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Combating Off-Label Drug Use with a Tort Modernization Solution

*By David Tobias**

I. Introduction

It is common practice for doctors to prescribe drugs for uses that have not been approved by the FDA, a phenomenon known as "off-label" use. In fact, at least 20% of all drug prescriptions are off-label,[1] and some scholars quote figures as high as 60%.[2] In the fields of oncology and psychiatry, off-label drug use is even higher.[3] This practice has significant pros and cons. Many healthcare providers and patients consider off-label

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[1] Richard Epstein & Ryan Abbott, FDA Involvement in Off-Label Use: Debate Between Richard Epstein & Ryan Abbott, 44 SW. UNIV. L. REV. 1, 8 (2015).

[2] James B. Riley, Jr. & P. Aaron Basilius, *Physicians' Liability for Off-Label Prescriptions*, HEMATOLOGY & ONCOLOGY NEWS & ISSUES, May/June 2007, 24–27, 24 (2007).

[3] Epstein & Abbott, *supra* note 1, at 8 (oncology); Nicholas Christoff, *Drugs, Greed and a Dead Boy*, N.Y. TIMES, Nov. 5, 2015, http://www.nytimes.com/2015/11/05/opinion/drugs-greed-and-a-dead-boy.html (phsychiatry).

use necessary in order to get drugs to patients who need them.[4] However, off-label drug use correlates with significant increases in adverse drug effects for patients, especially when the use is not supported by significant scientific research,[5] and it has caused significant harm to the public.[6] In order to stop these negative effects without stifling off-label drug use's benefits, this article proposes a two-part solution that will encourage physicians to prescribe and administer off-label drugs in accordance with society's expectations of safety.[7]

This article approaches the problem posed by off-label drug use through a medical malpractice litigation perspective. Part I of the proposed solution is that courts change the standard of care for the physician in medical malpractice cases where the key issue is harm arising from off-label drug use. In those cases, in order to meet the standard of care, a doctor prescribing an off-label drug must obtain reliable, up-to-date information from sources other than word-of-mouth. This rule accounts for the added risks[8] of off-label drug use and requires

[4] Epstein & Abbott, *supra* note 1, at 5–6.

[5] Tewodros Eguale, et al., *Association of Off-Label Drug Use and Adverse Drug Events in an Adult Population*, JAMA INTERNAL MEDICINE (Nov. 2, 2015), http://archinte.jamanetwork.com/article.aspx?articleid=2467782.

[6] *See* Kate Cohen, *Fen Phen Nation*, PBS.ORG: FRONTLINE, A DANGEROUS PRESCRIPTION (Nov. 13, 2003), http://www.pbs.org/wgbh/pages/frontline/shows/prescription/hazard/fenphen.html (Fen Phen off-label use causes heart disease); Jerry Avorn & Aaron Kesselheim, *A Hemorrhage of Off-Label Use*, ANNALS OF INTERNAL MEDICINE, Apr. 11, 2011 (rFVIIa was prescribed off-label 97% and was found not to decrease mortality but to increase thromboembolism in patients); Sandra G. Boodman, *Off-Label Use of Risky Antipsychotic Drugs Raises Concerns*, KAISER HEALTH NEWS, Mar. 12, 2012, http://khn.org/news/off-label-use-of-risky-antipsychotic-drugs/.

[7] *See* Epstein & Abbott, *supra* note 1, at 11–12 (discussing the problems with FDA regulation).

[8] Eguale, et al., *supra* note 5; *see* Richardson v. Miller, 44 S.W.3d 1, 15 (Tenn. Ct. App. 2000); Staudt v. Froedtert Mem'l Lutheran Hosp., 580 N.W.2d 361, 363 (Wis. Ct. App. 1998).

doctors to be cognizant of this increased risk regardless of the widespread nature of a particular off-label use.[9] Therefore, regardless of whether off-label use of a particular drug has come to prominence, a doctor must become educated on safe off-label uses in order to meet the medical standard of care.[10]

Part II of this proposal is that, in this type of malpractice litigation, the burden of establishing that the off-label use was consistent with the medical standard of care should fall on the physician. This would increase the prescribing doctors' cognizance of the cautionary steps they should take in order to ensure that the use is consistent with the standard of care. By relying on the principles of tort modernization[11] and the rules of

[9] *Richardson*, 44 S.W.3d at 15; *Staudt*, 580 N.W.2d at 363.

