p.o. b.i.d. on even days and 1 p.o. t.i.d. on odd days. No refills. Recheck in about one month. I do not think he needs further lab work. I reviewed side effects to look out for. He will notify me if any significant side effects occur. Recheck in one month to decide the duration of treatment.

Samuel returned in November 1996 for his checkup. He reported a lot of skin dryness on his face and arms and occasional achy joints. No other side effects were noted and Samuel reported that he thought his acne had improved. Dr. Berg rechecked Samuel's lab work and

called in another Accutane prescription. He also ordered a follow-up appointment in a month, at which time he would decide whether an additional month of treatment would be beneficial.

Dr. Berg cancelled Samuel's December 1996 checkup appointment due to illness. However, the medical note indicates that Samuel and his mother reported that they wanted Samuel to continue his Accutane for another month. Additional lab work results were satisfactory and on December 19, 1996, Samuel was prescribed Accutane for another month.

In late December 1996 or early January 1997, Samuel indicated to his girlfriend, Brook, that he was feeling depressed and had thought about ways to kill himself. Brook spoke with Samuel's football coach, who contacted Samuel's mother, Susan, on January 10, 1997. Susan offered to take Samuel to a counselor but Samuel declined. On January 13, 1997, Susan called Dr. Berg's office and informed them that Samuel had expressed concern about depression lately and wondered if it could be related to Accutane. The medical note states: "Per Dr. Berg Sue advised that there is a possibility that it could be related."

Samuel was advised to stop taking the Accutane and to discard any leftover medication. Dr. Berg's office scheduled a two-week follow-up appointment. On January 14, 1997, Samuel met with the mother of one of his friends who had a master's degree in psychiatric mental health nursing. Samuel expressed feeling depressed both when in the company of his friends and when he was not among them. On January 16, 1997, Samuel and Brook gathered at a friend's house. While there, Brook felt Samuel was distant and ignoring her. Samuel went home, took off his shoes inside the front door as was customary at his house, and called Brook. Sometime thereafter, Samuel went down to the basement of his home and committed suicide by hanging himself with a rope. Samuel left a suicide note.

Samuel's parents and his estate brought this lawsuit against Roche and Dr. Berg.

In an Amended Complaint, plaintiffs assert the following claims against Roche:

Claim 2: Roche caused Samuel's death by negligently failing to do adequate testing of Accutane prior to marketing and distributing and failed to provide users with an adequate warning of the danger of depression and suicide associated with Accutane use. Roche was aware that Accutane posed a serious risk of depression and suicide but was negligent in failing to warn users of that danger, and was negligent is other respects not enumerated.

Claim 3: Roche's negligence caused Samuel's depression, loss of enjoyment of life, and emotional distress prior to his death to such a degree of severity that he was driven to end his life.

Claim 4: Roche's negligence caused Samuel's parents to suffer severe physical and emotional distress, anxiety, loss of enjoyment of life, and economic losses after Samuel's death after Samuel's father discovered Samuel hanging in the basement of the family's home.

Claim 5: Roche is strictly liable for the injuries suffered by plaintiffs by virtue of Roche's knowledge of the drug's dangerous side effects of depression and suicide and its failure to warn plaintiffs of those side effects.

Claim 6: Roche's conduct in manufacturing and distributing Accutane while failing to warn users of the drug's dangerous side effects, which Roche was knowledgeable of, was outrageous and in intentional disregard of plaintiffs' rights, making Roche liable for punitive damages.

The Amended Complaint makes the following allegations against Dr. Berg:

Claim 1: Dr. Berg was negligent in over-prescribing Accutane for Samuel's acne and in failing to properly monitor Samuel's condition, and in other ways not specifically enumerated.

Claim 3: Dr. Berg's negligence caused Samuel's depression, loss of enjoyment of life, and emotional distress prior to his death to such a degree of severity that he was driven to end his life.

Claim 4: Dr. Berg's negligence caused Samuel's parents to suffer severe physical and emotional distress, anxiety, loss of enjoyment of life, and economic losses after Samuel's death after Samuel's father discovered Samuel hanging in the basement of the family's home.

STANDARD OF REVIEW

The procedure for the court to follow on summary judgment is well established.

We first examine the complaint to determine whether it states a claim, and then the answer to determine whether it presents a material issue of fact. If they do, we then examine the moving party's affidavits to determine whether a *prima facie* case has been made. If it has, we then look

to the opposing party's affidavits to determine whether there are any material facts in dispute that would entitle the opposing party to a trial.

Benjamin v. Dohm, 189 Wis. 2d 352, 358 (Ct. App. 1994)(citations omitted). Summary judgment is appropriate only when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Kerns v. Madison Gas & Electric, 134 Wis. 2d 387, 391 (1986); Wis. Stat. §802.08.

DISCUSSION

I. ROCHE'S SUMMARY JUDGMENT MOTION

A. Claims 2, 4, 5, 6 (wrongful death negligence and punitive damages claims)

As moving defendant, Roche must present a *prima facie* defense that defeats plaintiffs' negligence and punitive damages claims as a matter of law. Preloznik v. City of Madison, 113 Wis. 2d 112 (Ct. App. 1983). In negligence cases, causation consists of two parts: "cause-in-fact" and "proximate cause". McMahon v. St. Croix Falls School District, 228 Wis. 2d 215, 223 (Ct. App. 1999). Cause-in-fact is a jury question and the test is whether the negligence was a substantial factor in causing the harm. Id. (citation omitted). "Proximate cause", the second component of causation in negligence cases, involves public policy considerations and is a question of law solely for judicial determination. Sanem v. Home Ins. Co., 119 Wis. 2d 530, 538 (1984). The public policy reasons for not imposing liability in spite of a finding of negligence as a substantial factor in producing the plaintiff's injury are: (1) the injury is too remote from the negligence; (2) the injury is too wholly out of proportion to the negligent tortfeasor's culpability (3) in retrospect, it appears too highly extraordinary that the negligence should have brought about the harm; (4) allowance of recovery would place too unreasonable a burden on the negligent tortfeasor; (5) allowance of recovery would be too likely to open up the way for fraudulent claims; or (6) allowance of recovery would enter a field that has no sensible or just

stopping point. Id. at 538. The parties agree that the issue of "cause-in-fact", that is, whether Accutane is pharmacologically capable of causing depression and suicide and whether it in fact was substantial factor in causing Samuel's death, is not ripe for determination because of on-going discovery and that that issue is not presently before this court on summary judgment. Generally it is better procedure for a court to submit negligence "cause-in-fact" issues to the jury before addressing public policy issues or legal cause. McMahon, 228 Wis. 2d at 223. However, a circuit court may grant summary judgment and deny recovery on public policy grounds before trial when the pleadings present a public policy question. Id.

