AS A MATTER OF FACT OR A MATTER OF LAW: THE LEARNED INTERMEDIARY DOCTRINE IN ALABAMA

The learned intermediary doctrine discharges a drug manufacturer's duty to warn of the side effects of its drug so long as it provides the prescribing physician with an adequate warning about any risks associated with a drug.[1] Hence, a drug company is only obligated to adequately warn the physician, not the patient.[2] In the numerous cases involving adverse side effects from prescription drugs, the adequacy of the warning is usually the focus of the litigation.[3] The plaintiff argues either the doctor was not warned, the factual content of the warning was inadequate, the expression of facts were inadequate, or the method of conveyance was inadequate.[4] The defense counters by invoking the learned intermediary doctrine and asserts the obligation of adequately warning the doctor was fulfilled.[5] In each instance, the question then invariably turns to which legal entity will determine whether the doctor was adequately warned: the judge or the jury.[6] This Comment will focus on whether the adequacy of a drug warning is a question of fact or question of law in Alabama. The focus will rely primarily on two cases in Alabama involving the learned intermediary doctrine and the resolution of this issue in other jurisdictions.

I. INTRODUCTION

As long as there are people, there will always be doctors. And as long as there are doctors, there will always be pharmaceuticals. In fact, the pharmaceutical industry in America composes thirteen percent of

1. Linnen v. A.H. Robbins Co., No. CIV.A. 97-2307, 2000 WL 89379 (Mass. Super. Dec. 14, 1999).
2. Toole v. McClintock, 999 F.2d 1430, 1433 (11th Cir. 1993).
3. *See, e.g.*, Hurley v. Lederle Lab. Div. of Am. Cyanamid Co., 651 F. Supp. 993, 1002 (E.D. Tex. 1986), *rev'd on other grounds*, 851 F.2d 1536 (5th Cir. 1988); Plummer v. Lederle Lab. Div. of Am. Cyanamid Co., 819 F.2d 349, 357 (2d Cir. 1987).
4. MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65 (Mass. 1985).
5. *MacDonald*, 475 N.E.2d at 68.
6. *Id.*

the gross domestic product[7] and has grown fifty-nine percent in the past twenty-five years.[8] In today's world, consumers are constantly bombarded by advertisements and brochures of drugs that profess to cure any and every ailment that may affect their being. Consumers can now visit their primary physician and stock up on pills that will cure their aching back, prevent Alzheimer's Disease, alleviate diabetes, appease their worried mind and even help their sex drive.[9] However, along with wonder drugs come the disturbing side effects that may counter the benefits and pleasures received from these miracle cures.

Liver damage, heart failure, stroke and insomnia are only a few of the counterparts to the story of the drugs that cure all. Although the risks of these side effects are announced to the general public, most are explained in small print. Known as the disclaimer, many pharmaceutical advertisements scurry through the potential dangers of their product in small package inserts and fast-paced statements that downplay the adverse effects of their drug. These disclaimers serve to abrogate a pharmaceutical company's liability, and in essence, serve as an "I told you so."

Despite the collage of warnings and inserts to the consumer, most drug companies are only required to adequately warn the treating physician—not the ailing patient—about these dangers.[10] In fact, the development of the learned intermediary doctrine abrogated all of the pharmaceutical industry's liability for failure to warn the ultimate consumer.[11] In most cases, courts have utilized the learned intermediary doctrine to detach the direct duty of pharmaceutical companies to warn patients, and instead, shifted the duty to warn to the acting physician.[12] Thus, a pharmaceutical company must adequately warn physicians of any dangers in prescribing its product, and its liability is related solely to the adequacy of its efforts in doing so.[13] In *Toole v. McClintock*,[14] the Eleventh Circuit, applying Alabama law stated: "Under the 'learned intermediary doctrine,' the adequacy of [the pharmaceutical company's] warning is measured by its effect on the *physician* . . . to whom it owed a duty to warn, and not by its effect on [the patient]."[15] Thus, it is usu-

7. Yvonne Bukstein, *Drug Products Liability: Duty to Warn*, 49 U. PITT. L. REV. 283 (1987).

8. *Id.*

9. These statements are examples of advertising claims used by Pfizer, Inc. on its websites. *See, e.g.*, Viagra (*sildenafril citrate*) tablets, Homepage, *at* http://www.viagra.com (last visited May 10, 2002).

