

2018 STAC Fact Pattern Clarifications

Editor's Note

In addition to the questions answered below, the fact pattern has been reposted, revised to reflect the following changes:

- A jury verdict form has been added to the fact pattern at STAC 94.
- Name of expert Eppi Lepsey has been adjusted to Eppi Leonard.
- The stipulations have been revised to reflect accurate numbering.
- Additional jury instructions have been added at STAC 91.
- Dr. Condon's age has been changed to 55.
- Bobby Daley's birthday has been changed to January 8, 1997.
- Sam Shields's birthday has been changed to June 7, 1989.
- Dr. Condon's deposition date has been changed to April 7, 2017.
- Part (c) of the Burden of Proof jury instructions at STAC 90 has been removed.

Answers to Team Questions

1. When was, if any, there diagnostic testing performed? Between STAC 53 & 54, the story changes from possibly needing testing in the future to no *further* testing needed.

Answer: No further information will be provided regarding this question.

2. In what state (thrown from car, etc?) was Sam Shields found by police after the accident? The report says that his restraint was a 9, which means unknown.

Answer: No further information will be provided regarding this question.

3. How long have each of the experts spent working on this case?

Answer: No further information will be provided regarding this question.

4. Can we get definitions for some of the medical acronyms? (VSS, ULE, PRN, etc.)

Answer: The definitions for medical acronyms are as follows:

VSS: Vital signs stable

ULE: Upper left extremity

PRN: When necessary/as needed

5. On page 11 of the rules, paragraph 2 states that on cross examination, a witness does not commit a violation when testifying to material facts not included in his or her affidavit as long as the witness's answer is responsive to the question posed. However, the remainder of that rule states that witnesses may only testify to facts provided in the fact pattern and reasonable inferences that may be drawn therefrom (text before paragraph 1), and that no inferred fact may be material (paragraph 3) and must be a reasonable inference

(paragraph 4). These rules conflict. May a witness, on cross examination, testify to a material fact not in the fact pattern that is not necessarily a “reasonable inference” (as defined in paragraph 4), as long as the material fact is not contradicted elsewhere in the fact pattern without violating the rules (as paragraph 2 states), or would such an inference be a violation (as described in paragraphs 3 and 4)?

Answer: The change in the rule regarding facts outside the record is designed to address potential abuse by teams on cross-examination, asking questions that cannot be answered based on information in the fact pattern purely in an effort to set up impeachment of that witness by omission.

If asked a question on cross-examination that is not answerable based on the fact pattern, a witness may testify to a material fact not in his or her affidavit so long as the witness’s answer is responsive to the question posed and does not conflict with anything in the affidavit. As in real trials, an attorney that asks a question he or she does not know the answer to risks getting an unfavorable answer from the stand.

As an example, in the 2017 fact pattern, it was undisputed that the bar patron who later caused an accident did not start drinking at the bar until after midnight when he was officially 21. No information was provided about whether the bartender checked the ID of that patron but teams asked on cross-examination whether s/he checked the ID. An answer of “yes” led to an impeachment by omission because that answer was not in the deposition testimony. Answers of “no” or “I don’t know” also were not in the deposition testimony but imputed more liability to the bartender/owner. Were the witness to be asked that question on cross-examination this year, any directly responsive answer – yes, no, or I don’t know – would not be considered a violation of the rules and teams may not then attempt to impeach by omission on this question.

6. In the Complaint, it states that Sam Shields resides at 6711 Kessel Rd, Penns Woods, in the District of Steelton. However, in Shield’s deposition and on the driver accident report, the address given is 269 Kessel Road, Steelton. Which is correct?

Answer: Sam Shield’s address is 269 Kessel Road, Steelton.

7. On STAC 50, one of the comments to the news story was made by Sam Shields. Is that authenticated as a statement by the plaintiff?

Answer: Yes, this comment was made by Sam Shields and the article is authenticated.

8. On page 12 of the rules, it states that counsel and witnesses may draw or make simple charts “subject to the rulings of the court.” Are those “rulings of the court” solely on evidentiary issues related to the items on the chart (i.e., that the charts or drawings may not reflect facts outside the record), or does the court have discretion to preclude the making of demonstratives entirely, independent of a substantive evidentiary objection to a demonstrative’s proposed content?

Answer: Judges are encouraged to allow for drawing of demonstratives. However, we cannot guarantee that you will not have a judge who does not allow you to do so. If there is an evidentiary issue, the judge may preclude the drawing.

9. Do health care providers report patients to District of Steelton Department of Motor Vehicles or to the Steelton Department of Transportation? Both are mentioned on STAC 4.

Answer: They report patients to the Steelton Department of Motor Vehicles.

10. In Bobby's 5/20/17 deposition, he says that he started going to Dr. Condon because he was having memory and concentration issues. Then, the attorney later asks him if he still has memory loss or loss of coordination. Was Bobby supposed to say that he was having concentration issues instead of coordination issues?

Answer: Yes. The fact pattern has been updated to reflect this change.

11. Is the photograph in Exhibit F a fair and accurate representation of what Kessel Road looked like at the date and time of the accident—inclusive of parked vehicles and other surroundings?

Answer: No, this is an image of the road taken after the accident.

12. The Joint Exhibit list does not include 75 Steelton Statutes § 5.71, 75 Steelton Statutes § 5.81, or 75 Steelton Statutes § 5.87. Can these statutes still be admitted as exhibits during trial?

Answer: No, they may not be admitted as exhibits but can be blown up and used as demonstratives.

13. The complaint pleads that Dr. Condon was negligent because the Dr. had a duty to report to SDOT, and the Dr. knew or should have known that failing to report Bobby Daley to SDOT put other members of the motoring public at risk. This would suggest that the only theory of liability against the Dr. is negligence by failing to report as required under the statutes. The jury instructions (STAC 92), however, state that even if the jury were to find that the Dr. did not violate the reporting statutes, the Dr. could still be held liable if the Dr. failed to act as a reasonable person would under the circumstances. Can the Plaintiff argue negligence by failing to act as a reasonable person would under the circumstances, independent of the reporting statutes, as set forth by the jury instructions, or is that argument waived by the Plaintiff's failure to specifically plead it in the complaint?

Answer: No further information will be provided regarding this question.

14. In the defendant's answer, the defendant raises a comparative/contributory negligence affirmative defense. The jury instructions do not have any language setting forth that defense, nor do they establish whether this is a comparative or contributory negligence jurisdiction. Is comparative/contributory fault a defense that the defense can legally

assert in this competition. If so will we be getting amended jury instructions to reflect that?

Answer: The jury instructions have been updated to reflect that the jurisdiction follows comparative negligence.

15. What definition of seizure is contemplated by the statute?

Answer: No further information will be provided regarding this question.

16. Are we allowed to read portions of Bobby's 2017 deposition into the record at any time as if the deposition is an admissible exhibit, or do we need to get them in through a witness?

Answer: Yes, portions may be read into the record by one advocate sitting on the stand as a witness and reading answers directly from the deposition transcript.

17. There is no indication in the file as to who could lay foundation for the photograph or for the handwritten drawing of the accident. No indication of who took the photo or when, or who drew the diagram and when. Are those exhibits admissible even without the proper foundational witness?

Answer: These exhibits are part of the Joint Exhibit list and are deemed authentic and admissible subject to objection on grounds that the proposed exhibit is otherwise inadmissible under the pertinent rules of evidence.

18. There appears to be no jury instruction on the defendant's burden for the affirmative defense; is that intentional?

Answer: No further information will be provided regarding this question.

19. Is there a definition anywhere of what a "superseding act" is as referenced in the jury instructions?

Answer: No further information will be provided regarding this question.

20. STAC 22 states that Bobby was treated by Dr. Condon five times, but there are only four dates of treatment in the medical records provided. Are we missing a record?

Answer: Bobby was treated by Dr. Condon four times and the fact pattern has been updated to reflect that change.

21. What road does Exhibit F show?

Answer: Exhibit F shows Kessel Road, the site of the accident location as stated in the Joint Exhibit List (STAC 11).

22. Dr. Condon advised Bobby Daley to schedule a follow-up appointment for six months after his last visit on March 7, 2016. Was Bobby Daley's six-month follow-up appointment actually scheduled with Dr. Condon?

Answer: No further information will be provided regarding this question.

23. Who drew the diagram in Exhibit A?

Answer: A police officer drew the diagram in Exhibit A, the Police Incident Report.

24. What variance and dosage of Gabapentin did Dr. Condon prescribe to Bobby Daley? Was it neurotin or one of the other three brand names (Gabarone, Gralise, Horizant) for it?

Answer: No further information will be provided regarding this question.

25. Are all of the doctors aware of the language of the statute at issue for the negligence per se, and can the jury instruction with the language of the statute be used during the evidence phase of trial?

Answer: Yes, all of the doctors are aware of the language of the statute at issue.

26. Page 12 of the rules states that no other instructions will be given to the jury. Does this mean that students cannot ask for a limiting instruction if evidence is admitted for a limited purpose?

Answer: Participants may not ask for a limiting instruction.

27. Are raising brief preliminary matters permitted, e.g. moving about the courtroom, questioning from the podium, approaching the witness, tendering as an expert, etc. but not including motions in limine or other legal motions?

Answer: Yes, you may ask about housekeeping matters. No motions in limine are permitted.

28. How is the time scored for preliminary matters and JMOL?

Answer: Preliminary housekeeping matters may be taken care of with no time penalty. For motions for JMOL, the full time counts against the side making the motion.

29. Should Stipulation 9 refer to the Federal Rules of Evidence as opposed to the rules of Civil Procedure?

Answer: Stipulation 9 should refer to both the Federal Rules of Evidence and the Rules of Civil Procedure.

30. Dr. Condon testifies that he is 42 at his deposition, making his date of birth sometime in 1975 (STAC 19:22). However, according to his CV, he graduated from Steelton State in 1983, and from medical school in 1987 (STAC 55). Are the dates in the CV typos on the part of the packet writers?

Answer: Dr. Condon's age has been changed to 55 to reflect consistency with his CV.

31. There is no jury instruction on comparative negligence. Is this a purposeful omission?

Answer: The comparative negligence jury instruction is as follows: Defendant claims that Plaintiff was negligent and Plaintiff's negligence was a factual cause of Plaintiff's injury. Defendant has the burden of proving by a fair preponderance of the evidence that Plaintiff was negligent and that the Plaintiff's negligence was a factual cause of the plaintiff's harm. Plaintiff does not have the burden to prove he was *not* negligent. The burden is not on Plaintiff to prove his or her freedom from negligence. You must determine whether Defendant has proven that Plaintiff, under all the circumstances, failed to use reasonable care for his or her own protection.

The fact pattern has been updated to reflect this change.

32. On STAC 16, does the 0.0 BAC test mean 0.00?

Answer: Yes.

33. On STAC 43, in paragraph 5, is the phrase "stroke disorder" a typographical error which should actually read "seizure disorder"?

Answer: Yes, the phrase should read "seizure disorder".

34. On STAC 29, Line 3, Bobby Daley's deposition from May 20, 2017, Ms. Chia references the defendant's deposition. According to the problem the defendant's deposition doesn't occur until June 7, 2017. Are these dates correct?

Answer: Dr. Condon's deposition date has been updated.

35. On STAC 33, Line 22 references 2016 as the date of the accident. Shouldn't this date be 2015?

Answer: Yes. The fact pattern has been updated to reflect this change.

36. Are students able to use laptops while at counsel table during the trial for their own means of preparation?

Answer: Participants may use technology while at the counsel table for their own preparation as long as such use does not violate any other rules, such as communication with a coach during a trial. You cannot provide the device to another participant, such as a witness to read off of. Please note that you may not unplug any electronics already present in the courtroom in order to plug in your device and some courthouses may not allow you to bring laptops or other devices into the courthouse. Also, Wi-Fi connection is not guaranteed nor are students allowed to request Wi-Fi passwords from the regional coordinator.

37. Are students able to use any technology while at counsel table during the trial for their own means of preparation?

Answer: Participants may use technology while at the counsel table for their own preparation as long as such use does not violate any other rules, such as

communication with a coach during a trial. You cannot provide the device to another participant, such as a witness to read off of. Please note that you may not unplug any electronics already present in the courtroom in order to plug in your device and some courthouses may not allow you to bring laptops or other devices into the courthouse. Also, Wi-Fi connection is not guaranteed nor are students allowed to request Wi-Fi passwords from the regional coordinator.

38. The rules state “no pretrial motions of any kind” are allowed. Does this mean that there will be no opportunity to argue motions in limine at the beginning of the trial/round?

Answer: No motions in limine are allowed to be argued at the beginning of the trial.

39. Is the doctor-patient privilege waived or trumped by the statute?

Answer: Doctor/patient privilege is waived by operation of law.

40. May we use outside medical information about the diagnosis of seizures?

Answer: No.

41. Was Sam Shield wearing a seatbelt?

Answer: No further information will be provided regarding this question.

42. Please give us an example of a “reasonable inference”—this issue comes up every year and this year’s standard is different from previous years’.

Answer: As one example, Sam Shields testifies that he usually goes to his grandmother’s house on Sundays “to cut her grass and help her with some things that she could not do.” A reasonable inference is that those “some things” included things like putting in or taking out a window air conditioner, getting into the attic crawl space to get something stored up there, replacing ceiling lights, etc.

43. Please define “aura” under the applicable law of Steelton.

Answer: No further information will be provided regarding this question.

44. Where is the stop sign that Daley allegedly ran? Please reconcile discrepancy between diagram and Sam Shields’ report.

Answer: No further information will be provided regarding this question.

45. On STAC 29, Bobby states that Dr. Condon “mentioned it after the accident.” Does he mean the June 2015 attack or the September 2016 car accident?

Answer: No further information will be provided regarding this question.

46. The rules say that the case will be tried on liability only. However, on STAC 90, under burden of proof, it says “In this case, the Plaintiff has the burden of proving the following claims: (c) ...The extent of damages caused by the Defendant’s negligence. Does that mean Plaintiff can present evidence of the extent of damages or if not, that the jurors will

be told even though the jury instructions say Plaintiff must prove it, Plaintiff is not permitted to do so?

Answer: Part (c) has been removed from the instruction. Please refer to the fact pattern for the updated instruction.

47. On STAC 41, is Lepsey's (Leonard's) expert opinion meant to state that "Dr. Condon consistently reports in the medical records . . ." instead of "Bobby consistently reports in the medical records . . .?"

Answer: Yes. The fact pattern has been updated to reflect this change.

48. Is it stipulated that Bobby is at fault for the crash? If not, is the fault showing he was at least 51% at fault.

Answer: Please refer to the jury instructions for guidance.

49. Is the date on the police report intentionally left blank?

Answer: The police report was made the day of the accident.

50. Do we need to assert all of the affirmative defenses listed on STAC 7? Based on the jury instructions, if the defendant's negligent conduct was one of the factual causes of the harm, then the defendant is fully responsible for harm suffered regardless of the extent to which defendant's conduct contributed to the harm. As a result, would affirmative defenses two and three, which appear to address contributory negligence, be applicable in this case? Or might the defendant be claiming in Affirmative Defense 2 that the plaintiff was solely responsible?

Answer: It is up to the advocates to determine how to defend the case.

51. The Concurring Causes jury instruction appears to negate the affirmative defense of superseding cause. Is there no affirmative defense instruction in this case?

Answer: No further information will be provided regarding this question.

52. 75 Steelton Statutes 5.87 states that "[e]very provider who treats a person who has experienced a single seizure shall provide a report to the Department of Transportation . . ." Shall we interpret this to mean that, under the statute, we need not show that Dr. Condon knew or should have known about the seizures, only that (1) Dr. Condon treated Dailey; (2) Dailey suffered a seizure prior to the accident; and (3) Doctor Condon did not report this to the Department of Transportation?

Answer: No further information will be provided regarding this question.

53. May we research medical terminology and assume that definitions out of medical textbooks/journals are "reasonable inferences"?

Answer: No outside definitions may be used at trial.

54. On STAC 20, line 4, when Dr. Condon states he was “seeing” a patient, does he mean dating or treating?

Answer: Dr. Condon’s reference to “seeing” means treating a patient.

55. Bobby Daley’s deposition testimony can only be brought in through both the expert doctors on both sides, but not Sam Shields or Dr. Condon, correct?

Answer: Yes, this testimony cannot be brought in by witnesses other than the experts.

56. The diagram of the accident and the Driver’s Accident Report show different initial impact points (STAC 47-48); is this an intentional mistake?

Answer: No further information will be provided regarding this question.

57. On STAC 15, there is a reference to Sam Shields getting a ticket for running a stop sign. Did Sam Shields receive the traffic citation for running the stop sign before or after they consumed two beers at family dinner?

Answer: Sam Shields received the traffic citation after they consumed two beers at the family dinner.

58. On STAC 11 (Joint Exhibit List), numeral 6 mentions “photographs” of the accident location; however, there is only one photo of the accident location. Is this a typo?

Answer: Yes. The fact pattern has been updated to reflect this change.

59. Did Bobby Daley transport themselves to and from treatment?

Answer: Yes, Bobby Daley transported themselves to and from treatment.

60. What were causes of the Clara DePaul and the Max Petrunya accidents? Is there a specific reason for Clara DePaul getting her license revoked? What is the reason or condition under SDOT for license revocation?

Answer: No further information will be provided regarding this question.

61. On STAC 16, line 14, the plaintiff says the accident occurred two blocks from home in his deposition, but the Complaint and Exhibit A show that the accident occurred on Kessel Road where the plaintiff resides. Where did the accident occur?

Answer: The accident occurred on Kessel Road, further down the road from the plaintiff’s home.

62. Bobby Daley’s birthday is listed as 11/22/95 in his medical records and 1/8/97 in the accident report. Which is correct?

Answer: Bobby Daley’s birthday is 1/8/97.

63. Sam Shields says he is 27 in his deposition but his birthday is listed as 6/7/1992 in the accident report. Which is correct?

Answer: Sam Shields was born on 6/7/1989 and was 27 years old at the time of the deposition.

64. How many hours did Eppi Leonard and Bran Hertz spend on their expert reports?

Answer: No further information will be provided regarding this question.

65. Did D prescribe Gabapentin or thought about prescribing it? Eppi Leonard said he prescribed, but D's depo says he considered prescribing. Is this wording intentional?

Answer: Dr. Condon prescribed Gabapentin as noted on STAC 53.

66. Exhibit A (p. 46), states "Vehicle Code, Section 3747 states: All reports are confidential, not available as trial evidence." Are the teams bound to this statement or can we attempt to enter the exhibit?

Answer: The statement has been removed.

67. Did Dr. Condon tell him that the Gabapentin was for seizures or not? There are conflicting statements about this on STAC 29 and 30

Answer: No further information will be provided regarding this question.