Wisconsin courts follow the general rule that "suicide constitutes an intervening force which breaks the line of causation from the wrongful act to the death and therefore the wrongful act does not render the defendant civilly liable." See McMahon, 228 Wis. 2d at 224 citing Bogust v. Iverson, 10 Wis. 2d 129, 137 (1960). A superceding cause is an intervening force that relieves an actor from liability for harm that his negligence was a substantial factor in producing. Id. (citation omitted). The doctrine of superceding and intervening cause is another way of saying that the negligence is too remote from the injury to impose liability. Id. This corresponds with the first public policy factor of Sanem and is the defense that Roche submits entitles it to summary judgment as a matter of law.

McMahon further explains that when suicide results from a "moderately intelligent power of choice," even if the choice is made by a disordered mind or by a morbid mind unable to tolerate pain, inconvenience or humiliation of its particular condition, the suicide is a new and independent cause of death that immediately ensues. McMahon, 228 Wis. 2d at 225 (citations omitted). A recognized exception to this general rule is when the defendant's negligence or wrongful act creates in the deceased an "uncontrollable impulse," a delirium, frenzy or rage,

during which the deceased commits suicide "without conscious volition to produce death." Id. (citation omitted). The exception recognizes a cause of action in which the defendant actually causes the suicide. Id. citing e.g. Bruzga v. PMR Architects, P.C., 693 A.2d 401, 403 (N.H. 1997) and Logarta v. Gustafson, 998 F. Supp. 998, 1004-05 (E.D. Wis. 1998). A suicide resulting from an uncontrollable impulse created by the defendant's wrongful conduct preserves the chain of direct causation. McMahon instructs that this is the only exception to the general rule recognized in Wisconsin. Id. at 228.

Roche contends that it is entitled to summary judgment because Samuel's suicide was volitional and the product of a moderately intelligent power of choice, thereby breaking the causal link between any allegedly negligent act by Roche and Samuel's death. Roche likens the circumstances surrounding Samuel's suicide to those in Logarta. In Logarta, after a gun owner's son gave the victim a loaded gun in exchange for money, the victim discussed shooting himself. The two boys went into a cornfield and before he left, the gun owner's son reminded the victim to think about what he was doing. When the son returned, the victim had been shot. On a motion to dismiss the complaint, the Logarta court concluded that there were no facts alleged in the complaint from which the court could conclude that the suicide resulted from anything but a moderately intelligent power of choice. There were no facts alleging the victim's mental state either before or after the shooting, or alleging that the son's conduct in providing the gun inflicted severe physical or emotional injury. Logarta, 998 F.Supp. at 1006. There were no facts alleging that the victim was deprived of an ability to recognize the nature and likely result of his actions. According to the complaint, the victim calmly asked for the gun, made his suicidal intentions known, selected a location and carried out his intentions.

Roche points to the following circumstances in the instant case, asserting that they demonstrate a similar deliberate frame of mind. Samuel confided in others about his suicidal thoughts and depressed emotional state in the weeks preceding his death. He shared his thoughts with his mother and spoke with a psychiatric nurse who was a family friend. When he returned home from his friend's house on the day of his death, he removed his shoes at the front door as was customary, called his girlfriend to say goodbye, wrote out a suicide note describing his inability to tolerate his psychic pain, walked downstairs to the basement, and hanged himself. Roche argues that from these facts that Samuel's suicide resulted from a moderately intelligent power of choice and that therefore Samuel's suicide was an intervening force between any allegedly negligent act by Roche and Samuel's death.

However, this court examines the exception to the doctrine of superceding and intervening cause that recognizes a cause of action when the defendant's wrongful conduct actually causes the suicide. A suicide resulting from an uncontrollable impulse created by the defendant's wrongful conduct preserves the chain of direct causation. In this case, the gravamen of plaintiffs' claims is that Roche manufactured and distributed a drug capable of producing side effects that included depression leading to suicide ideation and even suicide but failed to provide users of the drug adequate warnings of those particular side effects. In other words, the drug was capable of producing a physical or pharmaceutical reaction that could alter decedent's emotional state and create a mental condition that results in an uncontrollable impulse to commit suicide, not necessarily in a frenzied or delirious way, but in such a way that the decedent could not have decided against or refrained from killing himself. Accordingly, plaintiffs' argument is that the decedent committed suicide as a result of an uncontrollable impulse.

Here, there is evidence in the record that Samuel's mental condition could have been substantially altered by the Accutane he was prescribed for treatment of his acne. Significantly, when Samuel's alarmed mother called Dr. Berg's office to express her concern about Samuel's depression and to inquire whether it could be related to the Accutane, she was advised that there was a possibility of a medical relationship between Samuel's taking the drug and his emotional state. Samuel's mother was instructed to have Samuel stop taking the medication immediately and to discard the remaining medication. There is no evidence in the record that Samuel entertained suicidal thoughts or was depressed before he began his Accutane therapy. Nor does the record demonstrate that Samuel exhibited unusual behavior or that he was struggling with mood changes until he was well into his second course of treatment with Accutane. There is evidence in the record that there was an express warning that accompanied the medication warning of the risk of depression or of changes in mood. Given those facts, Roche has not foreclosed the possibility that Accutane can create a physical reaction that changes an individual's emotional state and can create a mental condition capable of resulting in behavior manifested by uncontrollable impulses. Although Roche urges this court to rule that public policy considerations require relieving Roche of liability as a matter of law because Samuel's suicide was too remote from Roche's alleged negligence and therefore was a superceding intervening cause, the record requires greater factual development in order for this court to reach that determination. Once the facts are more fully developed, once the parties place their cause in fact evidence in the record, it may become more apparent to the court that Samuel's suicide was too remote from Roche's alleged negligence and this court can then consider the public policy argument. However, on the present state of the record, this court concludes that it is not readily apparent that the injury was too remote from the negligence or that it is too extraordinary that the

alleged negligence might have brought about the harm. Roche has not presented sufficient factual basis for resolving the public policy issues. Coffey v. Milwaukee, 74 Wis. 2d 526, 543 (1976). Because Roche has failed to establish as a matter of law that its alleged negligence was too remote from the injury to impose liability, Roche has not met its burden of establishing a *prima facie* defense that defeats plaintiffs' claims 2, 4, 5, and 6 as a matter of law.