10. Wyeth Lab. v. Fortenberry, 530 So. 2d 688, 691 (Miss. 1988).

11. Hoffman v. Sterling Drug, Inc., 485 F.2d 132 (3d Cir. 1973).

12. *See, e.g., Hoffman*, 485 F.2d at 141-42.

13. *Id.*

14. 999 F.2d 1430 (11th Cir. 1993).

15. *Toole*, 999 F.2d at 1433.

ally the consumer's treating physician that is given the onerous burden of determining which patient will suffer an elevated risk of these side effects.

Developed by the New York Supreme Court in *Marcus v. Specific Pharmaceuticals*[16] more than fifty years ago, the doctrine was an absolute defense for "failure to warn" cases.[17] The Third Circuit later modified the rule in *Hoffman v. Sterling Drug*,[18] holding that the doctrine was not an absolute defense—the drug manufacturer was obligated to adequately warn the physician.[19] The doctrine was promoted on the notion that a patient's diagnosis was based on his personal attributes and conditions, and only the doctor—the learned intermediary—was able to properly determine whether a particular drug was dispensable to the patient.[20] "The rationale [for the rule] is that the prescribing physician, as the 'learned intermediary' standing between the manufacturer and consumer/patient, is generally in the best position to evaluate the potential risks and benefits of ingesting a certain drug and to advise the patient accordingly."[21] Once the doctrine is invoked, most courts must then decide whether to submit the question to the jury or decide as a matter of law. The focus will now turn to the varying approaches.

II. OTHER JURISDICTIONS

Many states allow the adequacy of a warning to be determined as a matter of law.[22] In *Felix v. Hoffman-LaRoche*,[23] the Supreme Court of Florida held that if the warning from the manufacturer to the doctor is "accurate, clear and unambiguous," the warning is adequate as a matter of law.[24] In *Felix*, the court was presented with the wrongful death of a child attributed to the ingestion of a pharmaceutical by his mother during pregnancy.[25] The drug, Accutane, was prescribed for the mother's acne and specifically warned her physician of the side effects to unborn fetuses.[26] The mother ingested large amounts of Accutane during her

16. 77 N.Y.S.2d 508 (1948).
17. *Marcus*, 77 N.Y.S.2d at 509-10.
18. *Hoffman*, 485 F.2d at 141-42.
19. *Id.*
20. *Id.*
21. Garside v. Osco Drug, Inc., 976 F.2d 77, 80 (1st Cir. 1992).
22. *See, e.g.*, Goodson v. Searle Lab., 471 F. Supp. 546, 549 (D. Conn. 1978); Brick v. Barnes-Hines Pharm. Co., 428 F. Supp. 496, 497 (D.D.C. 1977); Chambers v. G.D. Searle Co., 567 F.2d 269, 270 (4th Cir. 1977); Hurley v. Lederle Lab Div. of Am. Cyanamid Co., 651 F. Supp. 993, 1002 (E.D. Tex. 1986); Plummer v. Lederle Lab Div. of Am. Cyanamid Co., 819 F.2d 349, 357 (2d Cir. 1987).
23. 540 So. 2d 102 (Fla.1989).
24. *Felix*, 540 So. 2d at 105.
25. *Id.* at 103.
26. *Id.* at 103-04.

pregnancy and her child was born prematurely and subsequently died.[27] The mother filed suit, alleging negligence and inadequate warnings on the part of the drug manufacturer. The lower court entered summary judgment in favor of the drug company and the appellate court affirmed.[28]

On appeal to the Florida Supreme Court, the plaintiff argued the district court erred in allowing the adequacy of the defendant's warning to be determined as a matter of law.[29] In its holding, the court applied the learned intermediary doctrine, and noted that the drug manufacturer's duty to warn of the side effects of its drug was directed to the physician and not the patient.[30] More importantly, the court held that invoking the learned intermediary doctrine allowed a clear, accurate, and unambiguous warning to be determined as a matter of law.[31] The court affirmed the lower court's grant of summary judgment.[32]