[10] The standard of care for doctors in medical malpractice cases is the "reasonable skill and care as are commonly had and exercised by reputable, average physicians in the same general system or school of practice." Richard N. Pearson, *The Role of Custom in Medical Malpractice Cases*, 51 IND. L.J. 528, 528 (1976).

[11] For the purposes of this article, "tort modernization" is the modification of tort law to keep citizens safe from new dangers arising from societal innovation. The common goal of tort modernization rules is to deal with changes in society that increase the hazards that were not anticipated by older common law tort doctrine. One example of tort modernization is the "mode of operation" rule which allows a plaintiff in a self-service setting (for example, a grocery store) to prove that the defendant had notice of an actual hazard on the premises merely because the hazard that caused the injury was a reasonably foreseeable outcome of the self-service mode of operation. *See* 41 FLA. JURIS. 2D *Premises Liability* § 110 (2016). The rationale for this tort modernization rule was the increased risk associated with the rise of self-service establishments where customers, not employees, handle the merchandise. *See, e.g.,* Sheehan v. Roche Bros. Supermarkets, 863 N.E.2d 1276, 1279 (Mass. 2007). Another example is the abrogation of the locality rule in medical malpractice cases. Instead of measuring a doctor's conduct by the standard in that doctor's immediate region, the conduct should take into account the advances made across the medical profession. *See* Brune v. Belinkoff, 235 N.E.2d 793, 798 (Mass. 1968). The locality rule recognized that if tort law did not adapt to account for advances in the transmission of medical knowledge, many patients would be unnecessarily harmed. *See* Shier v. Freedman, 208 N.W.2d 328 (Wis. 1973) (The locality rule was created under the assumption that small town doctors lacked modern medical tools and knowledge to because of their remoteness so holding them to a standard based on their locality was acceptable. However, the court in *Shier* noted that with the increased interconnectivity of people

negligence, this proposal will only apply when patients are harmed, and therefore "renders the rule a cheaper, more efficient method of enforcing socially desired behavior than regulation."[12]

II. What Is Off-Label Drug Use?

Before any new prescription drug can go to market, the FDA must approve its labeling.[13] The label must contain "the essential scientific information needed for the safe and effective use of the drug."[14] Essential information about the drug includes diseases the drug treats and information about the drug's proper administration, dosage, effects on specific populations, adverse reactions, and interactions with other drugs.[15] Off-label use occurs when a provider uses an approved drug in a manner inconsistent with the information on the label[16] (for example, using it to treat a different disease, on children instead of adults, or via ingestion instead of injection).[17]

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and ideas, doctors from small towns could be held to the same standards and thus give their patients the same level of care. Not doing so would allow people in small towns to be exposed to a lower standard of care and thus more harmful treatment).

[12] Steven Shavell, A Fundamental Enforcement Cost Advantage of the Negligence Rule over Regulation, 42 J. LEGAL STUD. 275, 276 (2013).

[13] *Development & Approval Process (Drugs),* FDA.GOV, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ (last visited Feb. 2, 2016).

[14] 21 C.F.R. § 201.56(a)(1) (2015).

[15] *Id.* § 201.56(b)(1), (d)(1).

[16] Understanding Investigational Drugs and Off Label Use of Approved Drugs, FDA.GOV, http://www.fda.gov/ForPatients/Other/OffLabel/default.htm.