B. **Claim 3 –Samuel's Survival Claim**

Claim 3 alleges that Roche's negligence in failing to warn about the risk of depression associated with Accutane use caused Samuel's depression and emotional distress prior to his suicide. Roche contends that it is entitled to summary judgment dismissing this claim under the learned intermediary doctrine because Roche discharged its duty to warn about the risks of depression when it warned Dr. Berg, Samuel's prescribing physician, of the very risk that forms the basis for claim 3.

Claim 3 sounds in negligence as opposed to the strict product liability allegation in Claim 5. Negligence claims consider the manufacturer's behavior and whether a standard of reasonable care was met. Tanner v. Shoupe, 228 Wis. 2d 357, 365 (Ct. App. 1999). A negligence action requires proof of: (1) a duty of care on the part of the defendant; (2) a breach of that duty; (3) a causal connection between the conduct and the injury; and (4) an actual loss or damage as a result of the injury. Morden v. Continental AG, 2000 WI 51, ¶45, 235 Wis. 2d 325. The duty of care is the obligation of due care to refrain from any act which will cause foreseeable harm to others. Id. at ¶46.

The standard of care for a manufacturer of a product is to warn of dangers that he or she knows or should know are associated with the proper use of the product. This duty exists whether or not the product was properly designed. Strasser v. Transtech Mobile Fleet Serv.,

2000 WI 87, ¶58, 236 Wis. 2d 435. The jury instruction for Negligence: Duty of Manufacturer to Warn, provides in part:

A manufacturer of a product has a duty to exercise ordinary care to warn of dangers which he or she knows, or should know, are associated with the proper use of a product. This duty exists whether or not the product was properly designed. "Proper use" means a use which is intended by the manufacturer.

WIS JI-CIVIL 3242 (reflecting adoption of RESTATEMENT (SECOND) OF TORTS §388 (1965)). Thus, inadequate warning can be evidence of negligence on the part of a manufacturer. Haynes v. Am. Motors Corp., 691 F.2d 1268, 1273 (8th Cir. 1982).

Although Wisconsin courts have not addressed the application of the learned intermediary doctrine, courts of numerous other jurisdictions almost universally hold that in the case of prescription drugs, a manufacturer's provision of proper warnings to a prescribing physician will satisfy the manufacturer's duty to warn since the patient cannot obtain the drug except through the physician. Lukaszewicz v. Ortho Pharmaceutical Corp., 510 F.Supp. 961, 962 (E.D. Wis. 1981) (citations omitted).

In support of its defense that it provided legally adequate warnings to Dr. Berg, Roche supplies a copy of the physician package insert that accompanied the drug, the Physician's Desk Reference Manual (PDR) reference to Accutane, the patient information brochure relating to Accutane, and Dr. Berg's affidavit. The physician package insert, published in 1986, contains the following information under a section entitled "Adverse Reactions":

The following CNS reactions have been reported and may bear no relationship to therapy – seizures, emotional instability, dizziness, nervousness, drowsiness, malaise, weakness, insomnia, lethargy and paresthesias.

Depression has been reported in some patients on Accutane therapy. In some of these patients this has subsided with discontinuation of therapy and recurred with reinstitution of therapy.

The 1995 and 1996 PDR references on Accutane contain the identical 1986 language as the physician package insert. The patient information brochure, published by Roche in 1987, contains the following information:

For All Patients

If you have a family or personal history of medical conditions such as diabetes, liver disease, heart disease or depression please inform your doctor.

YOU SHOULD BE AWARE THAT ACCUTANE MAY CAUSE SOME LESS COMMON, BUT MORE SERIOUS SIDE EFFECTS. BE ALERT FOR ANY OF THE FOLLOWING:

CHANGES IN MOOD

IF YOU EXPERIENCE ANY OF THESE SYMPTOMS OR ANY OTHER UNUSUAL OR SEVERE PROBLEMS DISCONTINUE TAKING ACCUTANE AND CHECK WITH YOUR DOCTOR IMMEDIATELY. THEY MAY BE THE EARLY SIGNS OF MORE SERIOUS SIDE EFFECTS WHICH, IF LEFT UNTREATED, COULD POSSIBLY RESULT IN PERMANENT EFFECTS.

Based upon this evidence, this court concludes that as of 1996, Roche's materials informed treating physicians, including Dr. Berg, of the risk of depression from the use of Accutane.

Plaintiffs, however, contend that Roche's warning was not legally adequate because, given Roche's knowledge of the drug's side effects in 1995 and 1996, it failed to advise treating physicians of the severity of the risk of depression, that is, that it could induce a depression so severe that it could lead to suicidal thoughts, attempts and suicide. Roche first challenges plaintiffs' argument by asserting that plaintiffs are now "rewriting" claim 3 because that claim only relates to depression, not suicide. Claim 3 states that Roche's negligence caused Samuel's depression, loss of enjoyment of life, and emotional distress prior to his death to such a degree of severity that he was driven to end his life. Contrary to Roche's argument, the allegation sufficiently describes a severity of depression leading to suicide and that the alleged negligence,

as described in the prior claims, is that Roche's warnings inadequately described that severity of depression.