Other courts have similarly held that adequacy of warning can be a question of law.[33] However, there are some courts that allow the question to be determined by the trier of fact.[34] In *Linnen v. A.H. Robins Co.*,[35] a Massachusetts Superior Court held that where the adequacy of the drug company's warning is disputed, the question must ultimately be resolved by the jury.[36]

The *Linnen* plaintiff was prescribed fenfluramine and phentermine (fen-phen) for obesity. After suffering from certain side effects of the medication, the plaintiff was subsequently told to discontinue the medication. However, she developed pulmonary hypertension and died as a result of the side effects.[37] The decedent's estate filed suit, alleging negligence, breach of express warranty and inadequacy of warning. The lower court granted summary judgment on the inadequacy of warning, but the Superior Court reversed. In its holding, the Superior Court stated that, although the drug company's duty to warn the patient is discharged, they did have a duty to adequately warn the treating physi-

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27. *Id.* at 103.
28. *Id.* at 103-04.
29. *Felix*, 540 So. 2d at 104.
30. *Id.*
31. *Id.* at 105.
32. *Id.*
33. *See, e.g.*, Wooten v. Johnson & Johnson Prod., Inc., 635 F. Supp. 799, 803 (N.D. Ill. 1986); Weinberger v. Bristol-Meyers Co., 652 F. Supp. 187, 189 (D. Md. 1986); Johnson v. Am. Cyanamid Co., 718 P.2d 1318, 1325 (Kan. 1986), *aff'd*, 758 P.2d 206 (Kan. 1988); Nolan v. Dillon, 276 A.2d 36, 39 (Md. 1971); Wolfgruber v. UpJohn Co., 423 N.Y.S.2d 95, 97 (N.Y. App. Div. 1979), *aff'd*, 417 N.E.2d 1002 (N.Y. 1980).
34. *See, e.g.*, Savina v. Sterling Drug Co., 795 P.2d 915 (Kan. 1990).
35. No. CIV.A. 97-2307, 2000 WL 89379 at *4-*6 (Mass. Super. Dec.14, 1999).
36. *Linnen*, 2000 WL 89379 at *4.
37. *Id.* at *2.

cian.[38] Moreover, if a dispute arises to the adequacy of that warning, the focus then turns to a determination by the trier of fact.[39] The court, without any further reasoning, determined that all material issues of fact as to the adequacy of any warning must be put before the jury and held summary judgment was inappropriate.[40]

III. ALABAMA LAW

The state of the learned intermediary doctrine in Alabama comes from two cases,[41] with only one case decided by the Alabama Supreme Court.[42] Both cases recognize that the doctrine does exist and is a viable defense in failure to warn cases. However, the cases differ as to whether the question of adequacy is one of fact or law.

The most recent decision, *Toole v. McClintock*,[43] deals with a failure to warn in a breast implant case.[44] In *Toole*, the plaintiff alleged that the defendant, Baxter Healthcare Corp., failed to warn her doctor of the risks of ruptures during a "closed capsulotomy," a procedure used to remove scar tissue around the breast through an application of force and compression.[45] At the district court level, a jury ultimately found Baxter liable under either a negligent warning theory or for distributing an unreasonably dangerous product.[46] On appeal, Baxter argued the following: (1) their warning was clear on the dangers of using such a procedure; (2) the plaintiff admitted that if her physician had told her of the dangers, she would not have consented to the procedure; and (3) there was insufficient evidence for the jury to conclude a different warning would have caused the physician to behave differently.[47]

Applying Alabama law, the Eleventh Circuit held that under the learned intermediary doctrine, even though Baxter owed a duty only to warn the physician, the question of negligent warning was a jury question.[48] The court noted that a jury could have found that Baxter understated the risks of rupture from the procedure.[49] Moreover, the court held that although Baxter did warn of the potential dangers of closed

