In This Issue

Is the learned intermediary doctrine going the way of the cassette tape (or even the eight-track)? Should the proliferation of information available to the average patient undercut the long-established and well-reasoned doctrine, so as to place pharmaceutical manufacturers squarely between the physician and patient in the informed consent process? We do not think so, but at least two courts have roundly rejected the doctrine. This article examines those decisions, including the January 2015 decision by the Arizona Court of appeals, and explains why they should be outliers rather than the new trend.

Watts v. Medicis Pharmaceutical Corporation – Trend or Outlier?
Why This Case Should Remain on the Outskirts

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**Introduction.** Like many other aspects of our society, the medical field and pharmaceutical industry are constantly changing. Consumers of medical services and prescription drugs have more access to information than ever before given the myriad of websites and databases available on the internet. For example, WebMD and similar websites are the first places some people go when they begin to feel sick. Consumers also have direct access to drug information as the result of direct consumer advertising in an array of media. In fact, the FDA is currently evaluating the way consumers and drug companies relate to each other in the marketplace.\(^1\) New studies about the impact of television advertising for pharmaceutical products may lead to new regulations for drug companies to mitigate the burden on manufacturers and to better inform consumers of the risks.

The changes in the medical field and increased use of direct consumer advertising have caused some courts and legal commentators to question the continued viability of the learned intermediary doctrine. Although the environment in which medical services are provided is changing, the doctrine nevertheless continues to rest upon sound, fundamental principles. And there is no better time than now to reaffirm its legal and practical principles. Since 2007, two states have rejected the learned intermediary doctrine – one as recently as January 2015. These recent decisions exemplify a fundamental misunderstanding of the principles of the doctrine. This article will discuss the learned intermediary doctrine and its underlying principles. It will analyze the most recent case which rejected the learned intermediary doctrine, *Watts v. Medicis*,\(^2\) and explain why other courts should not follow its lead.

**Learned Intermediary Doctrine.** The term “learned intermediary” was first published in court opinions in the mid-1960s,\(^3\) and the doctrine has been adopted in the majority of states.\(^4\) Under the familiar learned intermediary doctrine, a drug manufacturer is not required to warn the consumer of the dangers of a prescription drug as long as the manufacturer has adequately warned the prescribing physician.\(^5\) The doctrine recognizes the reality of the informed consent process. That is, the prescribing physician, with whom the patient has a relationship and who has special knowledge of the patient’s medical history and circumstances, bears the responsibility of weighing the potential benefits and risks of a potential therapy given her patient’s unique circumstances and needs. Pharmaceutical manufacturers – which stand outside the physician-patient relationship – must provide prescribing physicians with sufficient and appropriate

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\(^1\) See e.g., Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices, 79 Fed. Reg. 34759 (June 18, 2014); Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs, 80 Fed. Reg. 6998 (February 9, 2015).


\(^3\) See, e.g., Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966).

\(^4\) See n. 12, infra.

warnings and information regarding the proposed drug therapy. The learned intermediary doctrine recognizes that the physician is better suited to receive the warnings, understand the potential benefits and risks, and convey those potential benefits and risks to her patient. The doctrine applies to both strict liability and negligence claims. Of course, some courts have carved out exceptions to the doctrine. For example, some courts find that a manufacturer will have a duty to warn the patient directly where the drug is a contraceptive (because of the personal lifestyle choices involved) or where doctors are not in a position to provide a personalized warning (e.g., mass vaccination programs). These exceptions allow the states flexibility in developing their law while still maintaining the important protections for doctors and drug manufacturers that the learned intermediary doctrine provides.

Traditionally, three basic principles underpin the doctrine. First, as noted above, a prescribing physician is in a superior position to warn the patient of the benefits and risks of a particular drug and can provide independent medical judgment regarding use of the drug for that specific patient, based on her knowledge of her patient’s unique circumstances. A prescribing physician also is likely to be the one monitoring her patient for potential side effects, and responding to any side effects that occur. Second, unlike physicians, manufacturers lack effective means to communicate with patients. And third, imposing a duty to warn on manufacturers would interfere with the doctor-patient relationship.