Plaintiffs support their summary judgment response with the affidavit of *pro hac vice* Attorney Perkins. Her affidavit supplies numerous exhibits that are copies of documents published on the United State House of Representatives and the Federal Food and Drug Administration websites. Roche challenges the admissibility of these documents as hearsay. Without first addressing the hearsay challenge, most of the documents have little probative value as to the state of Roche's knowledge of Accutane's risk for inducing severe depression that could lead to suicide or as to the adequacy of the warning in that regard prior to 1997. The majority of exhibits deal with label changes, Roche's state of knowledge, studies completed, FDA advisories and correspondence all after Samuel's January 1997 suicide. Exhibit 2 appears to be a 1998 FDA memorandum providing results of an FDA review of a spontaneous base reporting system in which suicide or suicide attempts were mentioned in association with Accutane therapy between 1985 and 1996. Even if this FDA document was admissible as a public record pursuant to Wis. Stat. § 908.03(8), there is no evidence presented establishing that Roche was aware of or provided these spontaneous reports prior to 1997. The FDA memo indicates only that the data was presented to the Division of Dermatologic and Dental Drug Products in January 1998. Two other exhibits, exhibits 1 and 11, purport to bear on Roche's state of knowledge prior to Samuel's death in 1997. These exhibits provide a chronology of Accutane related events. They describe a required change to the French labeling of Accutane/Roaccutane in March 1997 after a 1992-1994 French study showed users suffered from severe depression and suicidal ideation. The label change required "suicide attempt" to be added to Accutane's side effects. Exhibit 11 states that Roche did not inform the FDA of the new French warning, however, only two months

later in May 1997, the FDA began discussions with Roche concerning reports of serious psychiatric disorders associated with Accutane. According to the exhibit, the FDA did not become aware of the French labeling change, the prior French study, or that Roche did not disclose this information to the FDA until July 1998. Exhibits 1 and 11, and in particular the information described above that is contained therein, are inadmissible hearsay lacking foundation. They are collections of statements about Accutane, being offered to prove the truth of the matters asserted, coming from a congressman's web page with no discernible underlying sources for the statements. Any underlying documentation establishing the existence of the French study, the French order requiring the labeling change to include suicide attempt, or that the FDA was uninformed of this information is entirely absent. The fact that this chronology comes from a congressman's web page does not make it a public record hearsay exception because there is no indication the document was generated as part of the activity of the office or that it constitutes "matters observed pursuant to duty imposed by law." Wis. Stat. §908.03(8). Therefore, this court will not consider these exhibits as they are not admissible evidence as required under Wis. Stat. §802.08(3), the summary judgment statute. Plaintiffs' submissions in opposition to Roche's summary judgment motion on Claim 3 offer no admissible factual basis to support their argument that Roche failed to advise treating physicians of the severity of the risk of depression, that is, that it could induce a depression so severe that it could lead to suicidal thoughts, attempts and suicide.

Plaintiffs also urge this court to apply an exception to the learned intermediary doctrine where there is direct-to-consumer advertising by the drug manufacturer. This exception has been addressed by only a few jurisdictions and is recognized in RESTATEMENT (THIRD) OF TORTS:PRODUCTS LIABILITY §6(d) and comments b and e. Plaintiffs, however, have not

alleged that Accutane was advertised directly to consumers and their submissions fail to provide any evidence that Accutane was directly marketed to consumers. Therefore, this argument fails. Because plaintiffs' have not met their burden of overcoming Roche's learned intermediary doctrine defense, Roche's motion for summary judgment on Claim 3 is granted.

II. DR. BERG'S SUMMARY JUDGMENT MOTION

Dr. Berg moves for summary judgment solely on the grounds that suicide is an intervening and superceding force that breaks the chain of causation and precludes claims of negligence against Dr. Berg. Berg's argument mirrors that made by Roche. This court applies its same reasoning to Dr. Berg's motion and therefore the motion is denied.

ORDER

For the reasons stated above and based on the record herein, Roche's motion for summary judgment on claims 2, 4, 5, and 6 is denied. Roche's motion for summary judgment dismissing claim 3 is granted. Dr. Berg's motion for summary judgment is denied.

DATED: January 6, 2003.

BY ORDER OF THE COURT:

Sarah B. O'Brien, Judge
Circuit Court, Branch 16

Stupak v. Hoffman-La Roche, Inc.

United States District Court for the Middle District of Florida, Tampa Division
August 17, 2007, Decided; August 17, 2007, Filed
Case No. 8:05-cv-926-T-30TBM

Reporter: 2007 U.S. Dist. LEXIS 60498; 2007 WL 2350561

LAURIE A. STUPAK, Plaintiff, v. HOFFMAN-LA ROCHE, INC., et al., Defendants.

Subsequent History: Partial summary judgment granted by *Stupak v. Hoffman La Roche, Inc., 2007 U.S. Dist. LEXIS 71328 (M.D. Fla., Sept. 26, 2007)*

Prior History: *In re Accutane Prods. Liab., 511 F. Supp. 2d 1288, 2007 U.S. Dist. LEXIS 43690 (M.D. Fla., 2007)*

Core Terms

suicide, warning, prescribed, summary judgment, depression, patients, nonmoving, acne

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Judges: JAMES S. MOODY, JR., UNITED STATES DISTRICT JUDGE.

Opinion by: JAMES S. MOODY, JR.

Opinion

ORDER

THIS CAUSE comes before the Court upon Defendants Hoffman-La Roche, Inc.'s and Roche Laboratories Inc.'s Motion for Summary Judgment on Warning Adequacy (Dkt. 71), Plaintiff's Response in opposition to the same (Dkt. 84) and Defendants Reply (Dkt. 86). Upon review of the memoranda and hearing oral argument, the Court determines Defendants' motion should be **granted:**

BACKGROUND

This case arises out of the design, labeling, **[*2]** and sale of Accutane, a prescription acne medication manufactured by the Defendants. Plaintiff alleges Defendants failed to adequately warn physicians and patients of the risks of depression and suicide associated with Accutane use, and as a result, her son, Bartholomew Stupak, Jr. (hereinafter "BJ"), committed suicide after taking Accutane.

BJ was first treated by Dr. Micheal Smullen on April 2, 1998, for a mild form of acne. His acne subsequently worsened and Dr. Smullen

prescribed antibiotic and corticosteriod treatments. By December 7, 1999, BJ's acne again worsened and became unresponsive to prior treatments. Dr. Smullen recommended and prescribed Accutane for BJ's cystic acne as it was unresponsive to conventional medications.