68. Were there cars on the side of Kessel road near the accident? Sam Shields says in their deposition that they were not able to pull over, because there were other cars in the road, but there were not any other cars drawn by the police in their report.

Answer: No further information will be provided regarding this question.

69. What is the burden of proof for Defendant's affirmative defenses?

Answer: No further information will be provided regarding this question.

70. At last year's coaches meeting, it was decided that experts would not need to be qualified as such during the trial. Is that rule still applicable?

Answer: This can be decided at the coaches meeting if all coaches agree, however, we have provided enough information to qualify experts during trial.

71. Are we able to impeach the medical expert based on Exhibit E?

Answer: Yes, all exhibits are available to be used for impeachment purposes.

72. Are we able to call Dr. Condon as an expert witness?

Answer: No, participants are not able to call Dr. Condon as an expert witness.

73. The packet says “the use of videotape permits you to see and hear the witness as he appeared and testified under questioning by counsel” does this mean we can make a videotape of that deposition to present to the jury?

Answer: No, you may not make a videotape of the deposition. Testimony for an absent witness may be read by an advocate on the witness stand from the deposition transcript.

74. Does the 80 minute time limit for argument include openings and closings considering that isn't counted as argument?

Answer: Yes, the 80-minute time limit includes openings and closings.

75. On page 26, Line 9, Condon says that he or she puts a “line through an entry that needs to be changed or add new material that needs to be added. I will then add my initials to the modified entry.” Yet none of the Condon's “Progress Notes” have any lines through them or initials. However, on pages 51, 52 and 53, there is a recommendation that Bobby refrain from driving, which Condon never mentions in his or her statement, and which is written in larger print and in a different font. Were these comments intended to indicate that they were added later?

Answer: No further information will be provided regarding this question.

76. The Complaint states that the plaintiff lost their great toe; is this the big toe? If so, which foot is being described?

Answer: Yes, the great toe is plaintiff's big toe. No further information will be provided regarding the plaintiff's injuries.

77. Condon is not neurologist, he is an internist, correct? Does Dr. Condon have any training dealing with mood and psychological issues? He states that he commonly prescribes medicine for mood problems, but seems to only have training in neuroscience

Answer: No further information will be provided regarding this question.

78. Did the defendant ever report Bobby Daley to the Steelton DOT?

Answer: The defendant states that he or she never reported Bobby Daley to SDOT on STAC 25-26.

79. Which witnesses have personal knowledge of the drug fact sheet?

Answer: Sam Shields is the only witness who does not have personal knowledge of the drug fact sheet?

80. Ex A impact point-on Bobby Daley vehicle diagram or 1 v 2 o'clock is correct?

Answer: Exhibit A states that the initial impact point on Vehicle 1 was 1 to 2 o'clock and the initial impact point on Vehicle 2 was 10 to 12 o'clock.

81. In the deposition of Dr. Condon, Chia (Plaintiff's lawyer) says that there are several instances in the medical reports where Bobby says he lost time "for two or three minutes." However, there is no reference in the medical reports to any amount of time. Should that information be in the medical reports? Should we assume there are other medical reports of Bobby's visit to Dr. Condon that we don't have?

Answer: No further information will be provided regarding this question.

82. There are several prescription drugs that Bobby takes according to his medical records. Most of them are only mentioned by name, with no information anywhere in the packet re: what they are used for. Is the information about what a drug is used for considered a fact outside the scope of the packet (and thus off limits), or is it fair game since the drug is mentioned in the packet?

Answer: No outside research may be conducted.



AMERICAN
ASSOCIATION *for*
JUSTICE

STAC
STUDENT TRIAL
ADVOCACY
COMPETITION

**2018 NATIONAL
STUDENT TRIAL ADVOCACY
COMPETITION
(STAC)**

OFFICIAL RULES

and

FACT PATTERN

Endowed by Baldwin & Baldwin, LLP

Important Dates:

Requests for fact pattern clarification due: January 8, 2018
Team Participant Registration due (students must be AAJ members): January 31, 2018
Regional Competitions: March 1 – 4, 2018
National Final Competition: April 12 – 15, 2018

AAJ's 2018 Fact Pattern is authored by A. Michael Gianantonio of Pittsburgh, PA.
AAJ extends its thanks and appreciation to Mr. Gianantonio for developing the 2018 Fact Pattern. AAJ also extends its thanks and appreciation to our STAC co-chairs Lauren Barnes, Maria Glorioso, and Fred Schultz.

The competition fact pattern is copyrighted © 2017 by American Association for Justice (AAJ), formerly The Association of Trial Lawyers of America (ATLA®), and may not be used for purposes other than its intended use without the express written consent of AAJ.

Please note:

Information regarding the 2018 Student Trial Advocacy Competition is available at www.justice.org/STAC and will be updated frequently.

All questions and correspondence should be addressed to:

Kara Yoh
American Association for Justice
Formerly the Association of Trial Lawyers of America (ATLA®)
777 6th Street, NW
Suite 200
Washington, DC 20001
Phone: (800) 622-1791 or (202) 965-3500 ext. 8612
Fax: (202) 625-7084
STAC@justice.org

Table of Contents

1. General Information.....	4
a. Requests for Clarifications.....	4
b. Rule Violation and Filing of Complaints.....	4
c. Law School and Student Eligibility	4
2. Registration Procedures	5
a. Refund Policy.....	5
b. AAJ Law Student Membership and Student Team Registration	5
c. Coach Registration.....	5
d. Student Substitution Policy.....	5
3. Regional and Final Competition Assignments	6
4. Team Expenses	6
5. Competition Format.....	6
a. Regional Team Pairings in Qualifying Rounds	7
b. Team Rankings in All Other Rounds.....	7
c. National Finals Pairings.....	8
d. Determination of Team Representation	9
6. The Trial.....	9
a. Timing of the Trial.....	10
b. Facts Outside the Record	11
c. Witnesses	11
d. Jury Instructions.....	12
e. Exhibits	12
7. Scoring Criteria.....	12
a. Evaluator Shortage.....	12
b. Suggested Evaluation Criteria.....	13
c. Discrepancies in Remaining Match Time.....	13
d. Viewing of Score Sheets by Teams	14
8. Sample Judge’s Score Sheet	15
9. American Association for Justice Information	16
10. Law Student Membership Benefits and Scholarship Information	17

GENERAL INFORMATION

One of AAJ's goals is to inspire excellence in trial advocacy through training and education for both law students and practicing attorneys. One way AAJ accomplishes this goal is by sponsoring a national student mock trial competition. This is an exceptional opportunity for law students to develop and practice their trial advocacy skills before distinguished members of the bar and bench.

Because the purpose of this competition is to give law students the opportunity to develop their trial skills, the actual merits of the plaintiff's case and the defendant's case presented are irrelevant to this purpose. Competition rounds are decided not on the merits of a team's side but on the quality of a team's advocacy.

Requests for Clarification

Requests for clarifications of the rules or fact pattern must be submitted via an online survey no later than 5:30 p.m. (EST) on January 8, 2018. A link to the survey will be posted online at www.justice.org/STAC after the fact pattern is released. *Each school is limited to five (5) questions.* No school, regardless of the number of teams it has in the competition, may submit more than five questions. Each subpart of a question is counted as a question.

RULE VIOLATION AND FILING OF COMPLAINTS

A competitor or coach violating any of the rules governing the national Student Trial Advocacy Competition may be penalized or disqualified. If a team wants to file a complaint under the rules, the team's coach should immediately notify the regional coordinator at a regional competition or the final round coordinator at the final competition. The coordinator will review the complaint and make a ruling, which shall be binding for that round of competition. The coordinator's rulings will be governed by the rules of the competition and the objectives of the program.

Complaints after a regional competition or after the national competition must be filed in writing with Kara Yoh at the address on page 2 no later than the seven (7) days following the last day of the regional or final round, as appropriate. The AAJ Law Student Services Committee will promptly consider and rule on any such complaints.

LAW SCHOOL AND STUDENT ELIGIBILITY

The competition is open to all law schools nationwide. A law school may enter up to two teams. Each team shall be comprised of four law students. A school's selection method of its trial team(s) is left for the school to determine. However, for a student to be eligible, he or she must be enrolled for a J.D. degree and be a law student member of AAJ.

Students who graduate in December 2017 are eligible to participate only if the competition counts toward their credits for graduation and they will not be admitted to practice prior to March 2018.

Each student participant must be an AAJ student member by February 2, 2018 in order to participate.

REGISTRATION PROCEDURES

Refund Policy

Requests for a refund of a school's registration fee were due in writing before November 13, 2016. It is inevitable that a few teams drop out of the competition in the months leading up to the regionals. Teams placed on the waiting list because the competition is full will be contacted for participation in the order that their registrations were received. Teams on the waiting list will also be issued a refund check if it is determined that the team will not be competing. Schools that registered two teams but are only able to enter one team because the competition is full will receive a refund of the registration fee for the second team.

AAJ Law Student Membership and Student Team Registration

Student team members must be AAJ members by February 2, 2018 in order to participate. This year, all students must verify their membership and register for their respective team online at www.justice.org/STACParticipantRegistration. AAJ Law Student membership dues are \$15. If you have any questions about AAJ's law student membership, or if you have any trouble becoming a member online, please call AAJ's member hotline at (202) 965-3500, ext. 8611. If you have any questions about registering as a STAC team member, please call Kara Yoh, STAC Manager, ext. 3502.

Coach Registration

AAJ must receive the names of the coach for each team. A coach must accompany each team to the regional competitions. A coach may be a law student, but may not be a student who is competing in the competition. Coaches do not need to be members of AAJ, and should not register for the STAC event. Coaches, and other administrators traveling with the team, must complete an online survey listing the team coach that will be travelling with the team by February 3, 2017. This is the information that will be sent to the regional coordinators to communicate logistics onsite.

Student Substitution Policy

Substitution of team members after February 2, 2018 is not permitted except in the case of personal emergencies. Requests for substitution after the February 2 deadline must be made in writing with an explanation of why the substitution is needed and sent to Kara Yoh at AAJ for consideration. These requests can be made to STAC@justice.org.

REGIONAL AND FINAL COMPETITION ASSIGNMENTS

Entering teams will be assigned to one of 14 regional competitions based on geographical convenience *to the extent possible*. Teams from the same law school will be assigned to the same region. If a school's second team is waitlisted, there is no guarantee that second team will be sent to the same region as the first team. Teams will be notified of any date changes when regional assignments are made. Please remember that a school's second team will not be officially registered until one team from each law school has entered the mock trial competition. Then the second teams will be registered on a first-come, first-served basis until all the team slots are filled. If you paid for two teams and only one team is able to participate, you will receive a refund for the second team.

In order to officially compete in the competition, a team **must** receive its regional assignment. If a team is not informed by AAJ that it is able to compete, that team is not registered for the competition.

Coaches

A coach must accompany each team to the regional and the final competitions. The coach for a team that goes to the final competition does not have to be the person who coached the team at the regional competition.

A coach may be a law student, but may not be a student who is competing in the competition.

Only team coaches are permitted to attend the coaches' meeting. If a coach is unable to attend, he or she must notify AAJ and the regional coordinator. Only then can students be permitted to attend in the coach's absence.

Team Expenses

Travel expenses for the regional and final competitions are the responsibility of the participants. Teams competing in past competitions have obtained funds from law school deans and alumni associations, members of the local legal community, state and local trial associations, and AAJ law school chapters.

COMPETITION FORMAT

This is a trial skills competition. There is no motion or trial brief writing component. Each team will consist of four law students. Two students will be advocates and two students will play the witnesses for their side in each round. Advocates and witnesses may change their roles from round to round, but roles must remain consistent throughout each individual trial.

In the regional competitions:

- Each team will compete in three qualifying rounds
- The top four teams from the qualifying rounds will advance to a single elimination semifinal round
- The top two teams from the semifinal round will advance to a single elimination final round to determine which one team will advance to the National Final Competition

In the final competition:

- Each team will compete in three qualifying rounds
- The top eight teams from the qualifying rounds will advance to a single elimination quarter-final round
- The top four teams from the quarter-final round will advance to a single elimination semifinal round
- The top two teams from the semifinal round will advance to a single elimination final round

Regional Team Pairings in Qualifying Rounds

Pairing of teams in the qualifying rounds will be at random and conducted during the coaches' meeting prior to each competition. Teams may also be pre-assigned by the regional coordinator prior to the coaches' meeting; this practice is at the discretion of the regional coordinator. Each team will represent both plaintiff and defendant in the first two rounds. No two teams shall compete against each other more than once in the qualifying rounds. Teams from the same school will not compete against each other during any of the rounds of the regional competition or in the qualifying rounds of the national final competitions.

Team Rankings in All Other Rounds

In the semifinal round, the first-ranked team will meet the fourth-ranked team, and the second-ranked team will meet the third-ranked team.

Regional semifinal round (Normal pairings: 1 v. 4; 2 v. 3)

Situation 1: Teams ranked 1 and 4 are from the same school

New pairings: 1 v. 3; 2 v. 4

Situation 2: Teams ranked 2 and 3 are from the same school

New pairings: 1 v. 3; 2 v. 4

The ranking of teams to determine the semifinalists and finalists will be determined by the following factors (in this order):

1. Win/loss record
2. Number of winning votes
3. Number of total points awarded to the team

Each succeeding criterion above will be used only if the prior criterion does not fully rank the teams, and will be used only to break ties created by the use of the prior criterion. In the event that all three of these criterion are tied, the regional coordinator will announce a tie-breaker.

If paired regional semifinal teams have met in the qualifying rounds, they will each represent different sides than in the previous meeting. If they have not yet met, each team will take the side they represented only once in qualifying rounds. If matched teams represented the same side only once, the winner of a coin toss will choose sides.

In the regional finals, the teams will represent a different side than in the semifinal round. If two opposing teams each represented the same side in the semifinal round, the winner of a coin toss will choose sides. The two regional finals teams will represent a different side than in the semifinal round. If matched teams in the final round represented the same side in the semifinal round, the winner of a coin toss will choose sides.

When an odd number of teams compete at a regional competition, one randomly chosen team will receive a “bye” in each qualifying round. For ranking purposes, a bye will count as a win and the team with the bye will be deemed to have had three votes and the points equal to the average of the team’s points from the two other qualifying rounds.

NATIONAL FINALS

Quarter-final round (Normal pairings: 1 v. 8; 2 v. 7; 3 v. 6; 4 v. 5)

Situation 1: Teams ranked 1 and 8 are from the same school

New pairings: 1 v. 7; 2 v. 8; 3 v. 6; 4 v. 5

Situation 2: Teams ranked 2 and 7 are from the same school

New pairings: 1 v. 7; 2 v. 8; 3 v. 6; 4 v. 5

Situation 3: Teams ranked 3 and 6 are from the same school

New pairings: 1 v. 8; 2 v. 7; 3 v. 5; 4 v. 6

Situation 4: Teams ranked 4 and 5 are from the same school

New pairings: 1 v. 8; 2 v. 7; 3 v. 5; 4 v. 6

Semifinal round (Normal pairings: 1 v. 4; 2 v. 3)

Situation 1: Teams ranked 1 and 4 are from the same school

New pairings: 1 v. 3; 2 v. 4

Situation 2: Teams ranked 2 and 3 are from the same school

New pairings: 1 v. 3; 2 v. 4

If teams from the same school are matched to compete based on rank in the semifinal and final rounds of a regional competition, regional hosts will re-pair teams according to the following scenarios:

Determination of Team Representation

If the four national and regional semifinal teams have already met in the qualifying rounds, they will represent different sides from the previous confrontation. If they have not yet met, each team will take the side they represented only once in qualifying rounds. If matched teams represented the same side only once, the winner of a coin toss will choose sides.

The national finals semifinal teams will represent a different side than in the quarter-final round. If matched teams represented the same side in the quarter-final round, the winner of a coin toss will choose sides. The two national final teams will represent a different side than in the semifinal round. If matched teams represented the same side in the semifinal round, the winner of a coin toss will choose sides.

THE TRIAL

The competition this year involves the trial of a civil lawsuit. The same fact pattern will be used in the regional and final competitions. The trial judge previously ruled that the case would be bifurcated, and the case being tried in the competition is the first phase of the case—the liability phase. Only evidence relevant to the liability issue will be received. There are no pending third-party claims.

The Federal Rules of Evidence (FRE) and Federal Rules of Civil Procedure (FRCP) are the applicable rules of evidence and civil procedure. Only these rules, and the law provided in the fact pattern, shall be used in argument. Specifically, no statutory, regulatory, or case law shall be cited unless such law is provided in the fact pattern.

Students may argue based upon the comments or advisory notes to the Federal Rules of Evidence but may not cite the cases contained therein. No written briefs or motions, trial notebooks, or other written materials may be presented to the judge hearing a case.

No pretrial motions of any kind are allowed.

Motions for a judgment as a matter of law and evidentiary objections are permitted.

The trial will consist of the following phases by each team in this order:

- Opening statements for plaintiff followed by defendant
- Plaintiff's case-in-chief
 - Plaintiff's direct of plaintiff's witness #1
 - Defendant's cross of witness
 - Plaintiff's redirect of witness
 - Similar for plaintiff's witness #2
- Defendant's case-in-chief
 - Defendant's direct of defendant's witness #1
 - Plaintiff's cross of witness

- Plaintiff's redirect of witness
- Similar for defendant's witness #2
- Closing argument
 - Plaintiff's closing
 - Defendant's closing
 - Plaintiff's rebuttal closing

Each side is limited to two live witnesses whom they may call in any order.

- Plaintiff must call Bobby Daley and Bryce Summerstein.
- Defendant must call Tracey "Scooter" Simon and Quinn Noonan.

The trial has six (6) major advocacy opportunities for each team: opening statement; direct/redirect examinations (2); cross-examinations (2); and closing argument. Each member of a team must handle three of the six opportunities. Opening statement and closing argument may not be done by the same person, and may not be split between team members. Each team member must do a direct and cross.

During the competition, each team will represent both parties. Pairing in the qualifying rounds will be at random, with each team representing both plaintiff and defendant at least once in the three rounds.

Except in the final round, the courtrooms will be off-limits to all team members, coaches, friends, and family members who are not associated with either team competing, unless their team has already been eliminated from the competition.

No team may receive any coaching from anyone in any form during a round, including any recesses or breaks. The regional or national coordinator, as applicable, has the authority to punish any violation of this rule by disqualifying the team from the remainder of the competition.

A team may record its trial if: (1) no additional lighting is required; (2) recording of the trial does not interfere with or delay its conduct; and, (3) all participants of the round, including the presiding and scoring judges and the regional or national coordinator, as applicable, agree. All recordings are subject to the local courthouse policy and discretion.