[17] *See* 21 C.F.R. § 201.56(d)(1). Terbutaline is one example of a drug that is administered through both injection and ingestion. News Release, FDA, FDA Warns Against Certain Uses of Asthma Drug Terbutaline for Preterm Labor, ¶7 (Feb. 7, 2011) http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm243840.htm.

a. Problems with Off-Label Use

Unfortunately, some doctors prescribing off-label drugs fail to observe the level of due diligence that society expects of them.[18] The Pediatric Society of America recommends that off-label drug use be supported by objective scientific testing that has been approved in at least two peer-reviewed articles.[19] The Tennessee Court of Appeals has stated that "physicians prescribing a drug . . . off-label have a responsibility to be well-informed about [it]."[20] However, a 2006 study found that only 27% of off-label uses "were supported by strong scientific evidence" for the indication they were used to treat.[21] Another recent study found that off-label drug use not supported by significant scientific research led to nearly twice as many adverse drug effects as on-label use in the same population.[22]

Beyond studies, there are harrowing examples of off-label drug use causing serious harm. One is the Fen-Phen disaster.[23] In 1983, a pharmacologist ran a study on people over 200 pounds and found that combining the diet drugs fenfluramine and phentermine into a non-FDA approved drug "cocktail" was an extremely effective weight loss

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[18] *See* Riley & Basilius, *supra* note 2, at 24–37.

[19] *Id.*

[20] Richardson v. Miller, 44 S.W.3d 1, 15, 22 (Tenn. Ct. App. 2000).

[21] Randall S. Stafford, et al., *Off-label Prescribing Among Office-Based Physicians*, JAMA INTERNAL MED. No. 9 (May 8, 2006), http://archinte.jamanetwork.com/article.aspx?articleid=410250.

[22] Eguale, et al., *supra* note 5, at 59 (finding that adverse outcomes occurred in 13.2 per 10,000 person-months when on-label drugs were prescribed versus 21.7 adverse outcomes for the same time period for off-label drugs. Importantly, this study also found that off-label drug uses that were supported by significant scientific research had a rate of adverse effects almost identical to that of on-label use).

[23] Cohen, *supra* note 6 (Fen Phen off-label use causes heart disease).

solution.[24] By the mid-1990s, millions of people were taking this drug cocktail, including many who were not obese,[25] despite the fact that the drug combination was thought to cause a 23- to 46-fold increase in the risk of an untreatable, and often fatal, heart condition.[26] By the time the combination was recalled, over 37,000 claims were brought by those alleging serious heart problems and by 2007, about one third of these claims had been addressed by a drug company compensation trust.[27]

b. Necessity of Off-Label Use

Any attempt to curtail the negative impacts of off-label drug use must be careful not to be overly restrictive because in some medical fields off-label drug use is a necessity.[28] A significant reason for this is because the costs of receiving approval for all potential uses of a drug are prohibitively high.[29] Establishing an additional indication for a drug

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[24] *Id.*

[25] Gina Kolata, How Fen-Phen, A Diet 'Miracle,' Rose and Fell, N.Y. TIMES, Sept. 23, 1997, http://www.nytimes.com/1997/09/23/science/how-fen-phen-a-diet-miracle-rose-and-fell.html?pagewanted=all (last visited Nov. 7, 2015).

[26] *Id.*

[27] Cohen, *supra* note 6 (explaining that Fen Phen off-label use causes heart disease). Even after the recall, many doctors looked to new diet drug combinations such as Phen-Pro (phentermine and Prozac) and Phen-Traz (phentermine and trazadone) as a way to profit off women trying to lose weight. Kolata, *supra* note 25.

[28] *See Off–label Drug Use*, AM. CANCER SOC'Y, http://www.cancer.org/treatment/treatmentsandsideeffects/treatmenttypes/chemotherapy/off-label-drug-use (last updated Mar. 17, 2015); Charles Fiegle, *Medicare Ordered to Pay for Off-Label Drugs,* AMENDNEWS.COM, Mar. 18, 2011, http://www.amednews.com/article/20110318/government/303189997/8/; Riley & Basilius, *supra* note 2, at 24.