### Adoption by the States

The vast majority of the states have adopted the doctrine. Forty-four states and Puerto Rico have adopted the doctrine. In twenty-two of those states, the

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7 Several states have carved out an exception from the learned intermediary doctrine for contraceptives, holding that a manufacturer has a duty to warn the consumer in addition to giving the prescribing doctor additional information. The reasoning behind the exception is that contraceptives involve an individual’s lifestyle choice and the typical individual is heavily involved in the decision making process.
9 See e.g., Vitanza v. Upjohn Co., 257 Conn. 365 (2001).
11 See e.g., Larkin v. Pfizer, Inc., 153 S.W.3d 758 (Ky. 2004).
highest court has explicitly adopted the doctrine or the legislature has codified it. In eight states, a federal district or circuit court of appeals has predicted that the state’s highest court would adopt the doctrine. Idaho has discussed the doctrine favorably but has not directly adopted it and three other states, Rhode Island, Vermont, and Wyoming, have not yet addressed it. Only two states have rejected the doctrine.

Watts v. Medicis Pharmaceutical Corporation. Recently, the Arizona Court of Appeals rejected the learned intermediary doctrine in Watts v. Medicis Pharmaceutical Corporation. In doing so, the court overruled Dyer v. Best Pharmacal, the 1978 Arizona Court of Appeals decision adopting the learned intermediary doctrine. The plaintiff in the case, Amanda Watts, was being treated for chronic acne in April 2008. Her doctor prescribed Solody, an oral antibiotic containing minocycline which she took as prescribed for about ten months. Watts received two pamphlets of information on Solody, neither of which contained information about the link between Solody and the development of auto-immune disorders. Her doctor, on the other hand, had access to the complete FDA-approved package insert for Solody, which included a specific warning of lupus-like symptoms that may result from long-term use of the drug and that auto-immune syndromes have been observed with other minocycline drugs. A little over two years later, Watts was diagnosed with drug-induced lupus and drug-induced hepatitis. Watts filed a complaint against the manufacturer of Solody, Medicis, alleging consumer fraud, product liability, and asserting a claim for punitive damages. The trial court granted Medicis’s motion to dismiss.
for failure to state a claim for common law product liability on the basis of the learned intermediary doctrine.\(^\text{23}\) On appeal, the Court of Appeals reversed the trial court’s decision, rejecting the learned intermediary doctrine as a defense to the common law products liability claim.\(^\text{24}\) The Court concluded that the learned intermediary doctrine was incompatible with the adoption of a pure comparative fault system and that direct consumer advertising of drugs had altered the foundations of the doctrine.\(^\text{25}\)

The Court first reviewed the history of the doctrine in Arizona and found that it was intended to be a doctrine of causation.\(^\text{26}\) When a doctor failed to properly warn a patient about possible side effects of a drug, the doctor’s omission would constitute an “unforeseeable, superseding force[] that would break the chain of causation” between the drug manufacturer’s distribution and the patient’s harm.\(^\text{27}\) However, the Court noted that the doctrine generally was not applied to determine whether causation was satisfied, but rather had become the standard for whether a drug manufacturer had satisfied its duty to warn.\(^\text{28}\) Once a manufacturer had satisfied its duty by providing adequate information to the physician, a manufacturer was shielded from liability for an insufficient warning to the consumer.\(^\text{29}\)