Timing of the Trial

- Each team will have 80 minutes to complete its argument; time will be stopped during objections.
- The time limit will be strictly enforced, although it is not necessary that all time allotted be used.
- There will be no time limits for specific aspects of the trial.
- Time on cross-examination is charged against the team conducting the cross-examination.
- Time will be stopped for objections and responses to objections.
- Performance at trial will be evaluated by a panel of judges and/or attorneys, one of whom will preside over the trial as Judge, making rulings as necessary, and the remainder (up to three) of whom will act as the jury.

Facts Outside the Record

Advocates must confine the questions, and witnesses must confine their answers, to the facts given in the fact pattern and inferences which may reasonably be drawn therefrom, with the following qualifications:

- (1) A reasonable inference is not any fact that a party might wish to be true; rather, it is a fact that is likely to be true, given all the facts in the case; and
- (2) No inferred fact may be material, which is defined (a) as a fact that changes the merits of either side of the case or (b) that bears on the credibility of any witness or litigant. The latter is defined to include any background information about a witness or litigant.

Except during closing argument, no party may make an objection that the opposing team is going outside the record. Instead, a party may address instances of testimony outside the record by means of impeachment of the offending witness or by contradiction using another witness or document.

When true and if asked, witnesses must admit that the “facts” they have testified to are not in their deposition or otherwise in the record: “yes, I did not say that in my deposition.” Witnesses may not qualify this response; for example, a witness may not say he or she was not asked about the issue at deposition or that the facts were contained in some portion of the deposition omitted from the record.

Like all officers of the court, coaches and team members must play fairly and ethically. This is a competition about trial advocacy skills—doing what you can with the facts provided and the witnesses in the courtroom. The coordinators will instruct the judges on the significance of impeachment efforts and that they may take unfair additions or changes to the record into account in their scoring of the witness’s team.

Witnesses

Any witness may be played by a person of either gender. Before the opening statement, each team should notify the other team of the gender of each witness they intend to call and any witness they could call but are choosing not to call.

Expert witnesses are assumed to have access to and have read all documents in the fact pattern. A lay witness can only attest to his or her deposition and related exhibits.

All depositions are signed and sworn. The same attorney conducting direct examination of a witness shall also conduct any redirect examination.

The only lawyer who may object during witness testimony is the lawyer who will be examining that witness.

Witnesses may not be recalled. Witnesses will not be sequestered.

JURY INSTRUCTIONS

The instructions provided in the fact pattern are the only instructions that will be given. The instructions are the only statements of the applicable substantive law. Instructions will not be eliminated or modified. No additional instructions may be tendered or will be given.

EXHIBITS

The use of demonstrative evidence is limited to that which is provided in the fact pattern, but participants are free to enlarge any diagram, statement, exhibit, or portion of the fact pattern if it is identical to the item enlarged, or if any changes provide no advantage to the party intending to use it.

Subject to rulings of the court, counsel and witnesses may draw or make simple charts or drawings in court for the purpose of illustrating testimony or argument. These materials may not be written or drawn in advance of the segment during which they are being used.

No demonstrative evidence, including charts or drawings, may reflect facts outside the record. Participants must clear all demonstrative evidence with the regional or national coordinator, as applicable, at the coaches' meeting preceding the competition.

All exhibits are stipulated as authentic and genuine for purposes of trial.

SCORING CRITERIA

Performances at trial will be evaluated by a panel of three judges and/or attorneys, one of whom will preside as the trial judge, with the others sitting as jurors. The trial judge will rule on any objections or motions for judgment as a matter of law.

Each member of the jury may award up to ten points in each phase of trial for each party. A sample score sheet is attached.

If at the end of the trial, an evaluator awards the same number of points to both the plaintiff and the defendant, the evaluator will award one additional point to either the plaintiff or the defendant for effectiveness of objections and/or overall case presentation in order to break the tie.

Evaluators have been instructed not to score teams on the merits of the case.

The following criteria for scoring trial performances are set forth to assist both judges and student advocates. Evaluators are not limited to these criteria and may consider other aspects of strategy, technique, and so forth, which they view as important.

Evaluator Shortage

For each match, there must be three votes from evaluators. In the event that, due to circumstances beyond AAJ's control, there are not three evaluators in a particular match, "ghost" evaluator(s) will be used to score the round. The vote of a ghost evaluator is determined by calculating the average of all other evaluators in the session.

Suggested Evaluation Criteria

OPENING STATEMENT

Did Counsel:

1. Generally confine statement to an outline of the evidence that would be presented?
2. Clearly present counsel's theory of the case?
3. Persuasively present counsel's theory of the case?
4. Personalize self and client?
5. Allow opposing attorney to make argument during opening statement?
6. Make unnecessary objections?

EXAMINATION OF WITNESSES

Did Counsel:

1. Ask questions that generated minimal valid objections?
2. Make/fail to make objections with tactical or substantial merit?
3. Respond appropriately to objections?
4. Know the rules of evidence and express that knowledge clearly?
5. Develop rapport with the witness?
6. Maintain appropriate general attitude and demeanor?
7. Address the court and others appropriately?
8. Demonstrate awareness of ethical considerations?

Did Direct-Examiner:

9. Use leading questions unnecessarily?
10. Develop testimony in an interesting and coherent fashion?
11. Follow up on witness' answers?
12. Present the witness in the most favorable light?

Did Cross-Examiner:

13. Appropriately use leading questions?
14. Control witness?
15. Follow up on answers and elicit helpful testimony?
16. Use impeachment opportunities?

CLOSING ARGUMENT

Did Counsel:

1. Present a cohesive theory of the case, pulling all the positive arguments together?
2. Deal effectively with the weakness(es) in his or her own case?
3. Make an argument that was persuasive?
4. Have an effective style of presentation?
5. Utilize the law effectively in the argument?
6. Inappropriately interrupt the argument of the opposing counsel?
7. Properly confine rebuttal to rebuttal matters?
8. Effectively counter the opponent's speech in rebuttal

Discrepancies in Remaining Match Time

Often, bailiffs are unavailable to keep time for rounds. In such cases, one or more judges in each match should be instructed to keep time according to the timekeeping rules.

Additionally, judges may ask the respective teams to assist with this process. Teams may also keep track of time used for their own purposes. They may not, however, report their time used or that of an opposing team to the bailiff or judge for any purpose, unless they were instructed to do so. Moreover, time use improperly reported by any team may not be considered or used by a bailiff or judge for any purpose.

Notwithstanding this limitation, in the event that the match judge or judges declare the time remaining as less than the team requires for closing or other parts of the trial, the coach or team member (whoever records the time discrepancy¹) should immediately consult with the Regional Coordinator during the break, who should then evaluate the circumstances and decide the amount of time remaining. Neither the team coach nor the team member should discuss the discrepancy with the match judge. Should the team be unable to consult with the Regional Coordinator before completion of the trial and the team requires additional time to complete the trial, the team may elect to complete the trial beyond the time allotted. When the trial is complete, the time will be evaluated by the Regional Coordinator. The team will lose two points from the number of total overall points for that round (as tallied on the ‘Trial Score Sheet’) for every five minutes—or fraction thereof—of time in excess of its allotment.

Viewing of Score Sheets by Teams

Viewing of the score sheets is done at the discretion of the Regional Coordinator. Each team will have the right to view their score sheets for each round. Team coaches may only view score sheets once the third round has commenced. This should be done one team at a time. Participating students should be unaware of how they were scored until the qualifying rounds are completed, and the semi-final teams are announced. Teams are not allowed to take score sheets with them or make any markings to the score sheets. Teams may view score sheets only in the presence of the Regional Coordinator. If team coaches require a copy of their score sheets, they should notify the Regional Coordinator and email AAJ staff.

¹Note that coaches and team members may not communicate during rounds



**2018 STUDENT TRIAL ADVOCACY COMPETITION (STAC)
JUDGE'S SCORE SHEET**

Teams are to be scored on their trial skills only, NOT on the merits of the case.

Do not give half-points. Do not tie teams. There must be a winner.

Do not write your name on this score sheet, and do not share your score with the participating students or coaches.

ROUND:

REGIONAL LOCATION: _____

TEAM _____ -- PLAINTIFF

Good

Average

Poor

Opening Statement	10	9	8	7	6	5	4	3	2	1
Direct Exam of Plaintiff's Lay Witness	10	9	8	7	6	5	4	3	2	1
Direct Exam of Plaintiff's Expert Witness	10	9	8	7	6	5	4	3	2	1
Cross Exam of Defendant's Lay Witness	10	9	8	7	6	5	4	3	2	1
Cross Exam of Defendant's Expert Witness	10	9	8	7	6	5	4	3	2	1
Summation	10	9	8	7	6	5	4	3	2	1

Total points awarded to PLAINTIFF _____

TEAM _____ -- DEFENDANT

Good

Average

Poor

Opening Statement	10	9	8	7	6	5	4	3	2	1
Cross Exam of Plaintiff's Lay Witness	10	9	8	7	6	5	4	3	2	1
Cross Exam of Plaintiff's Expert Witness	10	9	8	7	6	5	4	3	2	1
Direct Exam of Defendant's Lay Witness	10	9	8	7	6	5	4	3	2	1
Direct Exam of Defendant's Expert Witness	10	9	8	7	6	5	4	3	2	1
Summation	10	9	8	7	6	5	4	3	2	1

Total points awarded to DEFENDANT _____



AMERICAN ASSOCIATION FOR JUSTICE

MISSION

The Mission of the American Association for Justice is to promote a fair and effective justice system—and to support the work of attorneys in their efforts to ensure that any person who is injured by the misconduct or negligence of others can obtain justice in America’s courtrooms, even when taking on the most powerful interests.

ABOUT TRIAL LAWYERS

Trial lawyers ensure access to the civil justice system for the powerless in America: working families, individual workers, and consumers who often lack the resources to take their grievances to court.

Trial lawyers play a valuable role in protecting the rights of American families. They champion the cause of those who deserve redress for injury to person or property; they promote the public good through their efforts to secure safer products, a safe workplace, a clean environment and quality health care; they uphold the rule of law and protect the rights of the accused; and they preserve the constitutional right to trial by jury and seek justice for all.

Some of the types of cases our attorneys handle include:

- A child paralyzed after being struck by a drunk driver;
- A young woman unable to have children because of a medical mistake;
- A person denied a promotion due to racial discrimination;
- An elderly man injured in a nursing home; and,
- A community whose water was made toxic by a local manufacturer.

ABOUT AAJ

As one of the world’s largest trial bars, AAJ promotes justice and fairness for injured persons, safeguards victims’ rights—particularly the right to trial by jury—and strengthens the civil justice system through education and disclosure of information critical to public health and safety. With members worldwide, and a network of U.S. and Canadian affiliates involved in diverse areas of trial advocacy, AAJ provides lawyers with the information and professional assistance needed to serve clients successfully and protect the democratic values inherent in the civil justice system.

Six Benefits

to American Association for Justice Law Student Membership You Can Put to Work Today!

1.

Network with America's premier trial lawyers through **AAJ's Membership Directory**.

2.

Trial magazine's digital version gives you the latest developments in civil litigation, current tort and consumer law verdicts, and other career-enhancing information.

3.

AAJ's annual **Student Trial Advocacy Competition (STAC)** gives you the opportunity to participate in the nation's premier mock trial before sitting judges and practicing trial lawyers.

4.

AAJ Annual and Winter Conventions allow you to attend information-packed workshops and Continuing Legal Education (CLE)-approved education sessions on all aspects of trial law from those at the top of their field. You will have the opportunity to attend social events and meet attorneys in all stages of their professional careers. Visit www.justice.org/convention to learn more.

5.

Attend select **AAJ Continuing Legal Education** courses for only the price of the reference materials. AAJ Education seminars and teleseminars will give you insight into different practice areas, how to be an effective advocate, and prepare you for life after law school.

6.

AAJ Law Student Member scholarships and awards help you pay down student loans. Start laying the groundwork today for the successful career you look forward to tomorrow. Visit www.justice.org/lawstudents for information on law school scholarships and networking opportunities.

For just **\$15 a year**, you can invest in an American Association for Justice, formerly the Association of Trial Lawyers of America (ATLA®), Law Student Membership. That's a small price to pay for the kind of trial lawyer contacts, educational opportunities, and access to information you'll enjoy as a member of the world's largest trial lawyer bar.



777 6th Street NW, Suite 200, Washington, DC 20001 • www.justice.org
800-424-2727 or 202-965-3500, ext. 8611

American Association for Justice Law Student Member Scholarships and Awards

The Richard D. Hailey Law Student Scholarship

AAJ's Minority Caucus awards \$5,000 scholarships to first-, second-, and third-year African American, Hispanic, Asian American, Native American, and Biracial Law Student Members.

Trial Advocacy Scholarship

Open to all second- and third-year AAJ Law Student Members, this \$3,000 scholarship is awarded to the applicant who best demonstrates the following: commitment to AAJ and its mission; a desire to represent victims; interest and skill in trial advocacy; and financial need.

Leesfield Scholarship

Sponsored by AAJ and AAJ member Ira Leesfield, this scholarship awards \$2,500 to a Law Student Member to subsidize attendance at AAJ's Annual Convention. Available to first- and second-year AAJ Law Student Members.

Mike Eidson Scholarship

The Mike Eidson Scholarship Fund was established by the AAJ Women for Justice Education Fund in 2008, in honor of AAJ Past President Mike Eidson, whose vision and generosity inspired it. The Scholarship awards \$5,000 annually to a female student entering their third year of law school (the student can be enrolled in a three-year day program or four-year night program) who has demonstrated a commitment to a career as a trial lawyer, along with dedication to upholding and defending the principles of the Constitution, and to the concept of a fair trial, the adversary system, and a just result for the injured, the accused, and those whose rights are jeopardized.

Visit www.justice.org/lawstudents for more information on law school scholarships.



777 6th Street NW, Suite 200, Washington, DC 20001 • www.justice.org
800-424-2727 or 202-965-3500, ext. 8611

BE IN THE KNOW



Trial is AAJ's award-winning magazine for attorneys, law professors, students, judges, and others in the legal community. *Trial* brings readers news of the latest legal trends and developments, informative articles about civil law practice, coverage of recent verdicts and settlements in a wide range of practice areas, and commentary and analysis on emerging legal issues.

Learn more and subscribe:
justice.org/trial-magazine.

2018 AAJ Fact Pattern

SAM SHIELDS

v.

CHRIS CONDON, MD

**Prepared by A. Michael Gianantonio
of Robert Peirce & Associates**

The competition fact pattern is copyrighted © 2017 by American Association for Justice (AAJ), formerly The Association of Trial Lawyers of America (ATLA®), and may not be used for purposes other than its intended use without the express written consent of AAJ.

Table of Contents

Complaint.....	3
Answer and Affirmative Defenses.....	6
Stipulations	9
Joint Exhibit List.....	11
Deposition of Sam Shields.....	12
Deposition of Chris Condon, MD.....	18
Deposition of Bobby Daley (May 20, 2017)	27
Deposition of Bobby Daley (January 8, 2016)	32
Expert Opinion of Eppi Leonard, MD	39
C.V. of Eppi Leonard, MD	42
Expert Opinion of Bran Hertz, DO.	43
C.V. of Bran Hertz, DO.	45
Exhibit A.....	46
Exhibit B.	49
Exhibit C	51
Exhibit D.....	55
Exhibit E	56
Exhibit F.....	85
Jury Instructions.....	86
Verdict Form.....	94

2018 AAJ FACT PATTERN
Sam Shields v. Chris Condon, MD[©]

Prepared by A. Michael Gianantonio

©The competition fact pattern is copyrighted by the American Association for Justice (AAJ), formerly The Association of Trial Lawyers of America, and may not be used for purposes other than its intended use without the express written consent of AAJ.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF STEELTON

SAM SHIELDS;

Plaintiff,

GD No.: 16-008771

v.

CHRIS CONDON, MD;

Defendant.

COMPLAINT

AND NOW, comes Plaintiff, Sam Shields, and files the within Complaint, the following of which is a statement:

I. PARTIES

1. Plaintiff, Sam Shields, is an adult individual residing at 269 Kessel Road, Steelton, in the District of Steelton.

2. Defendant, Chris Condon, MD, is a medical doctor licensed by the District of Steelton Board of Medicine, with a business address of Suite 81, Fleury Building, 269 Chase Street, Penns Woods, in the District of Steelton.

II. FACTS

3. On September 4, 2016, Plaintiff was severely injured as a result of a motor vehicle accident in which Plaintiff's vehicle was struck by a vehicle driven by Bobby Daley.

4. Bobby Daley lost control of his vehicle after suffering a seizure while driving on Kessel Road.

5. As a result of this collision, Plaintiff suffered a broken tibia, broken humerus, multiple fractured vertebrae, a subdural hematoma, and loss of Plaintiff's great toe.

6. On June 6, 2015, Bobby Daley was involved in a well-publicized civil assault case in which he sustained, *inter alia*, massive head trauma at the hands of an assailant.

7. Specifically, as a result of this attack, Bobby Daley suffered a subdural hematoma, a fractured orbital socket, and a compound fracture of the humerus

8. Bobby Daley treated with Defendant for injuries sustained in that beating.

9. Despite being aware of Bobby Daley's significant medical condition, Defendant failed to take steps to report Bobby Daley's medical condition to the District of Steelton Department of Motor Vehicles.

10. For the reasons described herein, Defendant is liable to Plaintiff for the harm and injuries sustained by Plaintiff on September 4, 2016.

**COUNT I
Negligence**

11. Plaintiff incorporates by reference all previous Paragraphs of the Complaint as if set forth in their entirety herein.

12. Defendant knew, or should have known, that the injuries sustained by Bobby Daley would have prevented Bobby Daley from safely operating a motor vehicle.

13. To help keep the District of Steelton's roadways safe, it is the law in the District of Steelton that any health care provider authorized to treat and diagnose disorders and disabilities report to the Steelton Department of Transportation (SDOT) any patient who has been diagnosed as having a condition that could impair that person's ability to

safely operate a motor vehicle.

14. Bobby Daley was diagnosed with, and treated for, a condition that would impair Bobby Daley's ability to safely operate a motor vehicle.

15. Defendant did not report this condition to SDOT.

16. Defendant knew, or should have known, that Defendant's failure to report this condition put other members of the motoring public, such as Plaintiff, at risk.

17. Defendant's negligence caused Plaintiff to suffer great harm as pled above.

18. As a direct and proximate result of Defendant's negligence, Plaintiff sustained and will continue to sustain injuries and damages.

WHEREFORE, Plaintiff demands judgment against Defendant, exclusive of prejudgment interest, post-judgment interest and costs; for punitive damages; and for such other relief as this Court seems fit to award.

A JURY TRIAL IS DEMANDED

Respectfully submitted

/s/ Lizzie Chia
Attorney for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF STEELTON

SAM SHIELDS;

Plaintiff,

GD No.: 16-008771

v.

CHRIS CONDON, MD;

Defendant.