38. *Id.* at *3.
39. *Id.*
40. *Id.* at *5.
41. A third case, *Stafford v. Nipp*, 502 So. 2d 702 (Ala.1987), recognizes the doctrine but refuses to apply it to a pharmacist.
42. *See* Toole v. McClintock, 999 F.2d 1430 (11th Cir. 1993); Stone v. Smith Kline & French Labs., 447 So. 2d 1301 (Ala.1984).
43. 999 F.2d 1430 (11th Cir. 1993).
44. *Id.*
45. *Id.* at 1431.
46. *Id.* at 1432.
47. *Id.* at 1433.
48. *Toole*, 999 F.2d at 1433.
49. *Id.*

capsulotomies, a jury "could reasonably conclude that a different warning would have caused [the physician] to warn the [plaintiff] before her . . . surgery."[50]

In *Toole*, the plaintiff did not allege that Baxter did not warn her; rather, she claimed the warning was negligent in that it did not provide enough information to compel her physician to warn her of the risks.[51] As stated by the court, the plaintiff essentially alleged a complete failure to warn.[52] Her doctor testified that had he known of the significant risks, he would have warned his patients. However, Baxter allegedly understated the risks of rupture and therefore a different warning would have compelled the physician to warn before performing the surgery.[53] Nevertheless, the Eleventh Circuit found Alabama law required the question of adequacy be sent to the jury.[54]

The only Alabama Supreme Court decision on the learned intermediary doctrine is *Stone v. Smith, Kline & French Lab.*[55] This case came to the Alabama Supreme Court via the Eleventh Circuit on a certified question.[56] In *Stone*, the plaintiff sued the pharmaceutical drug manufacturer alleging her use of their product Thorazine resulted in jaundice and hepatitis. The plaintiff further alleged the defendant failed to adequately warn her of the risks involved in taking Thorazine.

The Alabama Supreme Court held that the plaintiff's arguments on failure to warn were insufficient as a matter of law.[57] The plaintiff admitted that the physicians were adequately warned of the side effects of Thorazine. However, she further contended that the warnings were of no consequence because they did not help the doctor in accurately predicting which patients would suffer from these adverse reactions.[58] In essence, the plaintiff's argument asserted that a physician was incapable of making an informed choice to prescribe Thorazine because he was unable to predict the occurrence of adverse reactions.[59] The court held that the role of the warning was to simply warn the physician of the potential side effects—it was up to the doctor, as a medical expert, to take into account the propensities of the drug and the susceptibilities of

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50. *Id.*
51. *Id.*
52. *Id.*
53. *Toole*, 999 F.2d at 1433.
54. *Id.*
55. 447 So. 2d 1301 (Ala. 1984).
56. *Stone*, 447 So. 2d at 1302-03. The Eleventh Circuit certified three questions, one of which asked whether "the adequacy of the warning determines whether an unavoidably unsafe prescription drug is unreasonably dangerous, is an adequate warning to the prescribing physician, but not to the ultimate consumer, sufficient as a matter of law?" *Id.* at 1303. The Alabama Supreme Court answered the question in the affirmative. *Id.* at 1304.
57. *Id.*
58. *Id.*
59. *Stone*, 447 So. 2d at 1304.

his patient.[60] The court held, as a matter of law, that Smith, Kline & French Laboratories met its duties and obligations to the physician on the warning claim and absolved defendant of any liability.[61]

IV. ANALYSIS

Based on the courts' analyses in *Toole* and *Stone*, there seems to be a contradicting standard for who will be the "judge" of adequacy. On the one hand, the Eleventh Circuit, in *Toole,* decided that similar to other adequacy questions in Alabama, the adequacy of the warning to the physician must be determined by the jury.[62] On the other hand, the Alabama Supreme Court determined the warning in *Stone* to be sufficient as a matter of law.[63] Although the court in *Stone* found the warning adequate as a matter of law, its decision was centered on the fact that the plaintiff conceded the doctor was adequately warned.[64] However, the court's analysis went further amidst arguments that the warning still did not adequately warn the doctor as to the occurrence of side effects, and held the warnings were adequate as a matter of law.[65] In light of these contradictory decisions, the analyses provided by other jurisdictions may clarify the standard.