According to the Court, shielding a defendant from liability for its own actions was incompatible with Arizona’s adoption of the Uniform Contribution Among Tortfeasors Act (the “UCATA”).\(^\text{30}\) The Act abolished joint liability between defendants in order to ensure that each defendant would be “individually responsible for its own contribution to the plaintiff’s injury, independent of the actions of the co-defendants.”\(^\text{31}\) The Court concluded that the learned intermediary doctrine and the UCATA were incompatible because the learned intermediary doctrine protects a drug manufacturer “for its own actions in distributing a product, simply because another participant in the chain of distribution is also expected to act” whereas the UCATA was premised on individual responsibility for each defendant who contributed to the plaintiff’s injury.\(^\text{32}\) According to the Court, the UCATA was designed to prevent one co-defendant from bearing responsibility for other defendants, but the learned intermediary doctrine allowed the physician to bear all the burden, even if the manufacturer gave inadequate warnings to the patient.\(^\text{33}\)

Further, the Court reasoned that the “realities of modern-day pharmaceutical marketing” had altered how patients receive information about drugs because of the prevalence of direct consumer advertising and the

\(^{23}\) Id. at *8.
\(^{24}\) Id. at *38.
\(^{25}\) Id.
\(^{26}\) Id. at *30.
\(^{27}\) Id.
\(^{28}\) Id. at *31.
\(^{29}\) Id. at *32.
\(^{30}\) Id. at *38.
\(^{31}\) Id. at *34.
\(^{32}\) Id. at *35.
\(^{33}\) Id. at *36.
availability of medical and drug information online. The increased use of advertising for pharmaceutical drugs caused patients to ask, encourage, and even pressure doctors into prescribing a specific name-brand medication. The Court reasoned that between direct consumer advertising and the availability of information on the internet, the doctor was no longer the sole source of information about the drug. Relying on the changes in modern medical practice, the Court concluded that the reasons for the adoption of the learned intermediary doctrine in 1978 were no longer persuasive.

The reasoning of Watts substantially parallels the reasoning in an earlier case from West Virginia, which is the only other state outside of Arizona that has expressly rejected the doctrine. In 2007, the Supreme Court of West Virginia in State ex rel. Johnson & Johnson Corp. v. Karl declined to adopt the learned intermediary doctrine, reasoning that the doctrine was outdated. It relied on significant changes in modern medical practice, noting the rise in direct-to-consumer advertising of prescription drugs, the resulting change in the doctor-patient relationship, and the proliferation of pharmaceutical information on the internet. The Court held these changes had sufficiently undermined the foundations of the doctrine and changed the doctor-patient relationship so drastically as to warrant abandoning the doctrine altogether. In contrast to several decades ago, the Court reasoned that modern consumers often base health care decisions on information they find online or in other media. Furthermore, doctors report that patients increasingly pressure them into prescribing specific medications. The Court found that direct consumer advertising and its resultant impact on the doctor-patient relationship negates the reason that the doctrine exists. The Court noted “with rare and wonderful exceptions, the ‘Normal Rockwell’ image of the family doctor no longer exists.” The Court therefore rejected the learned intermediary doctrine, stating that due to the prevalence of direct consumer advertising, it can no longer be suggested that the manufacturers do not have effective means to communicate with patients. Since it is the drug manufacturers who financially benefit from the sale of prescription drugs and the drug manufacturers know the most about the specific drug, the Court held that manufacturers should be required to provide appropriate warnings to the ultimate users of their products.