ANSWER AND AFFIRMATIVE DEFENSES

AND NOW, comes Defendant, Chris Condon, MD, and files the within Answer and Affirmative Defenses, the following of which is a statement:

ANSWER

1-2. The averments of Paragraphs 1-2 of Plaintiff's Complaint are admitted.

3-7. As to the averments of Paragraphs 3-7 of Plaintiff's Complaint, Defendant lacks knowledge or information sufficient to form a belief about the truth of these allegations. As such, the averments are denied.

8. The averments of Paragraph 8 of Plaintiff's Complaint are admitted.

9. The averments of Paragraph 9 of Plaintiff's Complaint are denied. To the contrary, Defendant was under no duty to report Bobby Daley to SDOT, and Defendant had no duty to Plaintiff, who is a complete stranger to Defendant.

10. The averments of Paragraph 10 of Plaintiff's Complaint are denied. Defendant is not liable to Plaintiff.

11. As the averments of Paragraph 11 of Plaintiff's Complaint are merely an incorporation paragraph, no responsive pleading is required.

12. The averments of Paragraph 12 of Plaintiff's Complaint are denied. Defendant is not liable to Plaintiff.

13. As the averments of Paragraph 13 of Plaintiff's Complaint reference a law and/or regulation, the averments of this paragraph are denied to the extent that they attempt to paraphrase and/or interpret the same. By way of further response, as the averments of Paragraph 13 constitute conclusions of law, no responsive pleading is required.

14-18. The averments of Paragraph 14 of Plaintiff's Complaint are denied. Bobby Daley did not suffer from any condition that would require Defendant to report the same to SDOT. By way of further response, as the averments of Paragraph 14-18 constitute conclusions of law, no responsive pleading is required.

AFFIRMATIVE DEFENSES

1. Plaintiff's Complaint fails to set forth a cause of action upon which relief may be granted.
2. Plaintiff's Complaint is barred by Plaintiff's own negligence.
3. Plaintiff's claims were caused or contributed to by the superseding and intervening acts of persons, entities, or circumstances beyond the control of Defendant.
4. Defendant owed no duty to Plaintiff.

WHEREFORE, Defendant, Chris Condon, MD, respectfully requests that this Honorable Court enter judgment against Plaintiff and dismiss Plaintiff's Complaint in its entirety.

A JURY TRIAL IS DEMANDED

Respectfully submitted

/s/ Mark Trojan
Attorney for Defendant

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF STEELTON

SAM SHIELDS;

Plaintiff,

GD No.: 16-008771

v.

CHRIS CONDON, MD;

Defendant.

STIPULATIONS

AND NOW, come the parties to this matter, and file the within Stipulations to be used at Trial, which shall have the binding effect of being taken as established facts if so offered:

1. On Saturday, June 6, 2015, Bobby Daley was attacked and sustained multiple injuries including massive head trauma.

2. Bobby Daley was deposed, but has since moved out of the jurisdiction. Bobby is unavailable to testify, as that term is defined by the Federal Rules of Civil Procedure and the Federal Rules of Evidence, and not subject to the subpoena power of this jurisdiction at the trial of this matter.

3. Bobby Daley received a citation for careless driving following the motor vehicle accident on September 4, 2016.

4. The parties agree that Bobby Daley's May 20, 2017 deposition may be used at trial and the deposition testimony itself is not subject to a hearsay objection. As such, the deposition testimony may be used for any purpose so long as the intended use is otherwise admissible under the Federal Rules of Evidence.

5. The parties further agree that Bobby Daley's January 8, 2016 deposition may be used at trial and the deposition testimony itself is not subject to a hearsay objection. As such, the deposition testimony may be used for any purpose so long as the intended use is otherwise admissible under the Federal Rules of Evidence.

6. The District Court for the District of Steelton follows the Federal Rules of Evidence.

7. The District Court for the District of Steelton follows the Federal Rules of Civil Procedure.

8. The depositions are signed and sworn to by each respective deponent as being accurate and authentic.

9. The expert reports were produced by the parties simultaneously before trial. Experts have reviewed all documents contained within this case file and may testify to the same; however, the expert's testimony is limited by the applicable Federal Rules of Civil Procedure and Federal Rules of Evidence.

10. The expert reports have been prepared and signed by each respective expert.

11. Plaintiff must call Sam Shields and Eppi Leonard, M.D. as witnesses.

12. Defendant must call Chris Condon, M.D. and Bran Hertz, D.O as witnesses.

13. This case has been bifurcated into a liability phase and a damages phase.

For purposes of this trial, the parties will try the liability phase only.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF STEELTON

SAM SHIELDS,

Plaintiff,

GD No.: 16-008771

v.

CHRIS CONDON, MD;

Defendant.

JOINT EXHIBIT LIST

AND NOW, comes the parties to this matter, by and through their respective counsel, and submit the following proposed joint exhibit list. The parties agree the identified exhibits are authentic and admissible subject to objection on grounds that the proposed exhibit is otherwise inadmissible under the pertinent rules of evidence.

1. Police Incident Report for September 4, 2016;
2. April 12, 2014 *Steelton Post-Gazette* newspaper article entitled “Local Resident Drives into Building”;
3. Pertinent medical records for Bobby Daley;
4. CV of Chris Condon, MD;
5. Medication data sheet for Gabapentin;
6. Photograph of accident location on Kessel Road.

1 **Deposition of Sam Shields**

2 And now, this 30th day of April, 2017, Sam Shields, being duly sworn by the
3 undersigned appeared at the offices of Kickem and Strait, for the purposes of
4 deposition by oral questioning.

5 (Questioning by Mark Trojan)

6 Q. Good morning. We met earlier today before your deposition, but for purposes of
7 the record, can you please state your name?

8 A. Sure, my name is Sam Shields.

9 Q. How old are you?

10 A. I am 27.

11 Q. And where do you live?

12 A. I live here in Steelton.

13 Q. And your address is?

14 A. Oh, sorry. 269 Kessel Road, Steelton.

15 Q. Do you live there alone?

16 A. No, well, not any more.

17 Q. What do you mean by that?

18 A. Prior to my accident, I lived with my significant other, Danny Thomas. After the
19 accident, I was in such bad shape that Danny had to take care of me. I guess Danny
20 couldn't handle it anymore and left. However, I still needed some help with some
21 day-to-day things, so my friend, Shane Edge, moved in with me.

22 Q. It is my understanding that you are now fully recovered from the car crash.

23 A. I am.

1 Q. And Shane still lives with you

2 A. Yes.

3 Q. Why?

4 A. Well, not only did I lose my job after the accident, I lost half of the rent when Danny

5 left. Shane lives there now to help me with rent as well.

6 Q. Okay. Let's talk about the day of the accident. Can you describe your day for me

7 on the date of September 4, 2016?

8 A. Sure, that was a Sunday so I did not work.

9 Q. I don't mean to interrupt you, but where did you work at the time?

10 A. That's okay. I was a laborer at Legstrong Industries. We made ceiling tile. I sure

11 don't miss that job.

12 Q. You say you don't miss that job, I take it you no longer work there?

13 A. That's correct. I could not after the accident. I am trying to get my job back, but

14 they have me on a waiting list.

15 Q. What do you do for money now?

16 A. I am still collecting unemployment. Also, I received about \$100,000.00 from

17 Bobby Daley's car insurance. Well, a little less than that after my attorney was

18 paid.

19 Q. Okay, sorry to interrupt you. Tell me about that day.

20 A. Sure, because it was Sunday, I would usually go over to my grandmother's house

21 to cut her grass and help her with some things that she could not do.

22 Q. What is your grandmother's name?

23 A. Clara DePaul.

1 Q. Wait, you mean the same Clara DePaul that treated with Chris Condon and was
2 involved in a separate accident?

3 A. Yes. That's her.

4 Q. What do you know about that accident?

5 A. I know that she drove through a wall at a local gas station. She told me, and I guess
6 everybody else that would listen, that she thought her car was in reverse, but it was
7 still in drive. When she pressed down on the accelerator, she went forward through
8 the wall as opposed to backing out. Fortunately nobody was hurt.

9 Q. If I recall the news stories correctly, she lost her license as a result of that, right?

10 A. She did.

11 Q. And your grandmother was a patient of Dr. Condon, right?

12 A. Yes.

13 Q. And, again, if I am remembering things right, there were some newspaper articles
14 about senior citizens being permitted to drive?

15 A. And whether or not doctors should start revoking licenses. Don't think the irony is
16 lost on me, counselor.

17 Q. Did you read any of these articles?

18 A. I do not remember, that was a while ago, and my memory is sometimes a little
19 foggy.

20 Q. Other than cutting the grass, did you do anything else at your grandmother's house?

21 A. Yeah, I remember that day because she had some plumbing issues and I fixed her
22 sink for her. I think I had to make three separate trips to the Residence Repair store
23 to get the right fixtures.

- 1 Q. Did you have any troubles driving that day?
- 2 A. Not really, except I did get a ticket for running a stop sign. I was frustrated and in
3 a hurry, and I guess, at least according to the officer, that I did not come to a
4 complete stop at a stop sign on the way to the store.
- 5 Q. What happened with that ticket?
- 6 A. I paid the fine. I was in no shape to show up and fight it because of the accident.
- 7 Q. Is that the only ticket that you ever received for a motor vehicle violation?
- 8 A. No, I got a speeding ticket a couple of months after I first got my license when I
9 was 16. I have been a pretty careful driver ever since.
- 10 Q. What time did you leave your grandmother's house that day?
- 11 A. It was probably around 7 that night.
- 12 Q. And what time did you get there?
- 13 A. Around noon.
- 14 Q. Between noon and seven, did you do anything other than fix the sink and cut the
15 grass?
- 16 A. We had dinner. We usually had the whole family over and that Sunday was no
17 exception. It was my cousin's 21st birthday.
- 18 Q. 21? Did you guys have any alcohol?
- 19 A. I had a couple of beers at dinner.
- 20 Q. What time was that?
- 21 A. Probably around 4.
- 22 Q. You ate at 4?

1 A. Yeah, it seems early, but it is more of a big lunch. It is usually the only meal that
2 we eat that day.

3 Q. So you are sure it was a couple of beers? Was it two, three, or maybe more?

4 A. It was only two. I still had a lot of work to do, and I was working the morning shift
5 the next day.

6 Q. So you were not impaired?

7 A. No. In fact at the hospital after the accident I know that they did a blood draw and
8 my BAC was 0.0.

9 Q. Okay, tell me about your drive home. How far of a drive is it?

10 A. Not very far. About 30 minutes.

11 Q. And this accident occurred at approximately 7:37 p.m.

12 A. That is my understanding.

13 Q. And how far from home were you when the accident occurred?

14 A. About two blocks.

15 Q. Did you know Bobby Daley?

16 A. Not really. I think I knew that Bobby lived in the neighborhood.

17 Q. Okay, so tell me what you remember about the accident.

18 A. I was driving toward my apartment on Kessel Road.

19 Q. Can you describe Kessel Road for me, at least at the location of the accident?

20 A. Sure, it is a residential street with houses and apartments on both sides. Also, cars
21 park on both sides of the road as well, so sometimes it can seem a little narrow, but
22 it is more than wide enough to fit two cars.

23 Q. When did you first notice Bobby's vehicle?

1 A. Bobby was about a block away. The car ran a stop sign and was driving erratically.

2 Q. How did you know that the car ran a stop sign?

3 A. Well, I was particularly sensitive to that on that day, given the fact that I got a ticket

4 and was not pleased about it. Anyway, Bobby's car continued to sway from side

5 to side. I thought the driver was drunk. I slowed down and tried to move to the

6 right but it did not matter and I was struck.

7 Q. Did you notice anything about the driver before impact.

8 A. Yes, the driver's head was slumped over as if the driver was not even looking at

9 the road.

10 Q. What happened next?

11 A. I woke up in the hospital.

12 Q. Before your accident, did you know Dr. Condon?

13 A. I did not.

14 Q. Did you know who Dr. Condon was?

15 A. No, not really. I did not even know he was the doctor involved in with my

16 grandmother.

17 Q. When is the first time that you learned who Dr. Condon was?

18 A. When my lawyer told me.

19 Q. Thank you. I do not have further questions.

20 WHEREUPON the deposition was concluded.

1 **Deposition of Chris Condon, MD**

2 And now, this 7th day of April, 2017, Chris Condon, MD, being duly sworn by the
3 undersigned appeared at the offices of Beau, Bo and Bogey for the purposes of
4 deposition by oral questioning.

5 (Questioning by Lizzie Chia)

6 Q. Please state your name for the record.

7 A. My name is Chris Condon.

8 Q. Chris, my understanding is that you are a medical doctor?

9 A. That is correct.

10 Q. Do you mind if I call you Dr. Condon for purposes of this deposition?

11 A. Sure, I prefer Chris, but Dr. Condon is just fine.

12 Q. Dr. Condon, where do you live?

13 A. 178 Clay Street.

14 Q. Does anybody live there with you?

15 A. My spouse and two children.

16 Q. What is your spouse's name?

17 A. Francis Daley.

18 Q. Is Francis related to Bobby?

19 A. Yes, but only through marriage. I think they are second cousins or something like
20 that.

21 Q. Did you know Bobby before Bobby was a patient?

22 A. No, not really.

23 Q. What do you mean by that?

1 A. I saw Bobby at family reunions and things like that, but I never really spoke with
2 Bobby. It was not until Bobby's second visit that Bobby mentioned there may be
3 a familial relationship with my spouse.

4 Q. Doctor, before today's deposition, I was provided with a copy of your curriculum
5 vitae, which I am showing you now. Is this the most recent copy of your CV?

6 A. Yes.

7 Q. So all of the information provided on this document is accurate?

8 A. Yes, it is.

9 Q. The reason why I am asking is that I would prefer to skip over your background
10 information and simply proceed into more substantive matters. If you are going to
11 testify at trial, you would agree that everything listed on this CV is accurate?

12 A. Yes.

13 Q. Okay, with respect to some things that may not be listed here, have you ever had
14 your medical license suspended?

15 A. No.

16 Q. Have you ever had any disciplinary charges or investigations against you in a
17 professional capacity?

18 A. Yes, once.

19 Q. And would you care to elaborate on that doctor?

20 A. Sure. When I was a young doctor...

21 Q. Young, how old are you now?

22 A. Fifty-five.

1 Q. Okay, sorry for the interruption. You just do not seem that old to me. You can
2 continue.

3 A. No problem. As I was saying, when I was young, fresh off of my residency, I began
4 seeing a patient that became infatuated with me. Somehow this patient was able to
5 get my home phone number and email address and would keep bothering me
6 outside of office hours. The patient would also try to make appointments every
7 day.

8 Q. So what did you do?

9 A. I decided to terminate the physician/client relationship. After that, the patient filed
10 charges with the Steelton medical board.

11 Q. What did the patient allege?

12 A. That I made untoward advances against the patient, which is just ridiculous.

13 Q. What became of the charges?

14 A. They were shortly dismissed, and I learned a very valuable lesson about patient
15 interaction.

16 Q. So there were no blemishes on your record as a result of these allegations?

17 A. That is correct.

18 Q. What was the patient's name?

19 By Mr. Trojan: Objection, you know full well that Dr. Condon can't disclose that
20 patient's name. Not only is the complaint process under seal, it would violate the
21 patient's HIPAA rights. I am instructing the witness not to answer.

22 By Ms. Chia: So it is your position that allegations against your client concerning
23 his failures concerning patient interaction are not relevant.

1 By Mr. Trojan: That is part of it. Also, it is protected by HIPAA and Dr. Condon
2 could face penalties if the doctor were to reveal that information.

3 By Ms. Chia: Very well, I will move on.

4 Q. Have you ever been sued?

5 A. No.

6 Q. Have you ever testified in court before?

7 A. A couple of times.

8 Q. In what capacity?

9 A. I was an expert witness.

10 Q. Did you testify on behalf of the plaintiff or defendant?

11 A. Once for each. In different cases of course.

12 Q. What type of cases were they?

13 A. Medical malpractice.

14 Q. What did they involve?

15 A. Both cases concerned head injuries. More specifically, the cases involved damages
16 and limitations associated with concussions. One was concerning that hockey
17 player, Quinn Noonan. I only testified in the damages portion of that trial.

18 Q. So you would say that you are familiar with closed head injuries?

19 A. Yes.

20 Q. Before Bobby, did you ever treat a patient with a head injury?

21 A. Yes, numerous times.

22 Q. My understanding is that you treated Bobby after the June 6, 2015 attack, is that
23 right?

1 A. It is.

2 Q. How many times did Bobby treat with you?

3 A. Four times.

4 Q. I am handing you a copy of the records that your office provided prior to today's
5 deposition. Are these the only records that you have for Bobby?

6 A. Yes, they are.

7 Q. And doctor, when you make a medical record for your patients, how do you do it?

8 A. Mostly every time I am finished with a patient, I will dictate my notes before I see
9 the next patient.

10 Q. Do you have any reason to believe you would have done anything differently with
11 respect to these notes concerning Bobby?

12 A. No.

13 Q. Did Bobby ever tell you that he had a seizure?

14 A. Not specifically.

15 Q. What do you mean by not specifically?

16 A. Bobby had massive head trauma following the attack. Attendant to that head
17 trauma were issues with memory loss, loss of focus, loss of concentration and
18 irritability. These are all signs and symptoms associated with head trauma, but they
19 can be related to a seizure disorder as well. Based upon what I reviewed in the
20 police report, it seems as though Bobby had an atonic seizure.

21 Q. What is an atonic seizure?

1 A. That is sometimes referred to as a drop seizure. This occurs when a person's
2 muscles suddenly become limp. The head will drop and the person loses control of
3 the arms and legs. These usually last approximately 15-20 seconds.

4 Q. Okay, but there are several instances in your medical records where Bobby reports
5 the loss of time for two or three minutes. Aren't these symptoms associated with
6 grand-mal seizure?

7 A. They are consistent but not determinative. They are also consistent with other
8 conditions unrelated to seizures. I expected Bobby to have some cognitive deficits
9 likes this, but Bobby certainly never reported having a seizure to me.

10 Q. Did you ever consider diagnosing Bobby with a seizure disorder?

11 A. Not really.

12 Q. What do you mean by that?

13 A. Well, at first, there were some symptoms that were suggestive of the potential for
14 a seizure disorder, but not determinative. And Bobby's subsequent visits were not
15 convincing so I ruled it out.

16 Q. But you would agree with that if somebody's head slumped and they lost control
17 of their body movements, that could be indicative of seizure activity, right?