In February 1998, two years prior to BJ's use of Accutane, the physician package insert for Accutane was amended to include the following warnings concerning the risk of psychiatric side effects:

> **WARNINGS:** ***Psychiatric Disorders:*** **Accutane may cause depression, psychosis, and, rarely, suicidal ideation, suicide attempts, and suicide. Discontinuation of Accutane therapy may be insufficient; further evaluation may be necessary. No mechanism of action has been [*3] established for these events (see ADVERSE REACTIONS).**
>
> . . .
>
> **ADVERSE REACTIONS:. . .**
>
> In the post-marketing period, a number of patients treated with Accutane have reported depressions, psychosis, and rarely, suicidal ideation, suicide attempts and suicide. Of the patients reporting depressions, some reported that the depression subsided with discontinuation of therapy and recurred with reinstitution of therapy (see WARNINGS).
>
> . . .
>
> The following CNS side effects have been reported and may bear no relationship to therapy -seizures, emotional instability including depression, dizziness, nervousness, drowsiness, malaise, weakness, insomnia, lethargy and paresthesias.

(Dkt. 71 at Exhibit A) (emphasis in original). The physician package insert was also included in the 1999 edition of the Physician's Desk Reference. *Id.* at exhibit D. [1]

In prescribing medication, Dr. Smullen testified that he regularly reviews the information provided to him by the manufacturers **[*4]** of the drugs as well as the Food and Drug Administration (hereinafter "FDA") approved labeling for the medications. (Dkt. 71-8 at 5). While Dr. Smullen does not acknowledge being aware of Defendants' warning about suicide, he was aware of the published reports regarding depression and suicide experienced by Accutane users. *Id.* at 6-7. Notwithstanding, Dr. Smullen testified Accutane is very effective medication in the treatment of severe cystic nodular acne, the type from which BJ was suffering, and he continues to prescribe Accutane in his practice. *Id.* at 22. Moreover, he testified even if he had known about the adverse drug effect reports, he still would have prescribed Accutane to BJ. *Id.* at 33, 34.

DISCUSSION

A. *Summary Judgment Standard.*

Summary judgment is appropriate only when there are no genuine issues of material fact and the movant is entitled to judgment as a matter of law. *See* Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). The moving party bears the burden of meeting this rather exacting standard. *See Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157, 90 S. Ct. 1598, 26 L. Ed. 2d 142 (1970). In applying this framework, the evidence, and all reasonable factual inferences drawn therefrom, **[*5]** must be viewed in the light most favorable to the nonmoving party. *See Arrington v. Cobb County*, 139 F.3d 865, 871 (11th Cir.1998); *Allen v. Tyson Foods, Inc.*, 121 F.3d 642, 646 (11th Cir.1997).

Equally clear, however, is the principle that the nonmoving party bears the burden of coming

[1] Information regarding Accutane had also been previously provided to the Stupak family when Dr. Smullen prescribed Accutane to B.J's older brother Ken. Based on Ken's prior successful use of the drug, Dr. Smullen suggested the treatment for B.J.

forward with evidence of each essential element of their claims, such that a reasonable jury could find in his or her favor. *See Earley v. Champion Int'l Corp.*, 907 F.2d 1077, 1080 (11th Cir. 1990). The nonmoving party "[m]ay not rest upon the mere allegations and denials of [its] pleadings, but [its] response ... must set forth specific facts showing that there is a genuine issue for trial." *Fed.R.Civ.P. 56(e)*. "The mere existence of a scintilla of evidence in support of the [nonmovant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmovant]." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); *see also LaChance v. Duffy's Draft House, Inc.*, 146 F.3d 832, 835 (11th Cir.1998) ("Summary judgment may be granted if the evidence is 'merely colorable.'") (quoting *Anderson*, 477 U.S. at 248, 106 S.Ct. 2505). Further, **[*6]** and significantly, mere conclusory, uncorroborated allegations by a plaintiff in an affidavit or deposition will not create an issue of fact for trial sufficient to defeat a well-supported motion for summary judgment. *See Earley*, 907 F.2d at 1081. The failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial and requires the court to grant the motion for summary judgment. *See Celotex*, 477 U.S. at 322.

Defendants are seeking summary judgment on two grounds: (1) the warnings provided to BJ's treating physician clearly, adequately and unambiguously warned of the specific injury complained of by Plaintiff, i.e. suicide; and (2) BJ's suicide was not proximately caused by the Defendants' failure to warn.

B. Adequacy of Warnings.

"As a general rule the courts of this country universally hold that in the case of prescription drugs, the provision of proper warnings to a physician will satisfy the manufacturer's duty to warn since the patient cannot obtain the drug but through the physician." *Lukaszewicz v. Ortho Pharmaceutical Corporation*, 510 F. Supp. 961, 963 (E.D. Wisc. 1981). In determining whether a warning is adequate, a **[*7]** court must consider several factors including "whether the warning is accurate, clear, consistent on its face, and whether it portrays with sufficient intensity the risk involved in taking the drug." *Golod v. Hoffman La Roche*, 964 F. Supp. 841, 853 (S.D.N.Y. 1997). Plaintiff argues that the warnings provided to Dr. Smullen were inadequate because they did not advise that the use of Accutane could result in suicide without prior signs of depression, i.e., that Accutane patients could commit suicide spontaneously or impulsively.

In order for a warning to be adequate, it "must be commensurate with the risk involved in the ordinary use of the product." *Golod*, 964 F. Supp. at 854 (citations omitted). Additionally, the language of the warning must be "direct, unequivocal and sufficiently forceful to convey the risk." *Id.* As detailed above, the package inserts provided at the time Accutane was prescribed to BJ identify as possible side effects the possibility of suicide, suicidal ideation and suicide attempts with the use of Accutane. While the warning does not specifically warn of spontaneous or impulsive suicide, it does warn of the precise adverse effect suffered by B.J. (suicide) and the **[*8]** seriousness of the effect. Suicide is often spontaneous or impulsive. Those words do not make the word suicide any stronger or clearer. Moreover, the warning on the insert is presented in conspicuous bold face lettering. The warnings portray with sufficient intensity the risk involved in taking the drug. Therefore, Defendants' Motion for Summary Judgment will be granted.

