

Seven Tips for Cases Involving Medication

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Despite the lifesaving and symptom-relieving effects of medication, adverse effects can and do occur. When these adverse effects of using medication are severe and foreseeable, or result from negligence, the patient might be able to recover damages through litigation. However, these cases need careful consideration, planning, and expert help. Here are seven tips for cases about medication.

1. Know the types of adverse drug events (ADEs).

The use of medication always comes with some risk. No drug is perfectly safe, and all drugs come with *side effects* – common, minor and expected negative effects associated with taking the drug. Many who take the medication will experience these annoying effects.

More serious consequences of taking a drug are called *adverse drug events* (ADEs). Although these serious adverse effects occur less often than side effects, they can result in seeking medical attention, being hospitalized, being disabled, experiencing a threat to life, or dying.

2. Know the four drug misadventures (DMAs) that harm patients.

There are four ways medication cause serious adverse effects in patients: 1) adverse drug reactions, 2) drug interactions, 3) allergic drug reactions, and 4) medication errors.

Adverse Drug Reactions - There are two types of adverse drug reactions (ADRs). Type A ADRs are dose-related and are an extension of the drug's usual action (its pharmacology). An example is reduced breathing after receiving too much morphine. Type B ADRs are often termed "bizarre" as they cannot be explained by the size of the dose or by the drug's pharmacology. An example is someone's hair turning green after taking the drug.

Drug Interactions - There are two types of drug interactions. The first is between two or more drugs and the second is between drugs and food. Although there are many known drug interactions, their incidence and clinical significance vary widely.

Allergic Drug Reactions – Patients allergic to a drug or an ingredient in a medication (like a color dye) can experience adverse reactions that vary in severity from a minor annoyance to a threat to life.

Medication Errors – Medication errors are sometimes the result of human error, but more commonly happen because of the safety net in the medication use system breaking down. There are two types of medication errors. Slips are defined as attention

deficit errors. The person committing this error knew better, but because of inattention or distraction, an error occurred through commission or omission. *Mistakes* are knowledge deficit errors. These errors occur less often than *slips*, but are considered more egregious because the health professional should have known better.

3. Know which DMAs are preventable.

Many DMAs are foreseeable, and thus preventable. For example, all medication errors are preventable – none should happen. Also, all known drug interactions, Type A ADRs, and known drug allergies are preventable. In cases where the patient told their health professional that he or she was allergic to a drug, but the patient still receives the drug, the ADE is an error.

4. Know how often others have experienced the adverse drug effect.

It is important to know (in cases of litigation) whether the drug-induced adverse effect has occurred before and how often it has occurred. This provides credibility to the ADE. Doing a thorough search of the medical literature is the key to discovering this information, and this needs to be done by someone skilled in drug information retrieval and evaluation.

5. Know the likelihood of the drug being the direct and primary cause of the adverse effect.

One of the four requirements for proving negligence is proving the drug was the primary and direct cause of the damage. Just because it rains and you go outside and see frogs on the lawn and sidewalks does not mean that it rained frogs. Similarly, when a person suffers an adverse effect after taking a drug does not mean the drug caused the adverse event. It is easy to blame the drug when it could easily be something else like another drug, an exacerbation of the patient's disease, or other factors. *Association* does not mean *causation*. Causality assessment is a complex area that needs to be investigated by a trained professional.

6. Know the standard of care required for prescribing, dispensing, administering, and counseling of patients about their medication.

When a health professional makes an error that adversely affect a patient, they more than likely violated a standard of care, duty, law, policy, or procedure. Standards of care vary by health profession, and sometimes by location or practice. This is why having a peer as an expert witness is important in these cases.

7. Know which expert witness to hire.

Hiring a health professional as an expert witness in these cases is often the reason for being successful. Which professional to hire depends on the nature of the case and questions to be answered – Can it happen? Did it happen? How did it happen? And, could it have been prevented? Available experts include: drug information specialists, pharmacists, pharmacoepidemiologists, pharmacokineticists, pharmacologists, and

toxicologists. In cases of potential negligence, a peer of the defendant will be needed to testify to the standard of care.

Note: this review does not include cases where product liability may be involved. Other considerations are needed in these cases.

References

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