18 A. It could, but somebody would actually have to witness it and describe it before it
19 could be diagnosed.

20 Q. I see here in your June 22, 2015 note that you considered prescribing Gabapentin,
21 is that right doctor?

22 A. Yes, and what of it?

1 Q. Well, it is my understanding that Gabapentin is used to treat various seizure
2 disorders. Is that right?

3 A. Partially.

4 Q. Why do you say partially?

5 A. Because Gabapentin is used to treat multiple problems in addition to seizure
6 disorders. Doctors commonly prescribe Gabapentin to treat anxiety, pain, and other
7 mood disorders. Bobby was certainly experiencing all of those things, so that is
8 why I considered the drug.

9 Q. But you would agree with me that those are off-label uses.

10 A. Yes.

11 Q. And what is an off-label use?

12 A. Off-label means that the medication is being used in a way not specified in the
13 FDA's approved packing label. Every prescription drug marketed in the U.S.
14 carries an individual, FDA-approved label. This label is a written report that
15 provides detailed instructions regarding the approved uses and doses, which are
16 based on the results of clinical studies that the drug maker submitted to the FDA.
17 However it is common among doctors to prescribe various drugs for off-label use.
18 It is common to use Gabapentin in the manner that I considered using it.

19 Q. You would agree with me, however, that Gabapentin's indications and usages are
20 primarily directed at the treatment of postherpetic neuralgia and epilepsy, at least
21 according the FDA packing label, correct?

22 A. Yes.

1 Q. Did you ever consider reporting Bobby to SDOT because you were concerned that
2 Bobby may not be capable of safely driving a motor vehicle?
3 A. No, I did not.
4 Q. Why?
5 A. I never considered that Bobby was a danger to drive.
6 Q. Are you aware you have a duty to report certain physical conditions of your patients
7 to SDOT if they could affect their ability to drive?
8 A. I am. Ever since the Clara DePaul incident.
9 Q. Who is Clara DePaul?
10 A. A former patient of mine who drove through a convenience store wall. There was
11 a lot of press about whether or not she should have been driving or had her license
12 revoked.
13 Q. Was there any disciplinary action or investigation into your treatment of Ms.
14 DePaul.
15 A. No. The investigating authorities determined that the cause of the accident was not
16 something that fell within the statute.
17 Q. So, at the time you were treating Bobby, were you aware of the statute that required
18 you to report certain conditions to SDOT?
19 A. Yes. Of course.
20 Q. Dr. Condon, you are aware that if you suspect a patient has a seizure disorder, you
21 are required to report that to SDOT, right?
22 A. Yes.
23 Q. And to be clear, you never reported Bobby Daley to SDOT, correct?

1 A. That is correct.

2 Q. Have you ever reported anybody to SDOT because of their ability to drive safely?

3 A. No, never. Personally, I do not believe I have a duty to say who can and can't drive.

4 Q. Doctor, are you able to modify your medical records at any time?

5 A. Well, they are electronic. I can make changes if necessary.

6 Q. If you make a change, is there a procedure to do so?

7 A. Yes.

8 Q. What is it?

9 A. I have to put a line through an entry that needs to be changed or add new material
10 that needs to be added. I will then add my initials to the modified entry.

11 Q. And this is how you would indicate that you made a subsequent change to your
12 medical records?

13 A. Yes.

14 Q. Thank you. I have no further questions.

15 WHEREUPON the deposition was concluded

1 **Deposition of Bobby Daley**

2 And now, this 20th day of May, 2017, Bobby Daley, being duly sworn by the
3 undersigned appeared at the offices of Kickem and Strait, for the purposes of
4 deposition by oral questioning.

5 (Questioning by Lizzie Chia)

6 Q. Thank you, Bobby, for coming in again. As you know, this is not the first time that
7 we met, but I need to get some background information for the record. Can you
8 please state your full name?

9 A. Bobby Daley.

10 Q. And where do you live?

11 A. Right now I live here in Steelton, but I am getting ready to leave for Spain to spend
12 some time abroad.

13 Q. Really, how are you going to afford that?

14 A. I received a pretty big settlement from the Chase'm people, so it is always
15 something that I wanted to do.

16 Q. Sounds like fun. As you know, the reason we are here to talk today is because of
17 the motor vehicle accident that occurred on September 4, 2016.

18 A. Yes.

19 Q. What can you tell us about that accident?

20 A. I do not remember everything, but I will tell you what I can.

21 Q. That is all we are asking you to do.

22 A. Okay. I was driving to pick up a friend and I was heading down Kessel Road. The
23 next thing I know my airbag is deployed and there was a pretty big crash.

1 Q. So is it your testimony that you do not remember the actual collision?

2 A. That is correct. One minute everything is fine, the next I am sitting in a wrecked
3 car that collided head on with another.

4 Q. What is the last thing you remember?

5 A. I was driving, and there was a car about two hundred feet away coming at me.

6 Q. Do you remember how fast you were going?

7 A. Not very fast. Due to the speed limit, most likely. It was 25 miles per hour.

8 Q. Is this the first time you lost memory or time?

9 A. No, it happens every now and then. As I am sure you remember, I got beat pretty
10 badly last year. Ever since I have had some instances where I forget what I am
11 doing or how I got to certain places.

12 Q. Who is your doctor?

13 A. Dr. Condon.

14 Q. How long have you been treating with Dr. Condon.

15 A. I have been treating with Dr. C since about a month after the incident, which
16 happened on June 6, 2015.

17 Q. Dr. C? Is that Dr. Condon?

18 A. Yes, sorry. Dr. Condon is pretty laid back. At least with me, so I just use Dr. C.

19 Q. What are the reasons you were treating with Dr. Condon?

20 A. I had massive head trauma following the attack. I was starting to have issues with
21 my memory and concentration, and I was really irritable.

22 Q. And what about your seizures?

1 By Mr. Trojan: Objection to the form. You know there is nothing in the medical records
2 before September 4, 2016 concerning a seizure disorder.

3 By Ms. Chia: Yes, but Dr. Condon testified that Bobby may have had an atonic seizure
4 during Dr. Condon's deposition.

5 By Mr. Trojan: Yes, but that was specifically regarding Dr. Condon's thoughts after the
6 accident with Sam Shields.

7 By Ms. Chia: So you are saying Dr. Condon will not be offering an opinion as to seizure
8 activity at the trial of this matter?

9 By Mr. Trojan: What I am saying is there is no evidence in the medical records or any
10 place else for that matter that Dr. Condon diagnosed Bobby with a seizure disorder
11 prior to the accident. Please rephrase your question.

12 Q. Did Dr. Condon ever diagnose you with a seizure disorder?

13 A. No.

14 Q. Did Dr. Condon ever tell you that you had a seizure?

15 A. Dr. C mentioned it after the accident. Dr. C said something about an autumnal
16 seizure.

17 Q. Atonic?

18 A. Yeah, that is it.

19 Q. Did Dr. Condon ever prescribe you medication for a seizure disorder?

20 A. No, not really.

21 Q. What do you mean by not really?

22 A. Well, after the accident, Dr. Condon mentioned that if I did have problems with
23 seizures, the Gabapentin that I was taking should address that as well.

1 Q. Have you had any seizures following the accident?

2 A. Not that I am aware of.

3 Q. What about memory loss or loss of concentration.

4 A. That happens every so often. It has, ever since June 6.

5 Q. Did you tell Dr. Condon about these symptoms?

6 A. Yes.

7 By Ms. Chia: Those are all of the questions that I have.

8 By Mr. Trojan: I do have some

9 Q. You mentioned Gabapentin. Did Dr. Condon prescribe that for you?

10 A. Yes.

11 Q. Did Dr. Condon tell you why?

12 A. Because of the headaches and pain that I was having after the accident and because
13 of how irritable I had become.

14 Q. Did Dr. Condon tell you that the Gabapentin was for seizures, at least before the
15 car crash on September 4, 2016.

16 A. No.

17 Q. In your previous deposition, you did not mention Gabapentin. Only Xanax, do you
18 know why?

19 A. I guess I forgot. That happens to me a lot.

20 Q. Did Dr. Condon ever tell you that you could not drive?

21 A. No.

22 Q. Well, doesn't it say that in Dr. Condon's medical records?

23 A. I have no idea what is in those records.

1 Q. If Dr. Condon would have told you not to drive, would you have listened?

2 A. Yes.

3 Q. If your license was revoked, would you have driven?

4 A. No.

5 Thank you, that is all that I have.

6 WHEREUPON the deposition was concluded.

1 **Deposition of Bobby Daley**

2 And now, this 8th day of January, 2016, Bobby Daley, being duly sworn by the
3 undersigned appeared at the offices of Kickem and Strait, for the purposes of
4 deposition by oral questioning.

5 (Questioning by Mark Trojan)

6 Q. Good morning. We met earlier today before your deposition, but for purposes of
7 the record, can you please state your name?

8 A. Sure, my name is Bobby Daley.

9 Q. And where do you live?

10 A. I was supposed to start college this year, but I am living at home with my parents.

11 Q. Where is that?

12 A. Oh, sorry, in Steelton.

13 Q. That's okay. Can I have an address please?

14 A. Why do you need that?

15 Q. It's just background information. I am not going to stop over or anything.

16 A. Okay. It's 480 Pennsylvania Avenue, Steelton.

17 Q. How old are you?

18 A. 19.

19 Q. At the time of the accident, how old were you?

20 A. What accident? Do you mean the time I was savagely beaten and had a piece of
21 bone sticking out of my arm? Is that the accident that you are talking about?

22 Q. Listen, I understand this is not what you want to be doing right now, but if you
23 could just calm down and answer my questions, we could get you in and out of here
24 much quicker so that you can go about your day.

1 A. Sorry. I get worked up thinking about what happened to me that night.

2 Q. I understand. Not a problem.

3 A. I have a generalized anxiety disorder and I can't control it sometimes.

4 Q. Is that something you always had or something that happened since June 6, 2015?

5 A. It was not diagnosed until after the sixth, but it seems like I always had some sort
6 of problems in stressful situations.

7 Q. Do you take any medications for this problem?

8 A. I take Xanax, but only when I need it.

9 Q. Did you take Xanax today?

10 A. I did this morning, but I have not had any in a few hours.

11 Q. Do you think that is affecting your ability to testify here today?

12 A. No.

13 Q. Okay, well I will do my best to keep the stress levels down. How old were you on
14 June 6, 2015?

15 A. I was 18. I just graduated from high school. I was really never out after dark that
16 much with my friends before then. My parents were kind of strict.

17 Q. We'll get to that, but I want to talk to you about some other things first.

18 A. Alright.

19 Q. I assume you are familiar with the game Chase'm.

20 A. Yeah, I mean, I was. Nobody really plays that game anymore. It was a lot of fun
21 when it first came out, but there are new games that I play now.

22 Q. Let's focus on 2015 when you graduated high school and still played Chase'm.
23 When did you first start playing the game?

1 A. Probably when it first came out. I mean, not right away, because the servers were
2 so busy with new people trying to register that it took a while to get set up.

3 Q. So it would have been within the first couple of weeks?

4 A. Probably the first week.

5 Q. Do you remember when Chase'm first came out?

6 A. I think it was sometime in April.

7 Q. Can you tell me about the game? How do you win?

8 A. You really don't win in the traditional sense. It is more about collecting different
9 Chase Monsters. Depending on where you actually were in town, different Chase
10 Monsters would appear, and you would have to catch them.

11 Q. So the availability of different monsters depended on where you were physically
12 located?

13 A. Exactly.

14 Q. I think I understand. How do you go about catching these monsters?

15 A. Each Chase Monster Wrangler, that is what a player is called, has a Shooter Gun
16 that you use to stun and capture the Chase Monster. The rarer a Chase Monster
17 was, the harder it was to catch. You had to trade in your earlier catches to get more
18 powerful Shooter Guns, which in turn allows you to catch rarer Chase Monsters.

19 Q. Before June 6, how many Chase Monsters did you catch?

20 A. I probably had just over 60. I think there are 100.

21 Q. Did you have any rare Chase Monsters?

22 A. I had a good mix of common and mid-level ones. I had only just started catching
23 rare ones. That is why I was out that night.

1 Q. So, when you set out that day, you knew that you would be staying out late to catch
2 Chase Monsters?

3 A. Not exactly.

4 Q. What do you mean by not exactly?

5 A. Well, I was out with my friends, Rudy Mast, Brendan Newman and Shelley Primes,
6 and...

7 Q. I do not mean to interrupt you, but do you know where we can find Rudy, Brendan
8 or Shelley?

9 A. I really have no idea. They kind of fell off of the face of the earth after that summer.

10 Q. Really? Not even on My Face, Tweeter, or any of those other sites?

11 A. Not a word.

12 Q. Okay, let's go back to what we were discussing. You said you did not set out on
13 June 6 to catch Chase Monsters, or at least the rare ones I guess?

14 A. No, we went to see a baseball game. Rudy's little brother was playing and we went
15 for ice cream after.

16 Q. Is that how you got to Scooter's?

17 A. Yes.

18 Q. Had you been there before?

19 A. No, or not since it had become Scooter's. A few years back it used to be this shady
20 bar. A bunch of people got shot in the parking lot one night and they closed it
21 down.

22 Q. What can you tell me about the shooting?

1 A. Well, I was in junior high, but I do remember some of the details. Apparently
2 somebody hit on the wrong girl in the bar, and two groups went outside to fight.
3 Things got bad and some guy killed two people. It was big news here in Steelton.

4 Q. Do you know what happened to the shooter?

5 A. He went to jail for life, I think.

6 Q. Did you know that Scooter's was a Chase Place?

7 A. Not before I got there. But, when we arrived, there had to be at least 100 people in
8 the shop and around the parking lot, all staring at the phones. I took out my phone
9 and saw it was a Chase Place. Then, right on the wall, there was this big flyer about
10 the fact that all of these rare Chase Monsters could be caught there. And these rare
11 Chase Monsters only spawn something like five times at each location.

12 Q. I am going to show you an advertisement dated June 1, 2015. Does this appear to
13 be a copy of the flyer that you were talking about?

14 A. Yes, that's it.

15 Q. What do you mean by spawn?

16 A. Appear.

17 Q. Oh, thank you.

18 A. And, from what I could tell, no Petunia Choppers had been caught at that location
19 yet, which meant one was due to show up. The Petunia Chopper was one of the
20 rarest Chase Monsters there is, so even though I was not sure my Shooter Gun was
21 powerful enough to catch it, I wanted to take my chance at getting one.

22 Q. Did you buy anything at Scooter's?

1 A. Yes, I got some ice cream, it was not really that good, and that is hard to say about
2 ice cream.

3 Q. What time did you get to Scooter's?

4 A. Around 8 p.m.

5 Q. Did you stay after you finished your ice cream?

6 A. Yes.

7 Q. Even though you did not order anything else and the ice cream was not that good.
8 A. The place was packed with people just staring at their phones. Nobody asked us to
9 leave when we finished.

10 Q. Did you know that Scooter's closed at 10 p.m.?

11 A. I found out when they asked us to leave.

12 Q. Where did you go?

13 A. We tried to hang out in the parking lot, but we were asked to go stand on the
14 sidewalk next to the parking lot.

15 Q. Where did you end up going?

16 A. We went onto the sidewalk right next to the shop.

17 Q. This is a diagram of the property. Can you please place an X as to where you were
18 standing?

19 A. I was right here.

20 Q. What was the lighting like? All of the parking lights in Scooter's lot were on.
21 However, none of the lights on the street came on for some reason.

22 Q. What happened to all of the other people?

23 A. They started to leave until it was just us.

1 Q. Why did you not leave?

2 A. Brendan and I really wanted to take a shot at catching at least one rare Chase
3 Monster.

4 Q. What happened next?

5 A. Rudy mentioned that he saw some people coming our way and that maybe we
6 should get going. I said they were probably coming to play the game as well. He
7 said he did not think so, and then I heard a voice say, "I told you we could find
8 some of those video game nerds here. Easy pickings." I was hit in the head and
9 next thing I remember was waking up in the hospital a couple of days later.

10 Q. Do you know who hit you?

11 A. I do not.

12 Q. Do you know what happened to your friends? Were they attacked that night?

13 A. No. I guess I was the closest to those jerks so they started beating on me and my
14 friends ran away. Some friends, huh?

15 Q. I am sorry to hear that your friends left you. I do not have further questions.

16 WHEREUPON the deposition was concluded.

November 15, 2017

Lizzie Chia, Esquire
Beau, Bo and Bogey
1919 Dark Tower Rd.
District of Steelton, USA 12345

Re: Sam Shields v. Chris Condon, MD

Dear Ms. Chia:

Your office has retained me to determine whether or not Chris Condon, MD, knew or should have known that Bobby Daley had a seizure disorder prior to September 4, 2016. Attendant to this issue is whether or not Dr. Condon should have reported Bobby Daley to the Steelton Department of Transportation.

In short, it is my opinion that Dr. Condon, at a minimum, should have known that Bobby Daley had a seizure disorder prior to September 4, 2016 and, based upon the evidence, it appears that Dr. Condon actually did know that Bobby Daley had a seizure disorder. In turn, it follows as a matter of course that Dr. Condon was obligated to report Bobby Daley to SDOT to ensure that Bobby Daley's driver privileges were revoked.

In reaching my opinions, I have relied upon the following materials:

- Plaintiff's Complaint;
- Defendant's Answer and Affirmative Defenses;
- Exhibits provided identified in the Joint Exhibit List;
- Stipulations of Counsel;
- Deposition of Sam Shields;
- Deposition of Chris Condon, MD; and,
- Depositions of Bobby Daley

My opinions are set forth in detail below. All my opinions are held within a reasonable degree of medical certainty.

FACTS UNDERLYING OPINIONS

Sam Shields was viciously struck in a head on collision by a motor vehicle operated by Bobby Daley on September 4, 2016. Approximately fifteen months before the September 4, 2016 motor vehicle accident, Bobby Daley was involved in a physical altercation while playing the game Chase'm. Bobby sustained significant injuries in that

assault including, but not limited to, severe head trauma. Specifically, Bobby sustained a subdural hematoma and a fractured orbital socket.

Following the June 6, 2015 beating, Bobby began seeking medical treatment from multiple providers concerning injuries sustained. Most notably, with respect to your inquiry, Bobby began treatment with Dr. Condon on June 22, 2015. Medical records provided to me indicate that Bobby treated with Dr. Condon on June 22, 2015; July 7, 2015; August 7, 2015; and March 7, 2016.

On September 4, 2016, Bobby was involved in a motor vehicle accident with Sam Shields. Accordingly to materials made available to me, including the statement provided by Sam Shields, Bobby appeared to be “slumped” over the steering wheel of Bobby’s car and not actually driving at the time of, and immediately preceding, the impact.

As a result of the impact, Sam Shields sustained significant injuries. It is my understanding that Bobby was cited for careless driving.

OPINIONS

A. Bobby Daley exhibited signs and symptoms of a seizure disorder

There are multiple types of seizures that one can experience, however they are generally broken down into three categories. The first type, generalized onset seizures, affect both sides of the brain and include tonic-clonic, absence, and atonic. The second type of seizure is a focal onset seizure, which is a type of seizure that starts in a localized area of the brain. Finally, there is the unknown onset seizure, which is a seizure of unknown origin.