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34 Id. at *37.
35 Id.
36 Id.
37 Id. at 41.
39 See Karl, 647 S.E.2d at 906.
40 Id. at 907.
41 See id. at 913. Other courts have done a similar analysis when considering drug companies that directly advertise to consumers. But rather than get rid of the doctrine altogether, they have carved out an exception. In those jurisdictions, the learned intermediary doctrine will not apply where the drug manufacturer chose to directly advertised to consumers. See Perez v. Wyeth Laboratories Inc., 161 N.J. 1 (1999).
42 See Karl, 647 S.E.2d at 909-11.
43 Id. at 910.
44 Id. at 910.
45 Id.
46 Id. at 913.
47 Id.
Much of Watts court’s reasoning echoes the reasoning in the Karl decision. Like the Karl court, the Watts court concluded that the learned intermediary doctrine was outdated in light of increasing direct-to-consumer advertising and the availability and common use of the internet for medical advice. As will be explained below, as compelling as these arguments may be, they do not justify abandoning the learned intermediary doctrine altogether. Informed consent is at the heart of the learned intermediary doctrine. The vast majority of patients cannot truly inform themselves of a pharmaceutical drug on the internet or through a two minute television advertisement. It is the doctor, acting as the learned intermediary, who allows an average patient to understand the information they have received from the internet, direct advertising, or from the doctor herself and to consider that information and make an informed decision. Watts and Karl attempt to carve the doctor out of the equation, but in doing so, they fail to address how a patient could otherwise give informed consent. The learned intermediary doctrine remains – and should continue to remain – an important facet of the law. Other courts should not follow the lead of Watts and Karl for a host of reasons.

First, the Watts court’s reliance on the fact that some patients may pressure doctors into prescribing certain medications ignores the legal duty that physicians owe their patients. Physicians are more than mere dispensaries, and the court’s analysis did not properly account for the high ethical and legal standards required of physicians. Nearly all – if not all – prescription drugs carry with them the potential for some side effects. Physicians alone bear the burden of weighing the potential benefits of a particular therapy against its potential risks, together with their knowledge about their patients’ medical history and other unique circumstances. The only party in the position to understand the risks and evaluate the benefits is the prescribing physician.

Both the Watts court and the Karl court reasoned that the increase of medical information available online and in other media has caused patients to obtain prescription information from sources outside the parameters of the doctor-patient relationship. While that may be true, this argument only goes so far. The mere availability of WebMD and the myriad other medical databases and other sources of information does not replace a conversation about an illness and possible treatment options with one’s own physician. Medical practice and pharmaceutical products are, of course, complex and ever-changing. The average patient cannot fully understand these products without advanced education and

50 Id.
51 Restatement Third, Torts: Products Liability § 6, Comment b.
52 See Watts, 2015 Ariz. App. LEXIS 12, at *37; Karl, 647 S.E.2d at 907.
specialized training.\textsuperscript{53} Indeed, even the \textit{Karl} court recognized that the complexity of the subject matter is still a valid reason for continued viability of the learned intermediary doctrine.\textsuperscript{54} It is the doctor as the learned intermediary that provides her patient with the information necessary to give informed consent.\textsuperscript{55}

The \textit{Watts} and \textit{Karl} courts also reasoned that the increase in direct-to-consumer advertising for pharmaceutical products obviates the need for an intermediary because now drug manufacturers can and do communicate directly with consumers.\textsuperscript{56} However, drug manufacturers still lack \textit{effective} ways to communicate with patients. A drug manufacturer cannot tailor its warnings to each individual patient. And, of course, manufacturer’s “communications” with patients are almost exclusively one-way. That is, while the manufacturer may provide limited information to patients, the patients generally do not provide any information or otherwise communicate with the manufacturers. Only the doctor can use her individualized judgment for a patient based on her understanding of the patient’s medical history and test results, in conjunction with the information from the drug manufacturer. Manufacturers can reasonably expect that a doctor will evaluate whether the prescription is appropriate for that patient before filling the prescription.\textsuperscript{57} The same drug may be beneficial to one patient and dangerous to another. Doctors are in the best position to evaluate these benefits and risks. Thus, the manufacturer still lacks \textit{effective} means to communicate with patients. And while the \textit{Karl} court suggested that the traditional doctor-patient relationship does not exist anymore,\textsuperscript{58} the fact of the matter is that a doctor is still required in order to write a prescription. And it is the doctor that provides that patient with the knowledge to make an informed choice, through an explanation of the risks and benefits involved and with respect given to the individual’s medical history. This is the same process that existed fifty years ago.