[29] *See* Susan Ikpaktchian, *14 Drugs Identified as Most Urgently Needing Study for Off-label Use, Stanford Professor Says*, STANFORD MEDICINE NEWS CENTER, Nov. 24, 2008, https://med.stanford.edu/news/all-news/2008/11/14-drugs-identified-as-most-urgently-needing-study-for-off-label-use-stanford-professor-says.html (companies "aren't often interested" in spending additional money on this).

requires a series of clinical trials that can cost upwards of $22 million.[30] Once a drug is approved, a new use can be added to the label after obtaining approval for an efficacy supplement – that is, a supplement to an approved application proposing a new use.[31] The problem with these supplements is that, although regulations state that the supplement must "incorporate . . . at least one adequate and well-controlled study,"[32] it is unclear what is actually required. Some scholars claim that the efficacy supplement process requires the "same tedious, costly clinical-trials process needed to achieve the original marketing approval."[33] In addition, pharmaceutical companies are hesitant to go through this process because "physicians may prescribe a drug off-label anyway, in which case obtaining a new indication is unnecessary."[34] In addition to the high price, approval of new drug uses can take years.[35]

The time and cost barriers of getting a new drug approved can put doctors treating patients with cancer in the position of either prescribing drugs off-label or watching patients die.[36] Off-label drug use is essential in treating cancer because "chemotherapy treatments often combine

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[30] Aylin Sertkaya, et al., *Examination Of Clinical Trial Costs And Barriers For Drug Development* § 3.1, tbl. 1, ERG (July 24, 2014), https://aspe.hhs.gov/sites/default/files/pdf/77166/rpt_erg.pdf (assuming the process for testing a new use includes a phase III trial and FDA review phase).

[31] Changes made to the label by an efficacy supplement include (1) adding or modifying an indication or claim; (2) revising the dose or dose regimen; (3) providing for a new route of administration; or (4) significantly altering the intended patient population. 21 C.F.R. § 314.3 (2015).

[32] *Id.*

[33] David Bradford, John L. Turner, & Jonathan W. Williams, *Off-Label Use of Pharmaceuticals: Trends and Drivers*, at 20 (Mar. 2015), https://www.aeaweb.org/aea/2015conference/program/retrieve.php?pdfid=523.

[34] *Id.*

[35] Epstein & Abbott, *supra* note 1, at 5.

[36] *Id.* at 5–6.

drugs [and] these combinations might include one or more drugs not approved for that disease . . . . [O]ncologists and their patients are often faced with problems that have few approved treatment options . . . [and] may be more willing to try off-label drugs than other medical specialties."[37]

Pediatric care often involves off-label drug use as well. Less than half of all drugs are approved for children, so pediatricians "must prescribe off-label drugs . . . because an overwhelming number of critical drugs still have no information on the label for use in children."[38] Off-label drug use is even more critical for children with rare diseases as it is less likely that the drug has been approved for such a disease.[39] It is clear that our society must allow doctors to prescribe off-label drugs because the drugs are necessary for treating children and cancer patients, as well as those with rare medical issues.

III. Current Medical Malpractice Rules

The FDA has acknowledged that "state tort liability is the 'appropriate source of control for off-label uses of prescription drugs'" because the FDA cannot regulate physicians directly. [40] While acknowledging that whether a drug is off-label is an important fact for the

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[37] *Off–label Drug Use*, AM. CANCER SOC'Y, http://www.cancer.org/treatment/treatmentsandsideeffects/treatmenttypes/chemotherapy/off-label-drug-use (last updated Mar. 17, 2015).

[38] *AAP Makes Recommendations On Use of Off-Label Drugs for Children*, AM. ACAD. OF PEDIATRICS, (Feb. 24, 2014), https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/AAP-Makes-Recommendations-On-Use-of-Off-Label-Drugs-for-Children.aspx.