In atonic seizures, a person’s muscles will become limp or weak, much like what Sam Shields described of Bobby Daley immediately preceding the accident.

Seizures are not uncommon and, in fact, approximately 8-10 percent of the population will experience a seizure at some point in their lives. Seizures can result from traumatic brain injuries and are a long recognized complication associated with traumatic brain injury (TBI).

In that regard, seizures occurring more than one week after head injury reflect more permanent structural changes within the brain and demonstrate the onset of post-traumatic epilepsy. About 40 percent of individuals with post-traumatic epilepsy have onset within six months; 50 percent within one year; and about 80 percent within two years of head injury.

It is important to remember that when diagnosing a seizure, it is difficult, if not impossible, to rely upon a description of the event from the patient. That is why the medical records from Dr. Condon that were provided to me are so crucial. It is clear that while Bobby is relating signs and symptoms of seizure activities, either Dr. Condon fails to

recognize the same or chooses to ignore them. At the very least, the medical records indicate that further diagnostic imaging was warranted.

CONCLUSION

It is clear to me that Bobby Daley was suffering from a trauma-related, post traumatic seizure disorder. Dr. Condon consistently reports in the medical records that Bobby experiences loss of time, loss of memory and headaches. All of these are signs and symptoms of seizure and, at a minimum, warranted further diagnostic testing.

In fact, it is my belief that Dr. Condon suspected a seizure disorder because Dr. Condon prescribed Gabapentin. The primary use for Gabapentin is to treat seizure disorders. While I recognize that Gabapentin can be used to treat pain and certain mood disorders, I believe Dr. Condon simply got lucky with the prescription of this particular drug. Moreover, because Gabapentin is utilized to treat seizures, it is highly likely that Bobby would have had more seizures had Bobby not been on the medication.

In this regard it is clear that Dr. Condon should have identified a paroxysmal disruption of cerebral function characterized by altered consciousness, altered motor activity or behavior. Further, Dr. Condon should have known that Bobby had a seizure disorder. While the same was not electronically diagnosed, that is only because Dr. Condon failed to order the appropriate testing.

All of my opinions have been rendered within a reasonable degree of medical certainty.

Very truly yours,

Eppi Leonard, M.D.

CURRICULUM VITAE

Eppi Leonard, M.D.
1532 Forest Ave.
Steelton

Education

University of Steelton 1996
B.S. with a major in Biochemistry
Suma Cum Laude

Steelton Medical School 2000
M.D.
Cum Laude

Residency and Fellowship 2000-2005
Steelton University General Practice Group

Board Certification in Family Practice 2006

History

2006-2012
Steelton University General Practice Group

2012-present
Steelton Family Medical Center

Publications

Treating the Young to the Elderly and All that Falls Between, Steelton Medical Digest,
2007

Awards

Steelton Family Practice Doctor of the Year, 2014

Prior Testimony

I have not testified before. My hourly rate is \$700, half of which I donate to Steelton Children's hospital.

December 5, 2017

Mark Trojan, Esquire
Kickem and Straight
257 Wilderness Drive
District of Steelton, USA 12345

Re: Opinions as to Reasonable Care Offered by Dr. Chris Condon, M.D.

Dear Mr. Trojan:

It is with great pleasure that I offer the following opinions concerning my review of your client's care of Bobby Daley. In sum, Dr. Condon, at all times, acted within the standard of care. It is clear that Dr. Condon appropriately treated Bobby. Further, Dr. Condon's records do not suggest that Bobby was having any type of seizures warranting removal of Bobby's driver's license.

In fact, my review demonstrates that Dr. Condon went above and beyond what was needed by the standard of care. Despite the fact that Dr. Condon consistently advised Bobby not to drive, even though it was not required, it seems as though Bobby failed to heed these warnings.

In reaching my opinions, which are being offered within a reasonable degree of medical certainty, I have reviewed the all of the depositions that were taken in this matter (including the previous deposition of Bobby Daley), the exhibits that have been identified on the joint exhibit list, Dr. Condon's medical records and the relevant medical literature. I personally know Dr. Condon and I have found that Dr. Condon is an exceptional doctor who at all times goes the extra mile for patients.

Based upon my review, Dr. Condon began treating Bobby shortly after this individual was the victim of a horrendous attack. Of particular importance, Bobby sustained significant head trauma, followed by post-concussion syndrome.

I do not think that Bobby had a seizure disorder, but, rather, Bobby had a concussion and issues related to that concussion. Concussions are brain injuries. The brain is a soft organ that is surrounded by spinal fluid inside of the skull that serves to protect the brain from injury. However, certain events can cause the brain to move inside this liquid, which in turn, causes it to strike the skull and sustain injury, i.e., a concussion. Concussions can be difficult to diagnose as there is no actual physical manifestation that can be seen such as a bruise or a broken bone on an X-ray. A concussion can be sustained from any blow to the head. Here, it is uncontradicted that Bobby had multiple blows to the head.

There are several symptoms that are associated with concussions that permit diagnosis, and they can range from the obvious to the subtle. These symptoms, like with Bobby, can last months or even years. One of the more prominent symptoms associated with concussion is an issue with memory. Somebody who is concussed may have trouble remembering things, they may not be able to remember new facts, or they may seem to be

slower than normal. These symptoms may be observed through conversation with the individual, and by presenting him or her with questions concerning memory.

Bobby demonstrated all of these symptoms and related the same to Dr. Condon. Based upon these observations and details, Dr. Condon correctly identified Bobby as suffering from a concussion-related injury.

In addition to memory loss, there are some physical symptoms that may be present, the most common of which are headache, blurred vision, balance issues, and nausea. Clearly, Bobby demonstrated all of these symptoms as recorded by Dr. Condon in the medical records.

Also, there is an emotional component associated with concussions. The individual may feel angry or more aggressive than usual. Conversely, he or she may also appear to have a depressed effect, or appear to be anxious. Again, Dr. Condon recognized these symptoms and treated them as well.

It is not unusual for a person that has sustained a concussion to develop post-concussive syndrome. Basically, this means that the individual may continue to experience the above described symptoms.

Thusly, it is my opinion that Dr. Condon treated Bobby appropriately when Dr. Condon diagnosed Bobby as having post-concussion syndrome. Although many of the symptoms for post-concussion syndrome and seizure disorders overlap, I believe that Dr. Condon appropriately treated Bobby based upon the symptoms presented to Dr. Condon. While I am unable to substantiate the underlying etiology of the symptoms experienced by Bobby immediately before the crash on September 4, 2016, and I cannot rule out seizure, I do not think Bobby definitively suffered a seizure. As such, I see no reason that would have required Dr. Condon to revoke Bobby's driver's license.

As to the use of Gabapentin, I do not believe this indicates that Dr. Condon believed Bobby had a seizure disorder. There are many off label uses for the medication that fit Bobby's particular medical record.

It is my opinion, then, taking the above into consideration, that Dr. Condon acted appropriately and did not deviate from the standard of care. All of my opinions herein have been offered within a reasonable degree of professional certainty.

Very truly yours,

Bran Hertz, D.O.

CURRICULUM VITAE

**Bran Hertz, D.O.
123 Bayside Blvd.
Miami, FL**

Education

Steelton A & M 1988
B.S. with a major in Organic Chemistry

Steelton College of Osteopathic Medicine 1992
D.O.
Cum Laude

Residency 1992-1996
Steelton University Hospital
Head Resident 1996

Board Certification in Family Practice 1997

History

1997 to Present
Miami Family Practice and Wellness Group

Publications

I have multiple publications in various medical journals pertaining to general family practice, including articles relating to new types treatment, treatment of chronic illnesses and treatment of injuries following motor vehicle accident, including head trauma.

Volunteer Services

Doctors without borders, 1999-present

Prior Testimony

I have testified 12 times before this trial. Nine of those times I have offered testimony on behalf of Defendant doctors. 2 of those times I have offered causation testimony on injuries in motor vehicle accidents on behalf of Defendants. One time I testified on behalf of a patient in a medical malpractice case. My hourly rate is \$600 per hour, with a \$1500 flat rate for trial testimony.

COMMONWEALTH OF Driver's Accident Report

STEELTON

DEPARTMENT OF TRANSPORTATION

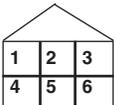
FORWARD THIS REPORT WITHIN 5 DAYS TO THE STEELTON DEPARTMENT OF TRANSPORTATION,
BUREAU OF HIGHWAY SAFETY AND TRAFFIC ENGINEERING, P.O. Box 2047, STEELTON 17105-2047
Steelton **Vehicle Code, Section 3747 states: All reports are confidential, not available as trial evidence**

TIME	Date of Accident (Month - Day - Year)	County Steelton	Day of Week Sunday	Hour (AM - PM) 1937	Check if Hit-Run <input type="checkbox"/>
	SEVERITY : Was Towing Required? UNIT 1: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO UNIT 2: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Number of Vehicles Involved 2	Number Injured 2	Number Killed 0	
LOCATION	TO PROPERLY LOCATE ACCIDENTS, USE AS LANDMARKS; SR SEGMENT NUMBERS, MILEPOSTS; INTERSECTION OF TWO HIGHWAYS; CITY, BOROUGH, TOWNSHIP, OR COUNTY LINES.	City - Borough - Township Steelton	On: (Street Name or Highway Number) Kessel Road		
		At Intersection With: no intersection	If Not At Intersection : _____ Feet N S E W Of Station Marker - Intersection - Etc...		
MY VEHICLE • NO 1	Operator's Name (First, Middle, Last) Mr. Bobby Daley Mrs. Miss	Date of Birth 1/8/97	Operator's License Number and State ST		
	Address (Street, City, State, Zip Code) 480 Pennsylvania Ave. Steelton	Vehicle License Number and State			
	Owner's Name (First, Middle, Last) Mr. Same Mrs. Miss	Year 2011	Make Chevy	Model Camaro	
	Address (Street, City, State, Zip Code)	PA TITLE OR OUT-OF-STATE VIN			

USE THE FOLLOWING SECTION TO RECORD VEHICLE NUMBER 2, PEDESTRIAN, OR OTHER PROPERTY

OTHER	Operator's Name (First, Middle, Last) Mr. Sam Shields Mrs. Miss	Date of Birth 6/7/89	Operator's License Number and State ST		
	Address (Street, City, State, Zip Code) 269 Kessel Road Steelton	Vehicle License Number and State			
	Owner's Name (First, Middle, Last) Mr. Same Mrs. Miss	Year 2015	Make Ford	Model Focus	
	Address (Street, City, State, Zip Code)	PA TITLE OR OUT-OF-STATE VIN			
	Description of Damaged Property Vehicle was totalled	Check If State Owned Property <input type="checkbox"/>			

IF MORE VEHICLES/PEDESTRIANS/OCCUPANTS ARE INVOLVED USE ADDITIONAL REPORTS.

PERSONS INVOLVED	NAME	AGE	SEX	VEH.NO.	INJURY CLASS	ACTIVE RESTRAINT	INJURY TYPE	SEATING POSITION	ACTIVE RESTRAINT	PASSIVE RESTRAINT
		Bobby Daley	20	M	1	0 - No INJURY 1 - DEATH 2 - MAJOR INJURY 3 - MODERATE INJURY 4 - MINOR INJURY 9 - UNKNOWN	0 - NONE 1 - SHOULDER HARNESS ONLY 2 - SEAT BELT ONLY 3 - COMBINATION (HARNESS & BELT) 4 - CHILD RESTRAINT 7 - MOTORCYCLE HELMET 8 - OTHER 9 - UNKNOWN	3	1	3
	Sam Shields	25	M	2			2	1	9	1
					POSITION 1 - DRIVER 2-6 - PASSENGER 7 - PEDESTRIAN 8 - OTHER					
										
						PASSIVE RESTRAINT 0 - NONE OR PEDESTRIAN 1 - AIRBAG (DEPLOYED) 2 - AIRBAG (NOT DEPLOYED) 3 - AUTOMATIC SEAT BELT 8 - OTHER 9 - UNKNOWN				

Insurance Information	Company	Insurance Information	Company
Unit 1	Policy No.	Unit 2	Policy No. STAC 46

WEATHER:

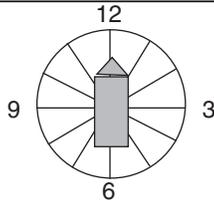
Rain Snow Clear Foggy Other

ROADWAY:

Wet Snowy Dry Icy Rain

0 = None
 1 = 1 o'clock
 2 = 2 o'clock
 3 = 3 o'clock
 4 = 4 o'clock
 5 = 5 o'clock
 6 = 6 o'clock
 7 = 7 o'clock
 8 = 8 o'clock
 9 = 9 o'clock

10 = 10 o'clock
 11 = 11 o'clock
 12 = 12 o'clock
 13 = Top of Vehicle
 14 = Vehicle Undercarriage
 15 = Use when the initial impact was with a towed unit (such as utility trailer vehicle, horse van, etc...)
 99 = Unknown



VEHICLE NUMBER 1:

INITIAL IMPACT POINT 1-2

LEGAL SPEED 25 MPH

ESTIMATED SPEED 20 MPH

VEHICLE NUMBER 2:

INITIAL IMPACT POINT 10-12

LEGAL SPEED 25 MPH

ESTIMATED SPEED 25 MPH

INSTRUCTIONS:

1. Draw Diagram As Clearly As You Can.
2. Show Your Vehicle As Number 1.
3. Label All Streets, Highways, and Landmarks.
4. Draw An Arrow In Circle Below So It Points North.
5. Complete Narrative.

Indicate North By Arrow



See attached diagram

GIVE A DETAILED DESCRIPTION OF THE ACCIDENT IMMEDIATELY PRIOR TO IMPACT, AT IMPACT, AND IMMEDIATELY AFTER IMPACT, REFER TO VEHICLES BY NUMBERS

Driver of unit 1 was heading east bound on Kessel. Reports are that Driver 1 was driving erratically and ran a stop sign. Driver 2 reports seeing Driver 1 slumped over steering wheel prior to impact

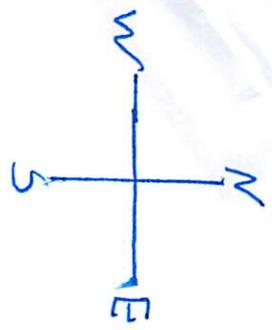
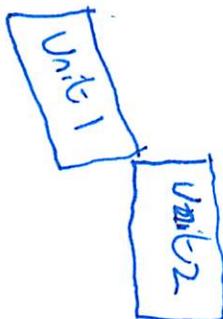
SIGNATURE

DATE

POLICE INVESTIGATED: YES NO

If Yes, Name of Police Department:

Step
1 Sign Vessel Road



LOCAL RESIDENT DRIVES INTO BUILDING



April 12, 2014—Steelton Local resident Clara DePaul sustained minor injuries following an incident last week when she drove into a local convenience store. No other individuals were hurt, however, several patrons of the store were reported to be visibly shaken.

The accident occurred because Ms. DePaul believed that her vehicle was in reverse. It was not. When she hit the accelerator, instead of moving backwards, her vehicle crashed through the window and destroyed a display case containing beef jerky and other processed meat products.

Mike Streib, owner of the store reports close to \$20,000.00 in damages to his property. “I can’t believe this happened again,” he stated referencing a similar incident occurring three years ago when Max Petrunya, another senior member of the Steelton community, was involved in a nearly identical incident.

This incident reintroduces the conversation of the safety for both drivers and the motor public in general as related to the competency of an individual to drive.

Both Ms. DePaul and Mr. Petrunya were patients of Dr. Chris Condon of Steelton. Dr. Condon indicated awareness of the Steelton statute that requires a physician to notify the Steelton Department of Transportation of an individual’s inability to drive. However, Dr. Condon refused to comment for this story.

Leave your comments below.

Krista Fullen: I think it is about time that these doctors be held accountable for letting people drive who should not be allowed to drive.

Doug Rowe: What a terrible tragedy. I do hope everybody is okay.

Ryan Matsook: Dr. Condon should be ashamed putting our lives at risk again.

Sam Shields: How is this Dr. Condon's fault? A doctor has no right to say who can and can't drive. This is America, right? I wish somebody would come along and make America great again...

Ryan Matsook: Sam, you are kidding right? This person could have killed an entire family.

Comments Closed

Condon Family Medicine

Progress Notes

Daley, Bobby

MRN: 01081977

DOB: 1/8/97

DOV: June 22, 2015

Social History: Chewing tobacco approximately one can every two days. Counseled to quit. Drinks 4-6 drinks per week. No illicit drug use. Single.

Family History: History reviewed and positive for cancer on mother's side. Father died at 59 related to heart disease. Grandfather had epilepsy.

ROS: VSS. Limited ULE movement due to casting related to open fracture. Positive for headaches, memory loss, and blurred vision.

Physical Examination

Subjective: Reports to me as a new patient. Was involved in an incident on the evening of June 6, 2015, concerning a physical altercation in which he was beaten pretty badly. Sustained open fracture of ULE and obvious closed head injury. Here for treatment involving the head injury. Reports headache, loss of memory, loss of focus, loss of concentration and pressure in the head and neck injury.

Current Medications: Vicodin as related to pain for fracture. Paxil and Xanax, prn for mood disorder and generalized anxiety.

Assessment: Post-concussion syndrome. Will continue to monitor. Will continue Paxil and prn Xanax. Will add Imitrex and Gabapentin off label. I do not suspect seizure disorder but some findings could be indicative of the same. Gabapentin should help in that case. Patient advised against driving for the time being.

Plan: Patient will return in two weeks for f/u.

Condon Family Medicine

Progress Notes

Daley, Bobby

MRN: 01081977

DOB: 1/8/97

DOV: July 7, 2015

Social History: Chewing tobacco approximately one can every two days. Counseled to quit. Drinks 4-6 drinks per week. Not drinking while on medication. No illicit drug use. Single. Patient still driving.

Family History: History reviewed and positive for cancer on mother's side. Father died at 59 related to heart disease. Grandfather had epilepsy.

ROS: VSS. Limited ULE movement due to casting related to open fracture. Positive for headaches, memory loss and blurred vision.

Physical Examination

Subjective: F/u appointment. ULE doing much better. No longer on opioid pain killers. Continues with post-concussive related symptoms.

Current Medications: Patient d/c Vicodin as no longer required. Continues with Paxil, Xanax, prn, Imitrex, and Gabapentin. No side effects reported.

Assessment: Continued post-concussion syndrome. Will continue to monitor. No medication change. Continue to advise patient against driving for the time being.

Plan: Patient will return in four weeks for f/u.