C. *Proximate Cause.*

In addition to establishing a duty and failure to warn, Plaintiff must also establish proximate cause. *See Kurer v. Parke, Davis & Company*, 2004 WI App 74, 272 Wis. 2d 390, 409, 679 N.W.2d 867 (Wis. App. 2004). In order to establish proximate cause, Plaintiff must "generally demonstrate that had appropriate warnings been given, the treating physicians would not have prescribed or would have discontinued use of the drug." *Golod*, 964 F. Supp. at 857; *Kurer*, 272 Wis. 2d at 410. Plaintiff can present no such evidence. While Dr. Smullen testi-

fied he not aware of case reports of adverse drug effects reporting suicide which Defendants concluded were probably associated with Accutane, (Dkt. 71-8 at 33), he did testify that even if he had known of the case reports reporting suicide, he still would have prescribed Accutane for BJ:

> Q: If you **[*9]** had known at the time that you prescribed Accutane to BJ that there were adverse drug effects reporting suicide in which Roche concluded that were probably related to Accutane, would you have still prescribed Accutane for BJ Stupak in December of '99?
>
> . . .
>
> THE WITNESS: The answer would be, yes.

(Dkt. 71-8 at p. 33). Additionally, Dr. Smullen testified that even if he knew Accutane could cause suicide without depression preceding suicide, he would still be comfortable prescribing the drug:

> Q: Okay. Dr. Smullen, do you have any understanding as to whether or not Accutane can cause suicide without depression preceding the suicide?
>
> . . .
>
> THE WITNESS: I'm not aware of it.
>
> . . .
>
> Q: Assuming that it could, would you still feel comfortable in prescribing Accutane to an adolescent that could cause him to commit suicide? Would you feel comfortable in doing that?
>
> . . .
>
> THE WITNESS: The answer is yes.

Id. at 36. In fact, Dr. Smullen stated that, even after the death of his patient, B.J. Stupak, he still prescribes Accutane to his patients:

> Q: Do you continue to use Accutane in your practice today, Doctor:
>
> A: Yes, I do.

Id. at 22; and that his discontinuation in usage would only occur with the removal of Accutane **[*10]** from the market:

> Q: Okay. Is there any type of -- can you give me an example of any type of warning that you would have to get from Roche so that you would stop prescribing Accutane?
>
> . . .
>
> THE WITNESS: Remove it from the market.

Id. at 36-37. Plaintiff has presented no evidence to refute Dr. Smullen's testimony. Accordingly, summary judgment is appropriate on this ground as well.

It is therefore ORDERED AND ADJUDGED that Defendants Hoffman-La Roche, Inc.'s and Roche Laboratories Inc.'s Motion for Summary Judgment on Warning Adequacy (Dkt. 71) is **GRANTED.**

DONE and **ORDERED** in Tampa, Florida on August 17, 2007.

JAMES S. MOODY, JR.

UNITED STATES DISTRICT JUDGE

Slip Copy, 2013 WL 695817 (E.D.Wis.)
(Cite as: 2013 WL 695817 (E.D.Wis.))

United States District Court,
E.D. Wisconsin.
Jeffrey Joseph MAYNARD, Plaintiff,
v.
ABBOTT LABORATORIES, Defendant.

No. 12–C–0939.
Feb. 26, 2013.

Jeffery Joseph Maynard, Combined Locks, WI, pro se.

Jonathan T. Smies, Douglas M. Poland, Godfrey & Kahn SC, Milwaukee, WI, Andrew P. Bautista, Jennifer S. Atkins, Michael P. Foradas, Renee D. Smith, Kirkland & Ellis LLP, Chicago, IL, for Defendant.

DECISION AND ORDER DENYING RULE 12(b)(6) MOTION TO DISMISS

WILLIAM C. GRIESBACH, Chief Judge.

***1** Plaintiff Jeffrey Joseph Maynard brought this *pro se* failure-to-warn action, alleging he suffered neurological damage from using Humira, a prescription drug manufactured by Defendant Abbott Laboratories. Plaintiff took Humira over the course of several years to treat rheumatoid arthritis, but stopped using the drug after he began experiencing symptoms of vision loss, optic neuritis, and multiple sclerosis. Defendant filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that plaintiff's complaint should be dismissed for failure to state a claim upon which relief can be granted because his failure-to-warn claim is directly contradicted by the FDA-approved pharmaceutical warning label. Defendant argues that Humira's label has at all times specifically warned of the potential association between use of Humira and neurological side effects including development of a demyelinating disease such as multiple sclerosis or vision problems. For the reasons that follow, defendant's motion will be denied.

BACKGROUND

Plaintiff began taking Humira to treat rheumatoid arthritis in October 2003. Humira is a TNF blocker generally prescribed for people with moderate to severe rheumatoid arthritis to reduce symptoms such as pain and swollen joints and to prevent further damage to bones and joints. (Poland Decl., Ex. 1 at 23, ECF No. 9–1 .) The Federal Drug Administration (FDA) initially approved Humira in December 2002.

Plaintiff took Humira "on a continuous basis" between 2003 and 2009. (Compl.5.) On September 16, 2009, plaintiff began experiencing extreme and sudden vision loss in his left eye. (Compl .5.) He had difficulty with coordination and with keeping his balance while walking. (Compl.6.) After several examinations and tests, doctors determined he was suffering from demyelination disease resulting from his Humira use, and he exhibited symptoms of optic neuritis and multiple sclerosis. (Compl.5–6.) After plaintiff was taken off the drug, his symptoms did not progress, but he has not regained vision in his left eye. (Compl.6–7.) He alleges that while similar brands of TNF blocking drugs warned of optic nerve damage and demyelinating disease, Humira's label downplayed or omitted any mention of the severity of these neurological risks. (Compl.6.) Plaintiff contends that the warnings included in the Humira label were inadequate. Under "WARNINGS" the October 2003 Humira label states:

Neurologic Events

Use of TNF blocking agents, including HUMIRA, has been associated with rare cases of exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease. Prescribers should exercise caution in considering the use of HUMIRA in

> patients with preexisting or recent-onset central nervous system demyelinating disorders.
> (Poland Decl., Ex. 1 at 13, ECF No. 9–1.) In 2005, this warning was updated to state that in addition to being associated with rare cases of exacerbation of clinical symptoms and/or radiographic 2 evidence of demyelinating disease, use of Humira has also been associated with rare cases of new onset of such symptoms. (Poland Decl., Ex. 5 at 12–13, ECF No. 20–1.)

*2 Under "ADVERSE REACTIONS" the label states that the most serious adverse reactions include "neurologic events" and refers to the neurologic events explained in the warnings section. (Poland Decl., Ex. 1. at 16, ECF No. 9–1.) Under "Other Adverse Reactions," the label lists multiple sclerosis and cataracts among the "infrequent serious adverse events occurring at an incidence of less than 5% in patients treated with HUMIRA." (Poland Decl., Ex. 1. at 20, ECF No. 9–1.)