[39] *Id.*

[40] Glenn E. Bradford & Charles C. Elben, The Drug Package Insert and the PDR as Establishing the Standard of Care in Prescription Drug Liability Cases, 57 J. MO. B. 233, 236 (2001).

jury to consider,[41] courts have held that off-label drug use is not prima face evidence of negligence,[42] and that the use of off-label drugs can even set the standard of care in medical malpractice cases.[43] However, standard medical malpractice laws are insufficient to deal with off-label drug use. A medical malpractice or professional medical negligence claim requires showing that a legal duty exists in the treatment of the patient and that the provider failed to conform to the relevant standard of care.[44]

Specific to professional medical negligence is the idea that a medical professional will not be held liable unless he or she fails to exercise the standard skill and prudence of an ordinary, reputable doctor in the same area of practice.[45] Thus, it is medical custom, rather than reasonableness, by which a doctor's conduct is measured.[46] Currently, medical custom supports the use of many off-label drugs even without proper scientific research as evidenced by the fact that less than a third of off-label drug use is based on significant scientific research.[47] Sometimes, like in the Fen-Phen disaster, doctors will still prescribe a drug off-label even when it is known to be dangerous.[48] Therefore, unless medical malpractice rules are adjusted when off-label drugs are used, even a

[41] Richardson v. Miller, 44 S.W.3d 1, 17 (Tenn. Ct. App. 2000).

[42] Gaston v. Hunter, 588 P.2d 326, 335 (Ariz. Ct. App. 1978).

[43] Mark Herrmann & Pearson Bownas, *Keeping the Label Out of the Case*, 103 NW. U. L. REV. COLLOQUY 477, 486 (2009).

[44] Akash M. Awati & Vanessa Mudda, *Professional Liability in Medical Practice: A 20 Years Retrospective Study at District Consumers' Forum Gulbarga (1991-2011)*, 3 J. OF DR. NTR UNIV. OF HEALTH SCI. 15 (2014), http://www.jdrntruhs.org/article.asp?issn=2277-8632;year=2014;volume=3;issue=1;spage=15;epage=18;aul.

[45] Pearson, *supra* note 10, at 528

[46] *Id.*

[47] Stafford, et al., *supra* note 21.

[48] *See* Kolata, *supra* note 25.

doctor who prescribes a known dangerous off-label drug may not be held liable if the drug is widely used.

IV. Duel Pronged, Tort Modernization Solution

Because current tort law remedies are inadequate,[49] in order to combat the specific misuse of "off-label" drugs, medical malpractice tort law solutions arising from off-label drug use should be modernized in keeping with the strategy of Tort Modernization.[50] The best way to do this is to formulate a heightened standard of care and to then place the burden of proof on the defendant to prove that the doctor met this heightened standard of care. Together, these rule changes would force doctors to acknowledge the added dangers associated with off-label drug use,[51] and encourage doctors to obtain, invest in, or help produce data that will objectively test the efficacy and safety of off-label drug use.[52]

a. The Proposed Standard of Care

In medical malpractice cases arising from off-label drug use, the standard of care should be modernized to require doctors to "obtain reliable, up-to-date information," including some objective scientific data and not merely word-of-mouth.[53] Doctors would no longer be able to rely on custom alone to support off-label prescriptions. The Tennessee Court of Appeals, in *Richardson v. Miller*, stated a similar standard. "[P]hysicians prescribing . . . off-label have a responsibility to be well-

[49] *See* discussion *supra* Section III.

[50] For definition of Tort Modernization *see supra* note 11.

[51] *See* Eguale, et al., *supra* note 5.

[52] This is not to say that doctors should begin to use off-label drugs in experiments but that, in an effort to show that an off-label use is effective and safe, a doctor would advocate or invest in experimentation to test that drug.