The \textit{Watts} court also concluded that the doctrine was inconsistent with the UCATA.\textsuperscript{59} The UCATA was adopted in 1984 and amended three years later to establish a pure comparative fault system, under which each co-defendant in a tort case is only liable for the damage she or it caused to the plaintiff based on their respective percentages of fault. The \textit{Watts} court reasoned that the learned intermediary doctrine was inconsistent with the UCATA because it did not allow part of the fault of injury to be placed on a drug manufacturer.

This argument misses the point. Under the doctrine, the pharmaceutical company would not bear any percentage of fault if it provided

\textsuperscript{53} See \textit{Garside v. Osco Drug, Inc.}, 976 F.2d 77, 80 (1st Cir. 1992).
\textsuperscript{54} See \textit{Karl}, 647 S.E.2d at 910.
\textsuperscript{55} Restatement Third, Torts: Products Liability § 6, Comment d.
\textsuperscript{56} \textit{Watts}, 2015 Ariz. App. LEXIS 12, at *37; \textit{Karl}, 647 S.E.2d at 910.
\textsuperscript{57} \textit{Wooderson v. Ortho Pharmaceutical Corp.}, 681 P.2d 1038, 1057 (Kan. 1984).
\textsuperscript{58} \textit{Karl}, 647 S.E.2d at 910.
the physician with all of the necessary warnings. The doctrine does not alleviate altogether the manufacturers’ responsibility to provide warnings. Rather, it places the same burden on a drug manufacturer, but merely directs the warning to the doctor rather than the consumer. The drug companies still have a “burden” to provide detailed and accurate warnings.60 Pharmaceutical drugs are different than other products because drugs have inherent dangers that cannot be eliminated, even if all possible caution is used. As a society, we recognize that for certain patients, the benefits of a drug will far outweigh the potential risks. The learned intermediary doctrine recognizes this careful balance to be struck, and recognizes that doctors are in the best position to understand the potential benefits risks and strike that balance.

Finally, the rejection of the learned intermediary doctrine ignores Congress’ comprehensive regulatory scheme, administered by the FDA, which specifically protects consumers against misinformation and misleading advertising about prescription drugs. The FDA is a regulatory agency specifically charged to prevent drug companies from proving false or misleading information to consumers. The FDA provides both civil and criminal penalties for violations of drug advertising and drug labeling. This comprehensive regime is a significant safeguard against the dangers of direct advertising that the Karl relies on to buttress its rejection of the doctrine.61 Rejecting the learned intermediary doctrine negatively impacts the doctor-patient relationship while providing no benefit that the FDA’s regulation scheme is not already providing.

**Conclusion.** It is unclear whether Karl and Watts are the beginning of a trend or just outliers. While some commentators have suggested that they are the beginning of a trend, the current state of the law suggests they remain outliers — at least for now.62 Whether Watts remains the law in Arizona remains to be seen, as the deadline to appeal is on April 1, 2015. Either way, other courts should not follow the lead of the Karl and Watts courts. The learned intermediary doctrine remains viable, recognizing the primacy of the physician’s role in the informed consent process. Injecting manufacturers into that relationship will be disruptive and is impractical. Requiring pharmaceutical companies to distill pages upon pages of an FDA-approved package insert into a comprehensive — and comprehensible — warning that the average patient can understand is simply impractical for a host of reasons. How long should the warning be? To what education level should the warning be directed? Should it be all-inclusive? If so, how should manufacturers avoid what is commonly referred to as “warning fatigue” — in other words, over-warning that might cause a patient not to read any of the warnings? If

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60 See Tootle v. McClintock, 999 F.2d 1430, 1433 (11th Cir. 1993).
61 See id. at 909.
it should not be all-inclusive, how should manufacturers choose which warnings to include and which to exclude? Regardless of whether patients obtain some information from other sources, it is not the place of courts to suggest that patients should now turn to manufacturers – who do not have any knowledge about the patients’ medical history or other unique circumstances – as the primary source of information regarding the potential benefits and risks of any particular treatment.
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