Likewise, the Humira patient insert warns that patients should tell their doctor before starting to take Humira if they have experienced "any numbness or tingling or have or have ever had a disease that affects [the] nervous system like multiple sclerosis." It also states:

> Any medicine can have side effects. Like all medicines that affect your immune system, HUMIRA can cause serious side effects. The possible serious side effects include:
>
> * * *
>
> *Nervous system diseases:* There have been rare cases of disorders that affect the nervous system of people taking HUMIRA or other TNF blockers. Signs that you could be experiencing a problem affecting your nervous system include: numbness or tingling, problems with your vision, weakness in your legs and dizziness.
>
> (Poland Decl., Ex. 1 at 24, ECF No. 9–1.)

Plaintiff alleges that the warnings provided were not adequate and therefore prevented him from making a well-informed decision about whether to take the drug and for how long. Plaintiff alleges that the label fails to warn about the "very serious potential side effects" of taking Humira, including deterioration of the optic nerves. (Compl.6.) Had he known the full extent of the possible side effects, he could have made a decision to stop taking Humira sooner, and his injuries would have been less serious. (Compl.6–7.) He alleges that his vision problems have caused numerous other injuries, including balance problems, headaches, and dizziness. He also suffered a compound fracture, acute renal failure, and a concussion after falling due to his vision loss. (Compl.6.) He also states that he will continue to require ongoing medical attention for his injuries resulting from his Humira use. Plaintiff contends that defendant knew or should have known that Humira posed risks to consumers but continued to manufacture and market the drug without adequately disclosing the alleged dangers it posed.

LEGAL STANDARD

Dismissal under Rule 12(b)(6) is proper "when the allegations in a complaint, however true, could not raise a claim of entitlement to relief." *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 558 (2007). To state a claim, a complaint must contain sufficient factual matter "that is plausible on its face." *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009) (quoting *Twombly,* 550 U.S. at 570). "[T]he plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009). To survive dismissal, a plaintiff "must plead some facts that suggest a right to relief that is beyond the 'speculative level.' " *Atkins v. City of Chicago,* 631 F.3d 823, 832 (7th Cir.2011) (quoting *In re marchFIRST Inc.,* 589 F.3d 901, 905 (7th Cir.2009)). In considering

a motion to dismiss, the court construes the allegations in the complaint in the light most favorable to the plaintiff, accepts all well-pleaded facts as true, and draws all inferences in favor of the non-moving party. *Estate of Davis v. Wells Fargo Bank,* 633 F.3d 529, 533 (7th Cir.2011). In addition, the court construes *pro se* complaints liberally. *Erickson v. Pardus,* 551 U.S. 89, 93 (2007).

***3** In deciding a motion to dismiss, district courts have discretion to consider certain documents outside the pleadings without converting the motion under Rule 12(b)(6) to a motion for summary judgment under Rule 56. *Levenstein v. Salafsky,* 164 F.3d 345, 347 (7th Cir.1998). In particular, documents submitted with a motion to dismiss may be considered part of the pleadings if they are "referred to in the plaintiff's complaint and are central to his claim." *188 LLC v. Trinity Indus., Inc.,* 300 F.3d 730, 735 (7th Cir.2002) (internal quotation marks omitted); *see also Brownmark Films, LC v. Comedy Partners,* 682 F.3d 687, 690 (7th Cir.2012) ("[T]he incorporation-by-reference doctrine provides that if a plaintiff mentions a document in his complaint, the defendant may then submit the document to the court without converting the defendant's 12(b)(6) motion to a motion for summary judgment.").

ANALYSIS

A. Subject Matter Jurisdiction

As an initial matter, plaintiff has made no mention of the Court's basis for jurisdiction, and defendant has likewise not raised the issue. Nevertheless, I address the issue *sua sponte. Hay v. Indiana State Bd. of Tax Com. Rs.,* 312 F.3d 876, 879 (7th Cir.2002) ("[N]ot only may the federal courts police subject matter jurisdiction *sua sponte,* they must."). A complaint must contain "a short and plain statement of the grounds for the court's jurisdiction." Fed.R.Civ.P. 8(a)(1). But a "document filed *pro se* is to be liberally construed and a *pro se* complaint, however inartfully pleaded, must be held to less stringent standards than formal pleadings drafted by lawyers." *Erickson v. Pardus,* 551 U.S. 89, 94 (2007). A court may assume jurisdiction where a *pro se* plaintiff has failed to include a jurisdictional statement if it is otherwise clear from the context the source from which jurisdiction arises. *Smoot v. Mazda Motors of Amer., Inc.,* 469 F.3d 675, 677 (7th Cir.2006) (finding amount in controversy requirement met for purposes of diversity jurisdiction based on the severity of the injuries alleged, including medical treatment and permanent injuries related to a jaw injury).

Here, I am satisfied that this Court has diversity jurisdiction pursuant to 28 U.S.C. § 1332. Plaintiff alleges that he is a citizen of Wisconsin and that defendant has its principal place of business in Illinois. It appears defendant is incorporated in Illinois as well. *See Abbott Laboratories v. CVS Pharmacy, Inc.,* 290 F.3d 854, 857, n. 2 (7th Cir.2002). In addition, the amount in controversy requirement is met based on the severity of the injuries alleged by plaintiff, including medical expenses, damages, and pain and suffering related to his alleged permanent vision loss and related symptoms resulting from neurological damage caused by taking Humira.

B. Failure to Warn

With regard to the substance of plaintiff's complaint, defendant argues that plaintiff's failure-to-warn claim must be dismissed because the complaint does not state a plausible ground for relief. Under Wisconsin law, a failure to warn claim or a strict liability claim regarding pharmaceutical labeling requires proof of (1) the existence of a duty to warn; (2) a failure to warn adequately; (3) causation; and (4) actual damages resulting from the injury. *Kessel v. Stansfield Vending, Inc.,* 2006 WI App. 68, ¶ 15, 291 Wis.2d 504, 714 N.W.2d 206. Manufacturers have a duty to warn consumers of dangers that they know or should know are associated with the proper use of a product. *Strasser v. Transtech Mobile Fleet Service, Inc.,* 2000 WI 87, ¶ 58, 236 Wis.2d 435, 459, 613 N.W.2d 142, 154.

