

## Pharmacist Negligence per se in Ohio and the Ohio Revised Code and Ohio Administrative Code

Lesson number 036-368-04-002-H03

Approved for one contact hour of Ohio Jurisprudence by the Ohio State Board of Pharmacy.

### **Objectives:**

After completing this lesson, the pharmacist will be able to:

1. Discuss the elements of a case of negligence,
2. Compare and contrast negligence and negligence per se,
3. Discuss the legal effect of legislative enactments and Board of Pharmacy rules in negligence and negligence per se,
4. Differentiate between negligence and liability.

The specter of medication errors is one of the pharmacist's worse nightmares. While pharmacists are human, patients, courts, boards of pharmacy, and malpractice insurers do not view human error as an excepted rationale for medication errors. This article will discuss Ohio law regarding negligence and negligence per se. The lesson will also discuss the legal difference between the Ohio Revised Code and the Ohio Administrative Code in pharmacy negligence cases.

In order to prevail in a negligence claim, a plaintiff such as for example a patient, must prove the following elements;

- (1) that the defendant [pharmacist] owed the plaintiff [patient] a duty to do or not do something,
- (2) that the defendant breached that duty, and
- (3) that the breach of the duty proximately caused the patient some injury, or damages.

Typically, exactly what "duties" a pharmacist owes a patient may be established either by common law, meaning a court, or by a legislative enactment. For example, a court may decide that a pharmacist owes a patient a duty to warn the patient that ingesting a prescribed antihistamine may cause drowsiness and make driving a motor vehicle more dangerous. The court may derive this duty of the pharmacist from:

- (1) the trusting nature of the relationship between the patient and the pharmacist,
- (2) the comparatively superior knowledge and training of the pharmacist,
- (3) the relatively low "cost" for the pharmacist to provide this information to the patient, and
- (4) the high potential for serious injury if the information is not provided.

In the State of Ohio, legislative enactments are promulgated by the General Assembly. Legislative authority is vested with the General Assembly. Members of the General Assembly are accountable to their constituents because they are elected to office. If the constituents are unhappy with policy determinations made by members of the General Assembly, the constituents can change the makeup of the General Assembly at the voting booth.

The Ohio State Board of Pharmacy does not promulgate legislative enactments. As a state administrative agency the members of the Board of Pharmacy are appointed, not elected. Therefore, the Board is not a public policy making entity in the same way as the General Assembly. Instead, the Board of Pharmacy places into effect a policy declared in the General Assembly's statutes by making and administering rules. Unlike the legislative process, rulemaking by the Board of Pharmacy does not involve the collaborative effort of elected officials.

The distinction between legislative enactments and Board of Pharmacy rules is important in negligence cases. Where a legislative enactment imposes a specific duty for the safety of others, failure to perform that duty is negligence per se. Application of negligence per se in a tort action, such as negligence, means that the plaintiff patient has conclusively established that the defendant pharmacist breached the duty owed to the plaintiff patient. It is not a finding of liability per se because the plaintiff patient still has to prove proximate cause and damages. Under negligence per se, the patient plaintiff does not have to prove the pharmacist owed the patient that duty. In effect, the General Assembly has already determined that the pharmacist owed the patient that duty by enacting the law in question.

In Ohio, the violation of an administrative rule does not constitute negligence per se. However, the violation of an administrative rule may be admissible as evidence of negligence. By contrast, violation of a legislative enactment does constitute negligence per se. Put somewhat differently, violation of a pharmacy related portion of the Ohio Revised Code does constitute negligence per se and makes it easier for a patient plaintiff to prevail in a negligence suit against a pharmacist. Violation of a Board of Pharmacy rule may be merely some evidence that the pharmacist was negligent.

### **Examples**

Let's take a concrete example of negligence per se. Ohio Revised Code 4729.51 (B) (3) (a) requires a pharmacist to observe an individual whom the pharmacist has immunized to determine whether the individual has an adverse reaction to the immunization. If a patient is immunized by the pharmacist and is subsequently injured from the immunization, and the pharmacist is shown to have not observed the patient as required, the pharmacist is negligent per se. To win an award of damages in court, the patient must still show the injury occurred because the pharmacist did not perform the required observation and the damages suffered by the patient were related to the negligence per se. The patient does not have to show the pharmacist had a duty to observe the patient after immunizing the patient – the Ohio General Assembly has already established that.