In *Toole*, the Eleventh Circuit did not consider the issue as a matter of law because Alabama case law holds that "the existence of a duty to warn and the adequacy of a warning are questions of fact for the jury."[66] However, the cases relied on by the *Toole* court that have addressed adequacy of warning did not involve the learned intermediary doctrine, but instead involved situations that required a direct warning to the consumer.

In *State Farm Fire and Casualty Co. v. J.B. Plastics, Inc.*,[67] which was relied upon by the court in *Toole*, the court reiterated that the adequacy of a warning is a question of fact for the jury.[68] The plaintiff in *State Farm* alleged an inadequate warning concerning a plumbing cap manufactured by the defendant. The plaintiff alleged that the cap manufacturer did not provide adequate warning as to the risk of rupture of

60. *Id.* The court adopted the reasoning of *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974), in determining the applicability of the learned intermediary doctrine. *Id.*
61. *Id.*
62. Toole v. McClintock, 999 F.2d 1430, 1433 (11th Cir. 1993).
63. *Stone*, 447 So. 2d at 1304.
64. *Id.*
65. *Id.*
66. 999 F.2d at 1433 (quoting State Farm Fire & Cas. Co. v. J.B. Plastics, Inc., 505 So. 2d 1223, 1227 (Ala. 1987)).
67. 505 So. 2d 1223 (Ala.1987).
68. *State Farm*, 505 So. 2d at 1227.

the plumbing cap or proper instructions on its installation.[69] As a result of these inadequate warnings, the plaintiff suffered water damage.[70] Although the court determined the jury should determine the adequacy of the warning, the legal conclusions of *State Farm* revolved around a duty to warn the ultimate consumer, not a learned intermediary theory.[71]

Moreover, Alabama case law has allowed some warnings directed to the consumer to be deemed adequate as a matter of law rather than sending the question of adequacy to the jury. For example, in *Yarbrough v. Sears, Roebuck and Co.*, the Alabama Supreme Court held that a specific, comprehensive and detailed warning adequately warned a consumer of the dangers of a product.[72] In *Yarbrough*, the plaintiff was injured when he substituted gasoline for kerosene in his kerosene heater.[73] The heater eventually caught fire and injured the plaintiff.[74] Despite allegations by the plaintiff that another warning would have prevented such an accident, the Alabama Supreme Court upheld the lower court's grant of summary judgment.[75] The Court stated the following: "These warnings, included with the kerosene heater, were specific, comprehensive, and detailed in notifying potential consumers of the possibility of the danger associated with the use of gasoline . . . as fuel for the heater."[76]

Hence, in *Yarbrough*, the Court diverged from the traditional rule of submitting adequacy questions to the jury and acknowledged that a "detailed, specific, and comprehensive" warning can be adequate as a matter of law.[77] This is the same approach that other courts have taken to allow adequacy of drug warnings to be decided as a matter of law. For example, in *Felix*, the Florida Supreme Court was required to deviate from a Florida law that required all adequacy questions be presented to the jury.[78] The court noted that while previous cases[79] dealing with warnings to the consumer justified submitting the question to the jury, they determined that if a drug warning is clear, accurate, and unambiguous for the physician, it is adequate as a matter of law.[80] Our courts

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69. *Id.* at 1225.
70. *Id.*
71. *Id.* at 1227.
72. 628 So. 2d 478, 482 (Ala. 1993).
73. *Yarbrough*, 628 So. 2d at 479-80.
74. *Id.*
75. *Id.* at 482.
76. *Id.*
77. *Id.*
78. Felix v. Hoffman-LaRoche, 540 So. 2d 102, 104 (Fla. 1989).
79. *Felix*, 540 So. 2d at 104 (citing Tampa Drug Co. v. Wait, 103 So. 2d 603 (Fla. 1958), and Ricci v. Parke Davis & Co., 491 So. 2d 1182 (Fla. 1986)).
80. *Id.*

should do likewise and further extend the *Yarbrough* decision to allow prescription drug warnings to be adequate as a matter of law if specific, detailed, and comprehensive.