Condon Family Medicine

Progress Notes

Daley, Bobby

MRN: 01081977

DOB: 1/8/97

DOV: August 7, 2015

Social History: No longer using chewing tobacco. Not currently consuming alcohol. No illicit drug use. Single. Patient still driving.

Family History: History reviewed and positive for cancer on mother's side. Father died at 59 related to heart disease. Grandfather had epilepsy.

ROS: VSS. Limited ULE movement due to casting related to open fracture. Positive for headaches, memory loss and blurred vision.

Physical Examination

Subjective: F/u appointment. ULE doing much better. Expects cast will be removed within the next two weeks. Continues with post-concussive related symptoms. Patient related that patient experienced several instances of significant memory loss. For instance, patient would wake laying on or near couch watching television when the last thing patient remembered was sitting on couch. One instance in shower. Patient relates 4-5 instances of this since last visit. New occurrence since last visit.

Current Medications: Patient d/c Vicodin as no longer required. Continues with Paxil, Xanax, prn, Imitrex, and Gabapentin. No side effects reported.

Assessment: Continued post-concussion syndrome. Will continue to monitor. No medication change. Symptom suggestive of potential seizure disorder, but not indicative of the same. If instances continue, will set schedule for appropriate diagnostic testing. Increase strength of Gabapentin. Continue to advise patient against driving for the time being.

Plan: Patient will return in six months for f/u.

Condon Family Medicine

Progress Notes

Daley, Bobby

MRN: 01081977

DOB: 1/8/97

DOV: March 7, 2016

Social History: Former tobacco user. Not currently consuming alcohol. No illicit drug use. Single. Patient still driving.

Family History: History reviewed and positive for cancer on mother's side. Father died at 59 related to heart disease. Grandfather had epilepsy.

ROS: VSS. ULE not returned to baseline, but I believe it is at maximum recovery. Continues to experience headaches, memory loss and blurred vision, but reports less frequency.

Physical Examination

Subjective: F/u appointment. ULE has reached maximum improvement. Continues with post-concussive related symptoms. Patient related that patient continues to experience instances of memory loss, but none within the past week. Frequency of approximately one incident every two to three weeks with the exception that none have been reported in last week. Headaches decreased as well as mood and blurred vision.

Current Medications: Patient d/c Vicodin as no longer required. Continues with Paxil, Xanax, prn, Imitrex and Gabapentin. No side effects reported.

Assessment: Continued post-concussion syndrome. Will continue to monitor. No medication change. Symptom no longer suggestive of potential seizure disorder. No need for further diagnostic imaging. Will continue Gabapentin and Imitrex.

Plan: Patient will return in six months for f/u.

CURRICULUM VITAE

**Chris Condon, M.D.
Suite 81 Fleury Building
269 Chase Street
Penns Woods**

Education

Steelton State 1983
B.S. with a major in Biology

Steelton Medical School 1987
M.D.

Residency and Fellowship 1987-1992
Penns Woods Regional Hospital

Board Certification in Family Practice 1993

History

1993-present
Condon Family Medical Group

Publications

I have focused on my patients rather than publishing article

Awards

Best Doctor, Penns Woods Gazette 1997, 1998, 2003, 2013, 2016

Neurontin[®] (gabapentin) Capsules
Neurontin[®] (gabapentin) Tablets
Neurontin[®] (gabapentin) Oral Solution

DESCRIPTION

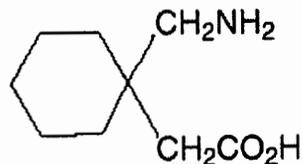
Neurontin[®] (gabapentin) Capsules, Neurontin (gabapentin) Tablets, and Neurontin (gabapentin) Oral Solution are supplied as imprinted hard shell capsules containing 100 mg, 300 mg, and 400 mg of gabapentin, elliptical film-coated tablets containing 600 mg and 800 mg of gabapentin or an oral solution containing 250 mg/5 mL of gabapentin.

The inactive ingredients for the capsules are lactose, cornstarch, and talc. The 100 mg capsule shell contains gelatin and titanium dioxide. The 300 mg capsule shell contains gelatin, titanium dioxide, and yellow iron oxide. The 400 mg capsule shell contains gelatin, red iron oxide, titanium dioxide, and yellow iron oxide. The imprinting ink contains FD&C Blue No. 2 and titanium dioxide.

The inactive ingredients for the tablets are poloxamer 407, copolyvidonum, cornstarch, magnesium stearate, hydroxypropyl cellulose, talc, candelilla wax and purified water.

The inactive ingredients for the oral solution are glycerin, xylitol, purified water and artificial cool strawberry anise flavor.

Gabapentin is described as 1-(aminomethyl)cyclohexanecarboxylic acid with a molecular formula of $C_9H_{17}NO_2$ and a molecular weight of 171.24. The structural formula of gabapentin is:



Gabapentin is a white to off-white crystalline solid with a pK_{a1} of 3.7 and a pK_{a2} of 10.7. It is freely soluble in water and both basic and acidic aqueous solutions. The log of the partition coefficient (n-octanol/0.05M phosphate buffer) at pH 7.4 is -1.25 .

CLINICAL PHARMACOLOGY

Mechanism of Action

The mechanism by which gabapentin exerts its analgesic action is unknown, but in animal models of analgesia, gabapentin prevents allodynia (pain-related behavior in response to a normally innocuous stimulus) and hyperalgesia (exaggerated response to painful stimuli). In

particular, gabapentin prevents pain-related responses in several models of neuropathic pain in rats or mice (e.g. spinal nerve ligation models, streptozocin-induced diabetes model, spinal cord injury model, acute herpes zoster infection model). Gabapentin also decreases pain-related responses after peripheral inflammation (carrageenan footpad test, late phase of formalin test). Gabapentin did not alter immediate pain-related behaviors (rat tail flick test, formalin footpad acute phase, acetic acid abdominal constriction test, footpad heat irradiation test). The relevance of these models to human pain is not known.

The mechanism by which gabapentin exerts its anticonvulsant action is unknown, but in animal test systems designed to detect anticonvulsant activity, gabapentin prevents seizures as do other marketed anticonvulsants. Gabapentin exhibits antiseizure activity in mice and rats in both the maximal electroshock and pentylenetetrazole seizure models and other preclinical models (e.g., strains with genetic epilepsy, etc.). The relevance of these models to human epilepsy is not known.

Gabapentin is structurally related to the neurotransmitter GABA (gamma-aminobutyric acid) but it does not modify GABA_A or GABA_B radioligand binding, it is not converted metabolically into GABA or a GABA agonist, and it is not an inhibitor of GABA uptake or degradation.

Gabapentin was tested in radioligand binding assays at concentrations up to 100 μ M and did not exhibit affinity for a number of other common receptor sites, including benzodiazepine, glutamate, N-methyl-D-aspartate (NMDA), quisqualate, kainate, strychnine-insensitive or strychnine-sensitive glycine, alpha 1, alpha 2, or beta adrenergic, adenosine A1 or A2, cholinergic muscarinic or nicotinic, dopamine D1 or D2, histamine H1, serotonin S1 or S2, opiate mu, delta or kappa, cannabinoid 1, voltage-sensitive calcium channel sites labeled with nitrendipine or diltiazem, or at voltage-sensitive sodium channel sites labeled with batrachotoxinin A 20-alpha-benzoate. Furthermore, gabapentin did not alter the cellular uptake of dopamine, noradrenaline, or serotonin.

In vitro studies with radiolabeled gabapentin have revealed a gabapentin binding site in areas of rat brain including neocortex and hippocampus. A high-affinity binding protein in animal brain tissue has been identified as an auxiliary subunit of voltage-activated calcium channels. However, functional correlates of gabapentin binding, if any, remain to be elucidated.

Pharmacokinetics and Drug Metabolism

All pharmacological actions following gabapentin administration are due to the activity of the parent compound; gabapentin is not appreciably metabolized in humans.

Oral Bioavailability: Gabapentin bioavailability is not dose proportional; i.e., as dose is increased, bioavailability decreases. Bioavailability of gabapentin is approximately 60%, 47%, 34%, 33%, and 27% following 900, 1200, 2400, 3600, and 4800 mg/day given in 3 divided doses, respectively. Food has only a slight effect on the rate and extent of absorption of gabapentin (14% increase in AUC and C_{max}).

Distribution: Less than 3% of gabapentin circulates bound to plasma protein. The apparent volume of distribution of gabapentin after 150 mg intravenous administration is 58 ± 6 L (Mean \pm SD). In patients with epilepsy, steady-state predose (C_{min}) concentrations of gabapentin in cerebrospinal fluid were approximately 20% of the corresponding plasma concentrations.

Elimination: Gabapentin is eliminated from the systemic circulation by renal excretion as unchanged drug. Gabapentin is not appreciably metabolized in humans.

Gabapentin elimination half-life is 5 to 7 hours and is unaltered by dose or following multiple dosing. Gabapentin elimination rate constant, plasma clearance, and renal clearance are directly proportional to creatinine clearance (see Special Populations: Patients With Renal Insufficiency, below). In elderly patients, and in patients with impaired renal function, gabapentin plasma clearance is reduced. Gabapentin can be removed from plasma by hemodialysis.

Dosage adjustment in patients with compromised renal function or undergoing hemodialysis is recommended (see DOSAGE AND ADMINISTRATION, Table 6).

Special Populations: Adult Patients With Renal Insufficiency: Subjects (N=60) with renal insufficiency (mean creatinine clearance ranging from 13-114 mL/min) were administered single 400 mg oral doses of gabapentin. The mean gabapentin half-life ranged from about 6.5 hours (patients with creatinine clearance >60 mL/min) to 52 hours (creatinine clearance <30 mL/min) and gabapentin renal clearance from about 90 mL/min (>60 mL/min group) to about 10 mL/min (<30 mL/min). Mean plasma clearance (CL/F) decreased from approximately 190 mL/min to 20 mL/min.

Dosage adjustment in adult patients with compromised renal function is necessary (see DOSAGE AND ADMINISTRATION). Pediatric patients with renal insufficiency have not been studied.

Hemodialysis: In a study in anuric adult subjects (N=11), the apparent elimination half-life of gabapentin on nondialysis days was about 132 hours; during dialysis the apparent half-life of gabapentin was reduced to 3.8 hours. Hemodialysis thus has a significant effect on gabapentin elimination in anuric subjects.

Dosage adjustment in patients undergoing hemodialysis is necessary (see DOSAGE AND ADMINISTRATION).

Hepatic Disease: Because gabapentin is not metabolized, no study was performed in patients with hepatic impairment.

Age: The effect of age was studied in subjects 20-80 years of age. Apparent oral clearance (CL/F) of gabapentin decreased as age increased, from about 225 mL/min in those under 30 years of age to about 125 mL/min in those over 70 years of age. Renal clearance (CL_r) and CL_r adjusted for body surface area also declined with age; however, the decline in the renal clearance of gabapentin with age can largely be explained by the decline in renal function. Reduction of gabapentin dose may be required in patients who have age related compromised renal function. (See PRECAUTIONS, Geriatric Use, and DOSAGE AND ADMINISTRATION.)

Pediatric: Gabapentin pharmacokinetics were determined in 48 pediatric subjects between the ages of 1 month and 12 years following a dose of approximately 10 mg/kg. Peak plasma concentrations were similar across the entire age group and occurred 2 to 3 hours postdose. In general, pediatric subjects between 1 month and <5 years of age achieved approximately 30% lower exposure (AUC) than that observed in those 5 years of age and older. Accordingly, oral clearance normalized per body weight was higher in the younger children. Apparent oral clearance of gabapentin was directly proportional to creatinine clearance. Gabapentin elimination half-life averaged 4.7 hours and was similar across the age groups studied.

A population pharmacokinetic analysis was performed in 253 pediatric subjects between 1 month and 13 years of age. Patients received 10 to 65 mg/kg/day given TID. Apparent oral clearance (CL/F) was directly proportional to creatinine clearance and this relationship was similar following a single dose and at steady state. Higher oral clearance values were observed in children <5 years of age compared to those observed in children 5 years of age and older, when normalized per body weight. The clearance was highly variable in infants <1 year of age. The normalized CL/F values observed in pediatric patients 5 years of age and older were consistent with values observed in adults after a single dose. The oral volume of distribution normalized per body weight was constant across the age range.

These pharmacokinetic data indicate that the effective daily dose in pediatric patients with epilepsy ages 3 and 4 years should be 40 mg/kg/day to achieve average plasma concentrations similar to those achieved in patients 5 years of age and older receiving gabapentin at 30 mg/kg/day (see DOSAGE AND ADMINISTRATION).

Gender: Although no formal study has been conducted to compare the pharmacokinetics of gabapentin in men and women, it appears that the pharmacokinetic parameters for males and females are similar and there are no significant gender differences.

Race: Pharmacokinetic differences due to race have not been studied. Because gabapentin is primarily renally excreted and there are no important racial differences in creatinine clearance, pharmacokinetic differences due to race are not expected.

Clinical Studies

Postherpetic Neuralgia

Neurontin was evaluated for the management of postherpetic neuralgia (PHN) in 2 randomized, double-blind, placebo-controlled, multicenter studies; N=563 patients in the intent-to-treat (ITT) population (Table 1). Patients were enrolled if they continued to have pain for more than 3 months after healing of the herpes zoster skin rash.

TABLE 1. Controlled PHN Studies: Duration, Dosages, and Number of Patients

Study	Study Duration	Gabapentin (mg/day) ^a Target Dose	Patients Receiving Gabapentin	Patients Receiving Placebo
1	8 weeks	3600	113	116
2	7 weeks	1800, 2400	223	111
Total			336	227

^a Given in 3 divided doses (TID)

Each study included a 1-week baseline during which patients were screened for eligibility and a 7- or 8-week double-blind phase (3 or 4 weeks of titration and 4 weeks of fixed dose). Patients initiated treatment with titration to a maximum of 900 mg/day gabapentin over 3 days. Dosages were then to be titrated in 600 to 1200 mg/day increments at 3- to 7-day intervals to target dose over 3 to 4 weeks. In Study 1, patients were continued on lower doses if not able to achieve the target dose. During baseline and treatment, patients recorded their pain in a daily diary using an

11-point numeric pain rating scale ranging from 0 (no pain) to 10 (worst possible pain). A mean pain score during baseline of at least 4 was required for randomization (baseline mean pain score for Studies 1 and 2 combined was 6.4). Analyses were conducted using the ITT population (all randomized patients who received at least one dose of study medication).

Both studies showed significant differences from placebo at all doses tested.

A significant reduction in weekly mean pain scores was seen by Week 1 in both studies, and significant differences were maintained to the end of treatment. Comparable treatment effects were observed in all active treatment arms. Pharmacokinetic/pharmacodynamic modeling provided confirmatory evidence of efficacy across all doses. Figures 1 and 2 show these changes for Studies 1 and 2.

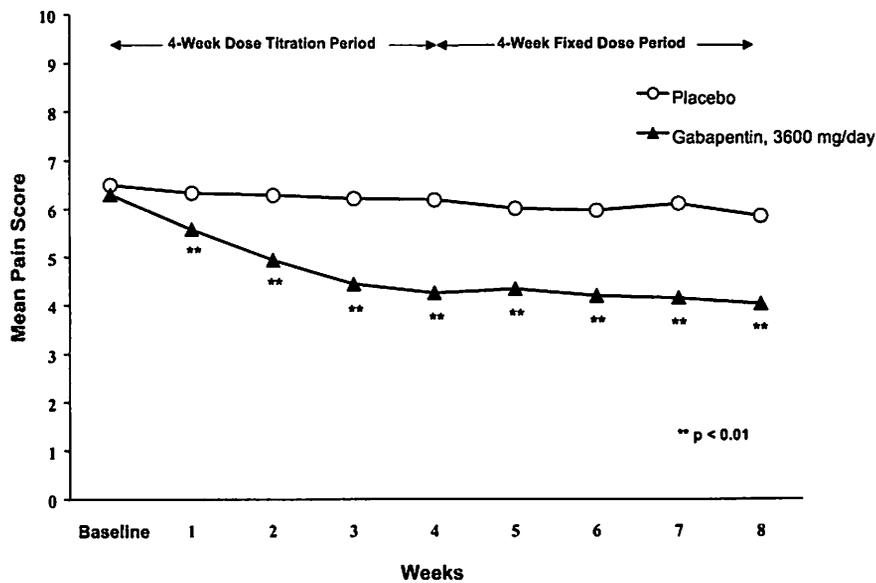


Figure 1. Weekly Mean Pain Scores (Observed Cases in ITT Population): Study 1

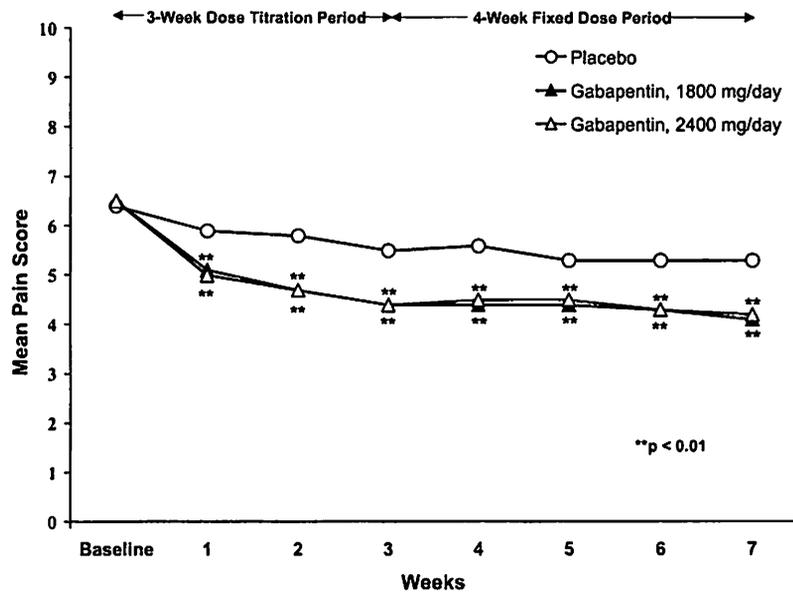


Figure 2. Weekly Mean Pain Scores (Observed Cases in ITT Population): Study 2

The proportion of responders (those patients reporting at least 50% improvement in endpoint pain score compared with baseline) was calculated for each study (Figure 3).