[53] Richardson v. Miller, 44 S.W.3d 1, 15 (Tenn. Ct. App. 2000); *see, e.g.*, Staudt v. Froedtert Mem'l Lutheran Hosp., 580 N.W.2d 361, 363 (Wis. Ct. App. 1998).

informed about the drug or device. In the absence of the information found in the FDA-approved labeling, physicians must obtain reliable, up-to-date information from other sources."[54] Specific examples of what the "up-to-date information" could include are: "(1) discussion with professional colleagues, (2) continuing medical education programs, (3) case studies in professional journals, and (4) reports of the clinical results of the use of the drug in other countries."[55] The key difference between the *Richardson* standard for off-label drugs and the normal standard of care is that when off-label drugs are involved, the physician must consult "up-to-date information," even when doing so is not part of medical custom.[56] *Richardson* stands for the proposition that we, as a society, demand more prudence when doctors prescribe drugs off-label because of their inherent danger.

By explicitly excluding custom as an excuse for carelessness when prescribing and administering off-label drugs, this proposal takes *Richardson* a step further. The problem with custom in the off-label drug context is that it does not necessarily incorporate objective scientific research and may even support the use of known dangerous drugs.[57] One could interpret *Richardson*'s inclusion of "discussion with professional colleagues" to implicitly excuse a doctor from examining evidence if the

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[54] *Richardson*, 44 S.W.3d at 15 (internal citations omitted).

[55] *Id.*

[56] *Compare id. with* Pearson, *supra* note 10, at 528 (stating traditional standard of care).

[57] See Camile N. Tragos, Fen-Phen Litigation Against American Home Products Corporation: The Widespread Use of Fenfluramine (Pondimin) and Dexfenfluramine (Redux) for Weight Loss, The Health Problems Associated with Those Drugs, the Resulting Litigation Against American Home Prod, at n. 205 (2000), http://nrs.harvard.edu/urn-3:HUL.InstRepos:8965626 (noting that the off-label use of Fen-Phen was widespread among doctors despite a lack of scientific evidence that the use was safe).

off-label use is currently popular. This is what occurred in the Fen-Phen disaster: doctors avoided numerous warnings that the drug may have been harmful and it became a widespread practice to prescribe it.[58] Under this proposal, a doctor accused of malpractice for using Fen-Phen off-label would fall below the standard of care if he or she failed to exercise due diligence by reading medical journal articles or FDA warnings about the drugs. This due diligence may have uncovered reports of harm caused by Fen-Phen[59] and warnings to avoid using the drug.

In some medical malpractice cases, courts have already deviated from the custom medical standard of care, finding the reasonably prudent specialist standard inadequate to offer the plaintiff reasonable protection.[60] In *Helling v. Carey*, the Supreme Court of Washington ruled that "reasonable prudence required the timely giving of the pressure test [for glaucoma] to [the] plaintiff," even though a medical expert testified that this was not a common practice for treating patients in the plaintiff's age group.[61] The court determined that the common practice was inadequate because there was evidence that administering the test may lead to better outcomes.[62] The court justified its dismissal of custom because "there are precautions so imperative that even their universal disregard will not excuse their omission."[63]

Carefully obtaining reliable, up-to-date information before prescribing or administering an off-label drug is one such imperative. Like

[58] *See* Cohen, *supra* note 6.

[59] *See* Kolata, *supra* note 25.

[60] *See, e.g.*, Helling v. Carey, 519 P.2d 981, 983 (Wash. 1974).

[61] *Id.* at 982–83.

[62] *See* Keith N. Hylton & Haizhen Lin, *Negligence, Causation, and Incentives for Care*, 35 INT'L REV. L. & ECON. 80, 89 n.27 (2013).