By invoking the learned intermediary doctrine, a pharmaceutical company distances itself from any obligation to the end-user.[81] The doctrine incorporates the sophistication of the reader and doctor, and follows the proper guidelines to ensure all necessary risks are described in detail.[82] In fact, "[p]rescription drug labeling is directed to health care professionals, not the ultimate consumer."[83] For example, in *Felix*, the court was required to determine whether a term in the warning, "tetragenecity," adequately alerted the doctor as to the severity of potential side effects.[84] The court noted the following: "While the word 'tetrogenecity' is not one with which all consumers might be familiar, we are convinced that, as to physicians, the warning concerning the dangerous side effects of . . . [the drug] was quite clear."[85]

This detailed warning/labeling requirement is undermined by allowing the jury to determine whether the warning was adequate. The Food and Drug Agency (FDA) "intends the labeling to ensure that the medical community is provided a complete and accurate explanation of the drug."[86] The drug manufacturer is essentially given the "green light" for its product and its label through FDA approval.[87] Simply stated, by allowing a corporation to place a prescription drug on the market, the FDA has inherently verified the adequacy of the warning.[88]

The FDA's task is to use scientific research and data to determine the very same question later posed to a jury—the adequacy of the warning. In fact, the FDA's Center for Drug Evaluation and Research creates teams of physicians, statisticians, chemists, pharmacologists and other scientists to review all new drug applications containing research data and proposed labeling to determine if a particular drug is labeled adequately for the treating physician.[89] Moreover, with the enactment of

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81. *See id.* at 103; *see also* Brown v. Glaxo, Inc., No. 99-1531, 2000 WL 1706282 (La. App. 1st Cir. Nov. 15, 2000).

82. In *Savina v. Sterling Drug, Inc.*, the Supreme Court of Kansas noted the following: "Comments by the FDA stated that the purpose of prescription drug labeling is 'to provide physicians with a clear and concise statement of the data and information necessary for the safe and effective use of the drug.'" 795 P.2d 915, 930 (Kan. 1990) (citing Rules & Regulations of FDA, 44 Fed. Reg. 37, 435 comment 6 (1979)).

83. *Savina*, 795 P.2d at 930 (citing 44 Fed. Reg. 37, 438-39 comment 21 (1979)).

84. *Felix*, 540 So. 2d at 102.

85. *Id.* at 105.

86. 44 Fed. Reg. at 437.

87. *See id.*

88. *See* 21 C.F.R. § 201.57(d) (1989).

89. Tamar Nordernberg, *Inside FDA: The center for drug evaluation and research*, FDA CONSUMER, July-Aug. 1996, *available at* http://www.fda.gov/fdac/features/696_cder.html (last visited May 10, 2002).

the Federal Food, Drug and Cosmetic Act, manufacturers are directed to place certain warnings on their products before they may be distributed.[90] Furthermore, numerous guidance bulletins supplement FDA approval to help manufacturers create the "adequate" warning. For example, in the guidance bulletin for "Labeling Human Prescription Drugs," the FDA states:

> In general, the ADVERSE REACTIONS section should include only information that would be useful to clinicians when making treatment decisions and in monitoring and advising patients. Long and exhaustive lists of every reported adverse event, including those that are infrequent and minor, commonly observed in the absence of drug therapy, or not plausibly related to drug therapy, *should be avoided.*[91]

Hence, aside from the requirements of the Cosmetic Act,[92] additional, discretionary warnings are also recommended and regulated by the FDA. The manufacturers thus rely on the FDA for the adequacy of the warning and comply with a federally regulated labeling requirement before they are even permitted to submit their product to physicians.

Allowing a jury to determine the adequacy of these warnings essentially wastes the resources and efforts of both the FDA and the drug manufacturer. "Every single drug that affects the body will have some side effects . . . . For every drug [the] FDA approves, the benefits are balanced against its risks. In addition, the FDA makes sure the labeling (package insert) outlines the benefits and risks reported . . . ."[93] The FDA balances the risks and benefits of each drug and ensures the physician is adequately warned.

However, allowing the jury to determine the adequacy of that warning would allow them to balance these considerations without the benefit of the same knowledge and expertise utilized by the FDA. The jury sits as the common layman whose only standard to determine adequacy is their own experiences, jury instructions, and information from expert witnesses. In a traditional adequacy of warning case, without a prescription drug, the jury is the ideal group to make the determination

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90. 21 U.S.C. § 355(c), (n); *see also* 21 C.F.R. § 210.57 (1989) (listing the requirements for prescription drug labeling).