Let's take a concrete example of possible negligence by a pharmacist that is not negligence per se. Ohio Administrative Code 4729-5-22 (A) (4) requires that prior to dispensing any prescription, a pharmacist must review the patient profile for the purpose of identifying drug-drug interactions. If a patient has a prescription filled by the pharmacist who does not review the patient profile for the purpose of identifying drug-drug interactions and is subsequently injured by a drug-drug interaction between the

prescription dispensed and a drug on the profile, the pharmacist may have been negligent. The pharmacist is not negligent per se. Ohio Administrative Code 4729-5-22 (A) (4) is enacted by the Board of Pharmacy, not the General Assembly.

In a negligence lawsuit against the pharmacist, the patient would contend, and the court may or may not agree, that the pharmacist had a legal duty to review the patient profile for the purpose of identifying drug-drug interactions. The existence of Ohio Administrative Code 4729-5-22 (A) (4) in this case is some evidence that the pharmacist had such a legal duty and some evidence the pharmacist was negligent, but it is not as conclusive on the matter as it would be had the General Assembly had enacted a law similar to 4729-5-22 (A) (4). As in the immunization example, the patient must also prove that the pharmacist's breach of the duty to review the patient profile for the purpose of identifying drug-drug interactions proximately caused the patient some injury, or damages.

### **Distinction**

The distinction between negligence and 'negligence per se' is the means and method of ascertainment. Negligence must be found by the jury from the facts, the conditions and circumstances disclosed by the evidence. Negligence per se is a violation of a specific requirement of law, the only fact for determination by the jury being the commission or omission of the specific act inhibited or required. Once either negligence or negligence per se is ascertained, the matter of damages and whether those damages were caused by the negligence or negligence per se must be determined. Keep in mind that a finding of negligence or negligence per se does not conclusively establish liability. A pharmacist can be negligent or negligent per se and still not be legally liable to pay damages. Those damages must still be shown to be caused by the negligence or negligence per se.

The Ohio Revised Code is a set of legislative enactments. The Ohio Administrative Code includes a set of Board of Pharmacy Rules. While both are law, the Ohio Revised Code is more important in establishing negligence per se. That is not to say that the Board of Pharmacy Rules are less important – they just don't get the patient plaintiff quite as far in a civil action, such as negligence, as the Ohio Revised Code does.

Questions – choose the one best answer. A passing score and one contact hour will be given for all persons who achieve seventy percent or more correct.

1. The Ohio State Board of Pharmacy promulgates legislative enactments.
  - a. true
  - b. false
  
2. Negligence per se is a violation of a specific requirement of law.
  - a. true
  - b. false

3. What “duties” a pharmacist owes a patient may only be established by a legislative enactment or a board of pharmacy rule.
  - a. true
  - b. false
  
4. Under negligence per se, the patient plaintiff does not have to prove the pharmacist owed the patient that duty.
  - a. true
  - b. false
  
5. Application of negligence per se in a tort action, such as negligence, means that the plaintiff patient has conclusively established that the defendant pharmacist breached the duty owed to the plaintiff patient.
  - a. true
  - b. false
  
6. Members of the Ohio Board of Pharmacy are accountable to their constituents because they are elected.
  - a. true
  - b. false
  
7. The violation of an administrative rule may be admissible as evidence of negligence.
  - c. true
  - a. false
  
8. A pharmacist can be negligent or negligent per se and still not be legally liable to pay damages.
  - a. true
  - b. false
  
9. Rulemaking by the Board of Pharmacy does not involve the collaborative effort of elected officials.
  - c. true
  - a. false
  
10. To win an award of damages in court, a patient suing a pharmacist must show the injury suffered by the patient occurred because the pharmacist did not perform the pharmacist’s legal duty and the damages suffered by the patient were related to the pharmacist negligence or negligence per se.
  - a. true
  - b. false



Lesson number 036-368-04-002-H03 Answer Sheet: Expires September 30, 2007

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Answer Sheet – circle the one correct best answer

Question	Answer	Question	Answer
1	True False	6	True False
2	True False	7	True False
3	True False	8	True False
4	True False	9	True False
5	True False	10	True False



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Program Evaluation (circle one response to each question):

1. How would you rate this educational program overall?  
 excellent | very good | Good | Fair | Poor
2. How well did this program achieve its educational objectives?  
 excellent | very good | Good | Fair | Poor
3. How well did this program improve your knowledge of the subject matter?  
 excellent | very good | Good | Fair | Poor
4. How useful and relevant will this lesson be in your practice?  
 Very | Somewhat | Not much | Not at all
5. About how much time did it take you to complete the lesson and exam?  
 30 minutes | 45 minutes | 60 minutes | 90 minutes | Over 90 minutes