[63] *Helling*, 519 P.2d at 983 (quoting The T.J Hooper, 60 F.2d 737, 740 (2d Cir. 1932)).

the pressure test in *Helling*, there is some evidence that implies that off-label drug use that is not supported by scientific evidence may be associated with adverse patient outcomes.[64] Therefore, courts should abrogate the legal protection granted to doctors by medical custom when off-label drug use is the cause of harm.

b. Necessity of Including Burden Shifting

One issue that arises under this scheme is the difficulty for a plaintiff to show that a doctor did not obtain up-to-date information. Herein lies the necessity of the second rule change. By putting the burden on the defendant, a doctor would need to produce evidence that he or she had actually taken precautions before prescribing off-label drugs. In addition to pressuring doctors to perform due diligence, this also encourages them to take more accurate notes when prescribing off-label. In turn, this would lead to improved medical knowledge about the off-label drug use because it would create more data points upon which to base scientific conclusions. This would not unduly stifle clinical innovation because it would merely re-enforce our societal standard of what doctors should do.[65]

Burden-shifting has appeared in other areas of tort law where the defendant has significantly more knowledge and control of the situation than the plaintiff.[66] One example is in premises liability cases.[67] In an

[64] Eguale, et al., *supra* note 5.

[65] Riley & Basilius, *supra* note 2, at 24 (the societal standards in this case are those promulgated by the American Academy of Pediatrics: (1) whether the drug has been approved by the FDA; (2) whether the off-label use has been subjected to objective scientific testing and has been approved in at least two peer-reviewed articles; (3) whether the off-label use is medically necessary to treat a specific condition; and (4) whether the off-label use is not experimental).

[66] *See* Owens v. Publix Supermarkets, Inc., 802 So. 2d 315, 330–31 (Fla. 2001); Safeway Stores, Inc. v. Smith, 658 P.2d 255, 258 (Colo. 1983).

ordinary premises liability case, the plaintiff must establish that the defendant had knowledge of the hazard that caused the injury.[68] However, in *Owens v. Publix Supermarkets*, the court established a rule that switched the burden of proof stating that cases involving premises liability "are appropriate cases for shifting the burden to the premises owner . . . to establish that it exercised reasonable care . . . eliminating the specific requirement that the customer establish that the store had constructive knowledge of" the hazard.[69]

The *Owens* court ruled that a burden-shifting scheme in premises liability cases involving supermarkets was necessary because the nature of supermarkets, which require customers to select objects directly from displays, creates extra hazards for customers.[70] In these cases, "the premises owners are in a superior position to establish that they did or did not regularly maintain the premises in a safe condition and they are generally in a superior position to ascertain what occurred by making an immediate investigation, interviewing witnesses and taking photographs."[71]

This article's proposed burden-shifting scheme involves similar dynamics. Like supermarkets with their self-service displays, off-label drug use may have some inherent additional hazards when compared to on-label use.[72] Further, doctors, like the premises owners in *Owens*, have a superior ability to ascertain what occurred and to monitor what steps

[67] *See, e.g., Owens*, 802 So. 2d at 330; *Safeway Stores, Inc.*, 658 P.2d at 258.

[68] Restatement (Second) of Torts § 343 (1965).

[69] *Owens*, 802 So. 2d at 331.

[70] *See id.* at 330.

[71] *Id.* at 330.

[72] Eguale, et al., *supra* note 5.

they took to ensure due diligence when prescribing or administering drugs off-label. Both off-label drug use and supermarkets involve enterprises with heightened hazards when compared to more traditional alternatives that negligence laws were created to protect against. Therefore, the burden-shifting rule that has been adopted for supermarket slip-and-fall cases will also combat the problem in off-label drug use.

At a practical level, switching the burden of proof would mean that if a jury were unclear about whether a doctor had obtained adequate information before prescribing or administering an off-label drug, it could still find the doctor liable for malpractice.[73]

V. Conclusion

Like other tort modernization solutions, this proposal will help keep society safe in the face of a growing practice with inherent danger. It strives to not be overly strict to the point of choking the positives of off-label use, but will only hold medical practitioners to the standard necessary to avoid excessive risk.

[73] Fleming James Jr., *Burdens of Proof,* 47 VA. L. REV. 51, 51 (1961).