91. United States Food & Drug Admin. Ctr. for Drug Evaluation & Research, *Guidance for Industry: Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics*, *available at* http:// www.fda.gov/cder/guidance/1888dft.htm (last visited May 10, 2002) (emphasis added).

92. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (1999 & Supp. 2002).

93. United States Food & Drug Admin. Ctr. for Drug Evaluation & Research, *Frequently Asked Questions to CDER: Once FDA Approves a Drug, Does This Mean that the Product is Perfectly Safe?*, *available at* http://www.fda.gov/cder/about/faq/ (last visited May 10, 2002).

because the questionable warning is directed to individuals like them. The court in *Toole* simply failed to see the legal distinction between inadequate warnings in consumer products and prescription drugs. The rationale in requiring the manufacturer of a plumbing cap to warn the user is found in a common duty to "warn of inherent and imminent dangers in a product when used in its usual manner."[94] The average layman, who would reap the benefit from an adequate warning, used this cap in its "usual manner." Hence, the concern with the adequacy of that warning was its effect on the consumer who used such a product.[95]

However, the drug warning is directed to a "learned intermediary . . . , a licensed practitioner with the education and training necessary to oversee the administration of potentially harmful drug products."[96] The doctrine allows the pharmaceutical company to rely on the physician to warn individual patients while the drug-maker relies on the FDA for their own guidance in developing the warning. Given the FDA's purpose and rigorous labeling requirements,[97] and Alabama case law that allows "detailed, specific, and comprehensive" warnings to be adequate as a matter of law,[98] future jurisprudence should allow the adequacy of drug warnings to be determined as a matter of law.

V. CONCLUSION

The learned intermediary doctrine serves as an incentive for pharmaceutical companies to focus their efforts on the research and development of new drugs. A drug company may find comfort in investing capital to develop new cures, with the caveat that they must adequately warn doctors of the adverse effect and not concern themselves with the idiosyncrasies of each consumer. Moreover, the drug companies are regulated by the FDA to ensure their product is safe for the consumer and that their warnings adequately portray the risks of side effects. However, the ability of a jury to undermine these efforts is relentless if presented with the opportunity to determine the adequacy of a warning that would inevitably deter pharmaceutical companies from developing new products that may be beneficial to the public but could be harmful

94. State Farm Fire & Cas. Co. v. J.B. Plastics, Inc., 505 So. 2d 1223, 1227 (Ala. 1987) (quoting Rivers v. Stihl, Inc., 434 So. 2d 766, 773 (Ala. 1983)).

95. *State Farm Fire & Cas. Co.*, 505 So. 2d 1227.

96. *Enforcing the Laws on Internet Pharmaceutical Sales: Where are the Feds?: Hearing Before the H.R. Comm. on Commerce Subcomm. on Oversight and Investigations*, 106th Cong. (May 25, 2000) (statement of William K. Hubbard, Senior Assoc. Comm'r for Policy, Planning & Legislation, Food & Drug Admin.), *available at* http://www.fda.gov/ola/2000/internetsales.html (last visited May 10, 2002), *and* http://com-notes.house.gov (last visited May 10, 2002).

97. 21 C.F.R. § 314.25 (1989) (stating that the FDA refuses to approve new drugs that provide inadequate safety and effectiveness information for the labeled indications).

98. Yarbrough v. Sears, Roebuck & Co., 628 So. 2d 478, 482 (Ala. 1993).

to a small group of consumers as well. As the court in *Felix* noted:

> [A] pharmaceutical manufacturer would be much less likely to make the capital investment in research, development, obtaining FDA approval, and marketing of a potentially beneficial drug which is accompanied by serious side effects if faced with the knowledge that, *no matter how accurate and well-phrased the warning, a jury could decide its adequacy every time a side effect occurred.*[99]

Alabama should thus clarify and adopt a standard of determining the adequacy of drug warnings as a matter of law.

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99. Felix v. Hoffman-LaRoche, 540 So. 2d 102, 105 (Fla. 1989) (emphasis added).