***4** Generally, the adequacy of a warning presents a factual issue for a jury. *Gracyalny v. Westinghouse Elec. Corp.*, 723 F.2d 1311, 1321 (7th Cir.1983) (citing *Schuh v. Fox River Tractor Co.*, 63 Wis.2d 728, 218 N.W.2d 279 (Wis.1974)); *Kurer v. Parke, Davis & Co.*, 2004 WI App 74, ¶ 24, 272 Wis.2d 390, 409, 679 N.W.2d 867, 876. The adequacy of a warning depends upon all the circumstances, taking into account factors such as whether the warning is accurate, strong, and clear. *Schuh,* 63 Wis.2d at 739, 218 N.W.2d at 285. "The clarity of any warnings that were provided is also important; accompanying a warning with misleading representations of safety may serve to render the warning inadequate." *Gracyalny,* 723 F.2d at 1321. Any ambiguity in the language of a warning "is to be construed against the one who chose the words used." *Schuh,* 63 Wis.2d at 739, 218 N.W.2d 279 at 285 (quotations omitted).

Plaintiff concedes that the Humira label provided warnings regarding the potential association between the use of Humira and certain neurological side effects including demyelinating disease, multiple sclerosis, and vision problems. Defendant asserts that as a result, the express warnings in the Humira label directly contradict the allegations in plaintiff's complaint that the label lacked sufficient warnings. However, while plaintiff does not dispute that the label contained warnings, he contends that the warnings were not adequate. He argues the warnings were misleading in that they omitted material information regarding the severity of the potential side effects and were not clear in explaining that patients without preexisting neurological conditions could also be at risk.

In particular, plaintiff argues that the Humira label's "WARNINGS" section only cautioned of risks of neurologic events for people with preexisting symptoms of a demyelinating disorder. Plaintiff alleges that the label thus "made the drug sound safe" for people without such preexisting symptoms. (Pl.'s Br. 1, ECF No. 18.) He states he did not have a recent onset of central nervous system demyelination disorder such as multiple sclerosis or symptoms such as numbness or tingling; as a result, he relied on the label in believing that the neurological side effects warned of would not affect him. Defendant contends that the label clearly warned of the risks of neurological conditions in all patients, and in any case, the label was changed in 2005 to warn that rare cases of "new onset" of demyelinating disease have also occurred in patients taking Humira. (Def.'s Reply Br. 4, ECF No. 19.) But plaintiff's reading of the label is also plausible; the warning regarding adverse neurological side effects reasonably appears to be applicable only to patients with preexisting demyelinating disorders or other existing symptoms of central nervous system disorders. At the very least, before 2005, the WARNINGS section of the label was arguably unclear.

***5** Plaintiff also argues that the label inadequately warned about the risks of developing optic neuritis or other permanent optic nerve damage. He claims that while the label warned that Humira users have developed rare cases of disorders affecting the nervous system, it only warned that signs that a person could be experiencing such problems included "problems with your vision." Plaintiff alleges that his vision loss was sudden, and by the time his doctors diagnosed the problem, his vision impairment was permanent. Plaintiff's contention that the label was misleading is plausible. The patient insert warns that a person taking Humira should seek medical attention if they begin to experience certain "rare" side effects such as vision problems. However, the insert and the label fail to alert patients that permanent vision impairment or optic neurosis are potential risks of taking Humira. *See Schuh,* 63 Wis.2d at 739, 218 N.W.2d at 284–85 ("Implicit in the duty to warn is the duty to warn with a degree of intensity that would cause a reasonable man to exercise for his own safety the caution commensurate with the potential danger." (quotations omitted)).

Plaintiff also alleges that as early as January 2002, other companies manufacturing TNF blocking drugs

prescribed for treating rheumatoid arthritis contained labels warning that optic neuritis was a side effect, and therefore, it can be inferred that defendant should have been on notice that optic neuritis and vision loss were risks. (Pl.'s Reply Br., Ex. A at 13, ECF No. 18–1; *Id.*, Ex. B at 9, ECF No. 18–2.) Drug manufacturers "have an affirmative duty to add new warnings to drug labels 'as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.' " *Forst v. SmithKline Beecham Corp.*, 602 F.Supp.2d 960, 967 (E.D.Wis.2009) (quoting 21 C.F.R. § 201.80(e)). Moreover, proof of compliance with FDA regulations does not necessarily insulate a defendant from liability; consequently, the fact that Humira's label was FDA-approved at all times relevant here does not in itself defeat plaintiff's claims. *Id.; Kurer,* 2004 WI App 74, ¶ 21. If what plaintiff alleges is true, and the risks of developing optic nerve damage associated with repeated use of Humira were known among manufacturers of TNF blockers such as Humira, then a reasonable fact-finder could determine that defendant had a duty to warn of these risks.

Defendant also contends that plaintiff's complaint should be dismissed because the Seventh Circuit Court of Appeals has rejected a similar failure-to-warn claim regarding Humira's label. *Cowley v. Abbott Labs., Inc.*, 476 F.Supp.2d 1053, 1060–61 (W.D.Wis.2007). But in *Cowley,* the court was applying North Carolina law and its decision relied on the application of the learned intermediary doctrine. *Id.* Under that doctrine, the court found that the label satisfied the defendant's duty to warn because it provided information regarding the risks and side effects to the patient's physician who testified he had been adequately warned of the adverse effects of the drug. *Id.* Wisconsin does not apply the learned intermediary doctrine, and as a result, Cowley is also not dispositive here.

***6** In sum, defendant's contention that plaintiff has failed to assert a plausible theory establishing that the warnings were not adequate cannot be sustained. Accepting the complaint's allegations as true, and considering the allegations in light of the label, plaintiff has alleged enough facts to assert a plausible claim for relief. At least at this stage of the proceeding, it is arguable that the label's warning was not adequate.

CONCLUSION

For the reasons set forth herein, plaintiff has stated a plausible claim upon which relief may be granted. Accordingly, defendant's motion to dismiss plaintiff's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) is **DENIED.** The Clerk will set this matter on the Court's calendar for a Rule 16 scheduling conference.

E.D.Wis.,2013.
Maynard v. Abbott Laboratories
Slip Copy, 2013 WL 695817 (E.D.Wis.)

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