

A Checklist for Pharmaceutical Claims

By D. Andrew List

As the United States population ages, Americans ingest more and more prescription medications. According to a recent study by the Centers for Disease Control and Prevention, more than forty-seven percent of the population ingests at least one prescription medication on an ongoing basis.¹ Moreover, nearly twenty-one percent of the population regularly uses three or more prescription drugs. Given these statistics, lawyers are more frequently being consulted by patients who have suffered injury or illness following prescription medication usage.

As with any area of law, case selection is essential to the effective management and representation of injured consumers. Recognizing the viable case – and quickly rejecting cases without merit – is critical to a successful practice. Although every case is unique, certain questions should always be asked when evaluating a potential pharmaceutical claim.

Have other lawyers pursued claims for injury caused by this drug?

Twenty years ago, answering this question took considerable effort. With the internet, however, the sole practitioner and small firm lawyer have access to a wealth of information.

One starting point is the United States Panel on Multidistrict Litigation where lawyers and consumers have access to information regarding federal cases that have been consolidated against a single pharmaceutical manufacturer.² Additionally, many states have similar mechanisms for consolidating and managing state court

cases.³ Accordingly, researching state court dockets where the drug's manufacturer is headquartered often provides insight into the viability of a particular case.

Gathering this history – which can be done quickly and without cost – avoids reinventing the wheel in cases that have been previously developed.

Did the manufacturer warn of the injury the consumer has suffered?

Although pharmaceutical claims can be based upon a variety of legal theories (design defect, manufacturing defect, violation of state consumer statutes, to name a few), many claims involve failure to warn. Specifically, did the manufacturer provide reasonable warning of the potential for the actual harm suffered?

The United States Food and Drug Administration maintains an online approval history, including letters, reviews, labels and patient package inserts.⁴ Using this resource, and without leaving her desk, a lawyer can make giant strides in determining the viability of a potential failure to warn claim.

Was the consumer using a brand name or generic drug?

This issue may sound simple, but without up-front investigation it can be a potential minefield. For chronic conditions, consumers may have taken both brand-name and generic drugs for the same illness or injury over a period of months or years. At a minimum, pharmacy records should be ordered to determine if both brand-name and generic manufacturers are involved.

Why does it matter?

While failure to warn claims have been upheld as to brand name manufacturers,⁵ such claims as to generic manufacturers remain in dispute. In December, 2010, the U.S. Supreme Court accepted *PLIVA, Inc. et al. v. Gladys Mensing*, through which the Court could potentially preempt failure to warn claims against generic makers.⁶

In *Mensing*, the consumer took the drug metoclopramide for four years to help fight diabetic gastroparesis. She filed a lawsuit against the generic drug's manufacturers and distributors, contending that the drug gave her a severe neurological movement disorder – tardive dyskinesia – but none of the generic drug's manufacturers and distributors made any effort to include warnings of the potential for this condition on the label.

Metoclopramide manufacturers, Pliva Inc and Actavis Elizabeth LLC, asked for the lawsuit to be thrown out, arguing that government regulations require generics to have the same label on metoclopramide as its brand-name equivalent, Reglan. Reglan did not have a warning about tardive dyskinesia while the consumer was taking metoclopramide.

The U.S. District Court for the District of Minnesota agreed, saying the lawsuit was preempted by federal regulations requiring the two labels to match. But the U.S. Court of Appeals for the Eighth Circuit overturned that ruling, holding that more should have been done to warn consumers about possible risks.

Oral argument in *Mensing* was held on March 30, 2011 before the U.S. Supreme Court, and no decision had been issued at the time of this writing. Until *Mensing* is decided, wise practitioners must continue to consider the risks of undertaking failure to warn claims involving generic drugs.

Is the consumer determined to proceed against his medical providers, in addition to the pharmaceutical's manufacturer?

In many situations, consumers who believe they have been injured by a dangerous drug, rightly or wrongly, also blame their prescribing physician or pharmacy. The differences among these claims must be explained to the consumer, and the scope of representation should be limited as soon as the preliminary investigation is complete.

Again, while every case is unique, it is often difficult to proceed with claims against the manufacturer – particularly, failure

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to warn claims – while simultaneously asserting that the prescribing physician or pharmacy should have known of the drug's risks and independently warned the consumer. Finally, as is true in any case, lawyers have the ethical duty to bring claims only against responsible parties. Pursuing claims against physicians, pharmacists or other medical providers, without evidence that these persons had knowledge above and beyond a drug's label and package insert, is unjustified.

Pharmaceutical claims are complex and difficult. However, if the above steps are followed, an attorney can better ensure that the viability of such a claim is properly vetted: the key to any successful practice.

¹ National Center for Health Statistics. Health, United States, 2010 With Special Feature on Death and Dying. Hyattsville, MD, 2011.

² www.jpml.uscourts.gov

³ Many pharmaceutical manufacturers are headquartered in New Jersey. New Jersey's "mass tort home" can be accessed at <http://www.judiciary.state.nj.us/mass-tort/faq.htm>.

⁴ <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?CFID=57558427&CFTOKEN=255677115d3992c4-D5EC007B-F6B1-E326-42E6DDE8EB454455>

⁵ Wyeth v Levine, 129 S.Ct. 337 (2008)

⁶ PIIVA, Inc. et al. v. Gladys Mensing, Case No. 09-993, accepted December 10, 2010.



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