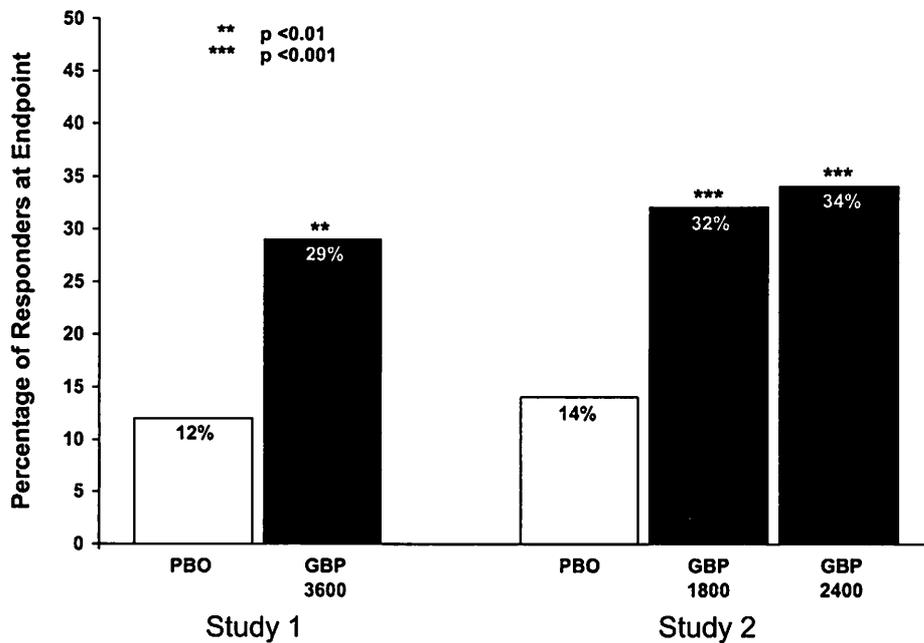


Figure 3. Proportion of Responders (patients with $\geq 50\%$ reduction in pain score) at Endpoint: Controlled PHN Studies

Epilepsy

The effectiveness of Neurontin as adjunctive therapy (added to other antiepileptic drugs) was established in multicenter placebo-controlled, double-blind, parallel-group clinical trials in adult and pediatric patients (3 years and older) with refractory partial seizures.

Evidence of effectiveness was obtained in three trials conducted in 705 patients (age 12 years and above) and one trial conducted in 247 pediatric patients (3 to 12 years of age). The patients enrolled had a history of at least 4 partial seizures per month in spite of receiving one or more antiepileptic drugs at therapeutic levels and were observed on their established antiepileptic drug regimen during a 12-week baseline period (6 weeks in the study of pediatric patients). In patients continuing to have at least 2 (or 4 in some studies) seizures per month, Neurontin or placebo was then added on to the existing therapy during a 12-week treatment period. Effectiveness was assessed primarily on the basis of the percent of patients with a 50% or greater reduction in seizure frequency from baseline to treatment (the “responder rate”) and a derived measure called response ratio, a measure of change defined as $(T - B)/(T + B)$, where B is the patient’s baseline seizure frequency and T is the patient’s seizure frequency during treatment. Response ratio is distributed within the range -1 to +1. A zero value indicates no change while complete elimination of seizures would give a value of -1; increased seizure rates would give positive values. A response ratio of -0.33 corresponds to a 50% reduction in seizure frequency. The

results given below are for all partial seizures in the intent-to-treat (all patients who received any doses of treatment) population in each study, unless otherwise indicated.

One study compared Neurontin 1200 mg/day divided TID with placebo. Responder rate was 23% (14/61) in the Neurontin group and 9% (6/66) in the placebo group; the difference between groups was statistically significant. Response ratio was also better in the Neurontin group (-0.199) than in the placebo group (-0.044), a difference that also achieved statistical significance.

A second study compared primarily 1200 mg/day divided TID Neurontin (N=101) with placebo (N=98). Additional smaller Neurontin dosage groups (600 mg/day, N=53; 1800 mg/day, N=54) were also studied for information regarding dose response. Responder rate was higher in the Neurontin 1200 mg/day group (16%) than in the placebo group (8%), but the difference was not statistically significant. The responder rate at 600 mg (17%) was also not significantly higher than in the placebo, but the responder rate in the 1800 mg group (26%) was statistically significantly superior to the placebo rate. Response ratio was better in the Neurontin 1200 mg/day group (-0.103) than in the placebo group (-0.022); but this difference was also not statistically significant ($p = 0.224$). A better response was seen in the Neurontin 600 mg/day group (-0.105) and 1800 mg/day group (-0.222) than in the 1200 mg/day group, with the 1800 mg/day group achieving statistical significance compared to the placebo group.

A third study compared Neurontin 900 mg/day divided TID (N=111) and placebo (N=109). An additional Neurontin 1200 mg/day dosage group (N=52) provided dose-response data. A statistically significant difference in responder rate was seen in the Neurontin 900 mg/day group (22%) compared to that in the placebo group (10%). Response ratio was also statistically significantly superior in the Neurontin 900 mg/day group (-0.119) compared to that in the placebo group (-0.027), as was response ratio in 1200 mg/day Neurontin (-0.184) compared to placebo.

Analyses were also performed in each study to examine the effect of Neurontin on preventing secondarily generalized tonic-clonic seizures. Patients who experienced a secondarily generalized tonic-clonic seizure in either the baseline or in the treatment period in all three placebo-controlled studies were included in these analyses. There were several response ratio comparisons that showed a statistically significant advantage for Neurontin compared to placebo and favorable trends for almost all comparisons.

Analysis of responder rate using combined data from all three studies and all doses (N=162, Neurontin; N=89, placebo) also showed a significant advantage for Neurontin over placebo in reducing the frequency of secondarily generalized tonic-clonic seizures.

In two of the three controlled studies, more than one dose of Neurontin was used. Within each study the results did not show a consistently increased response to dose. However, looking across studies, a trend toward increasing efficacy with increasing dose is evident (see Figure 4).

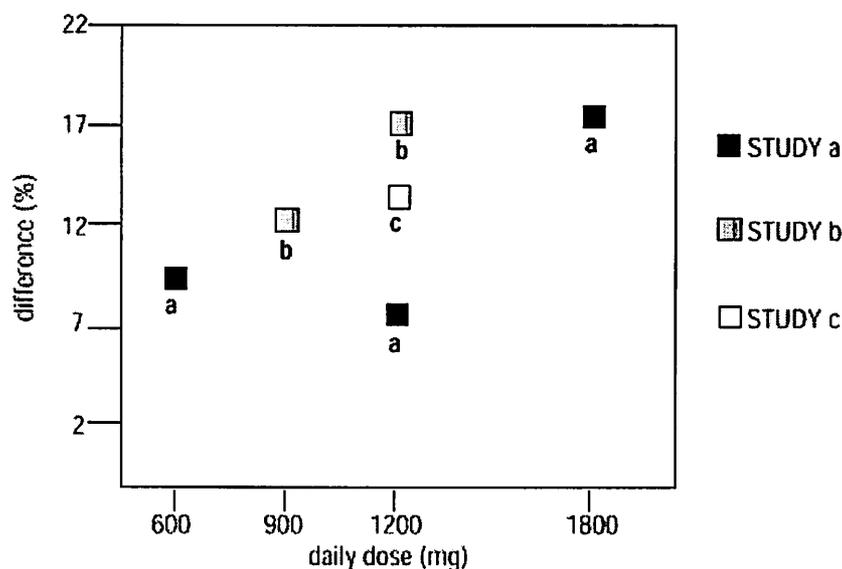


Figure 4. Responder Rate in Patients Receiving Neurontin Expressed as a Difference from Placebo by Dose and Study: Adjunctive Therapy Studies in Patients ≥ 12 Years of Age with Partial Seizures

In the figure, treatment effect magnitude, measured on the Y axis in terms of the difference in the proportion of gabapentin and placebo assigned patients attaining a 50% or greater reduction in seizure frequency from baseline, is plotted against the daily dose of gabapentin administered (X axis).

Although no formal analysis by gender has been performed, estimates of response (Response Ratio) derived from clinical trials (398 men, 307 women) indicate no important gender differences exist. There was no consistent pattern indicating that age had any effect on the response to Neurontin. There were insufficient numbers of patients of races other than Caucasian to permit a comparison of efficacy among racial groups.

A fourth study in pediatric patients age 3 to 12 years compared 25 – 35 mg/kg/day Neurontin (N=118) with placebo (N=127). For all partial seizures in the intent-to-treat population, the response ratio was statistically significantly better for the Neurontin group (-0.146) than for the placebo group (-0.079). For the same population, the responder rate for Neurontin (21%) was not significantly different from placebo (18%).

A study in pediatric patients age 1 month to 3 years compared 40 mg/kg/day Neurontin (N=38) with placebo (N=38) in patients who were receiving at least one marketed antiepileptic drug and had at least one partial seizure during the screening period (within 2 weeks prior to baseline). Patients had up to 48 hours of baseline and up to 72 hours of double-blind video EEG monitoring to record and count the occurrence of seizures. There were no statistically significant differences between treatments in either the response ratio or responder rate.

INDICATIONS AND USAGE

Postherpetic Neuralgia

Neurontin (gabapentin) is indicated for the management of postherpetic neuralgia in adults.

Epilepsy

Neurontin (gabapentin) is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients over 12 years of age with epilepsy. Neurontin is also indicated as adjunctive therapy in the treatment of partial seizures in pediatric patients age 3 – 12 years.

CONTRAINDICATIONS

Neurontin is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

WARNINGS

Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs), including Neurontin, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Pooled analyses of 199 placebo-controlled clinical trials (mono- and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.8, 95% CI:1.2, 2.7) of suicidal thinking or behavior compared to patients randomized to placebo. In these trials, which had a median treatment duration of 12 weeks, the estimated incidence rate of suicidal behavior or ideation among 27,863 AED-treated patients was 0.43%, compared to 0.24% among 16,029 placebo-treated patients, representing an increase of approximately one case of suicidal thinking or behavior for every 530 patients treated. There were four suicides in drug-treated patients in the trials and none in placebo-treated patients, but the number is too small to allow any conclusion about drug effect on suicide.

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.

The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5-100 years) in the clinical trials analyzed.

Table 2 shows absolute and relative risk by indication for all evaluated AEDs.

Table 2 Risk by indication for antiepileptic drugs in the pooled analysis

Indication	Placebo Patients with Events Per 1000 Patients	Drug Patients with Events Per 1000 Patients	Relative Risk: Incidence of Events in Drug Patients/Incidence in Placebo Patients	Risk Difference: Additional Drug Patients with Events Per 1000 Patients
Epilepsy	1.0	3.4	3.5	2.4
Psychiatric	5.7	8.5	1.5	2.9
Other	1.0	1.8	1.9	0.9
Total	2.4	4.3	1.8	1.9

The relative risk for suicidal thoughts or behavior was higher in clinical trials for epilepsy than in clinical trials for psychiatric or other conditions, but the absolute risk differences were similar for the epilepsy and psychiatric indications.

Anyone considering prescribing Neurontin or any other AED must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Patients, their caregivers, and families should be informed that AEDs increase the risk of suicidal thoughts and behavior and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Behaviors of concern should be reported immediately to healthcare providers.

Neuropsychiatric Adverse Events—Pediatric Patients 3-12 years of age

Gabapentin use in pediatric patients with epilepsy 3–12 years of age is associated with the occurrence of central nervous system related adverse events. The most significant of these can be classified into the following categories: 1) emotional lability (primarily behavioral problems), 2) hostility, including aggressive behaviors, 3) thought disorder, including concentration problems and change in school performance, and 4) hyperkinesia (primarily restlessness and hyperactivity). Among the gabapentin-treated patients, most of the events were mild to moderate in intensity.

In controlled trials in pediatric patients 3–12 years of age the incidence of these adverse events was: emotional lability 6% (gabapentin-treated patients) vs 1.3% (placebo-treated patients); hostility 5.2% vs 1.3%; hyperkinesia 4.7% vs 2.9%; and thought disorder 1.7% vs 0%. One of these events, a report of hostility, was considered serious. Discontinuation of gabapentin treatment occurred in 1.3% of patients reporting emotional lability and hyperkinesia and 0.9% of gabapentin-treated patients reporting hostility and thought disorder. One placebo-treated patient (0.4%) withdrew due to emotional lability.

Withdrawal Precipitated Seizure, Status Epilepticus

Antiepileptic drugs should not be abruptly discontinued because of the possibility of increasing seizure frequency.

In the placebo-controlled studies in patients >12 years of age, the incidence of status epilepticus in patients receiving Neurontin was 0.6% (3 of 543) versus 0.5% in patients receiving placebo (2 of 378). Among the 2074 patients >12 years of age treated with Neurontin across all studies (controlled and uncontrolled) 31 (1.5%) had status epilepticus. Of these, 14 patients had no prior history of status epilepticus either before treatment or while on other medications. Because adequate historical data are not available, it is impossible to say whether or not treatment with Neurontin is associated with a higher or lower rate of status epilepticus than would be expected to occur in a similar population not treated with Neurontin.

Tumorigenic Potential

In standard preclinical *in vivo* lifetime carcinogenicity studies, an unexpectedly high incidence of pancreatic acinar adenocarcinomas was identified in male, but not female, rats. (See PRECAUTIONS: Carcinogenesis, Mutagenesis, Impairment of Fertility.) The clinical significance of this finding is unknown. Clinical experience during gabapentin's premarketing development provides no direct means to assess its potential for inducing tumors in humans.

In clinical studies in adjunctive therapy in epilepsy comprising 2085 patient-years of exposure in patients >12 years of age, new tumors were reported in 10 patients (2 breast, 3 brain, 2 lung, 1 adrenal, 1 non-Hodgkin's lymphoma, 1 endometrial carcinoma *in situ*), and preexisting tumors worsened in 11 patients (9 brain, 1 breast, 1 prostate) during or up to 2 years following discontinuation of Neurontin. Without knowledge of the background incidence and recurrence in a similar population not treated with Neurontin, it is impossible to know whether the incidence seen in this cohort is or is not affected by treatment.

Sudden and Unexplained Death in Patients With Epilepsy

During the course of premarketing development of Neurontin 8 sudden and unexplained deaths were recorded among a cohort of 2203 patients treated (2103 patient-years of exposure).

Some of these could represent seizure-related deaths in which the seizure was not observed, e.g., at night. This represents an incidence of 0.0038 deaths per patient-year. Although this rate exceeds that expected in a healthy population matched for age and sex, it is within the range of estimates for the incidence of sudden unexplained deaths in patients with epilepsy not receiving Neurontin (ranging from 0.0005 for the general population of epileptics to 0.003 for a clinical trial population similar to that in the Neurontin program, to 0.005 for patients with refractory epilepsy). Consequently, whether these figures are reassuring or raise further concern depends on comparability of the populations reported upon to the Neurontin cohort and the accuracy of the estimates provided.

PRECAUTIONS

Information for Patients

Patients should be instructed to take Neurontin only as prescribed.

Patients, their caregivers, and families should be counseled that AEDs, including Neurontin, may increase the risk of suicidal thoughts and behavior and should be advised of the need to be alert

for the emergence or worsening of symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Behaviors of concern should be reported immediately to healthcare providers.

Patients should be advised that Neurontin may cause dizziness, somnolence and other symptoms and signs of CNS depression. Accordingly, they should be advised neither to drive a car nor to operate other complex machinery until they have gained sufficient experience on Neurontin to gauge whether or not it affects their mental and/or motor performance adversely.

Patients who require concomitant treatment with morphine may experience increases in gabapentin concentrations. Patients should be carefully observed for signs of CNS depression, such as somnolence, and the dose of Neurontin or morphine should be reduced appropriately (see Drug Interactions).

Patients should be encouraged to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry if they become pregnant. This registry is collecting information about the safety of antiepileptic drugs during pregnancy. To enroll, patients can call the toll free number 1-888-233-2334 (see PRECAUTIONS, Pregnancy section).

Laboratory Tests

Clinical trials data do not indicate that routine monitoring of clinical laboratory parameters is necessary for the safe use of Neurontin. The value of monitoring gabapentin blood concentrations has not been established. Neurontin may be used in combination with other antiepileptic drugs without concern for alteration of the blood concentrations of gabapentin or of other antiepileptic drugs.

Drug Interactions

In vitro studies were conducted to investigate the potential of gabapentin to inhibit the major cytochrome P450 enzymes (CYP1A2, CYP2A6, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A4) that mediate drug and xenobiotic metabolism using isoform selective marker substrates and human liver microsomal preparations. Only at the highest concentration tested (171 µg/mL; 1 mM) was a slight degree of inhibition (14%-30%) of isoform CYP2A6 observed. No inhibition of any of the other isoforms tested was observed at gabapentin concentrations up to 171 µg/mL (approximately 15 times the C_{max} at 3600 mg/day).

Gabapentin is not appreciably metabolized nor does it interfere with the metabolism of commonly coadministered antiepileptic drugs.

The drug interaction data described in this section were obtained from studies involving healthy adults and adult patients with epilepsy.

Phenytoin: In a single (400 mg) and multiple dose (400 mg TID) study of Neurontin in epileptic patients (N=8) maintained on phenytoin monotherapy for at least 2 months, gabapentin had no effect on the steady-state trough plasma concentrations of phenytoin and phenytoin had no effect on gabapentin pharmacokinetics.

Carbamazepine: Steady-state trough plasma carbamazepine and carbamazepine 10, 11 epoxide concentrations were not affected by concomitant gabapentin (400 mg TID; N=12) administration. Likewise, gabapentin pharmacokinetics were unaltered by carbamazepine administration.

Valproic Acid: The mean steady-state trough serum valproic acid concentrations prior to and during concomitant gabapentin administration (400 mg TID; N=17) were not different and neither were gabapentin pharmacokinetic parameters affected by valproic acid.

Phenobarbital: Estimates of steady-state pharmacokinetic parameters for phenobarbital or gabapentin (300 mg TID; N=12) are identical whether the drugs are administered alone or together.

Naproxen: Coadministration (N=18) of naproxen sodium capsules (250 mg) with Neurontin (125 mg) appears to increase the amount of gabapentin absorbed by 12% to 15%. Gabapentin had no effect on naproxen pharmacokinetic parameters. These doses are lower than the therapeutic doses for both drugs. The magnitude of interaction within the recommended dose ranges of either drug is not known.

Hydrocodone: Coadministration of Neurontin (125 to 500 mg; N=48) decreases hydrocodone (10 mg; N=50) C_{max} and AUC values in a dose-dependent manner relative to administration of hydrocodone alone; C_{max} and AUC values are 3% to 4% lower, respectively, after administration of 125 mg Neurontin and 21% to 22% lower, respectively, after administration of 500 mg Neurontin. The mechanism for this interaction is unknown. Hydrocodone increases gabapentin AUC values by 14%. The magnitude of interaction at other doses is not known.

Morphine: A literature article reported that when a 60-mg controlled-release morphine capsule was administered 2 hours prior to a 600-mg Neurontin capsule (N=12), mean gabapentin AUC increased by 44% compared to gabapentin administered without morphine (see PRECAUTIONS). Morphine pharmacokinetic parameter values were not affected by administration of Neurontin 2 hours after morphine. The magnitude of interaction at other doses is not known.

Cimetidine: In the presence of cimetidine at 300 mg QID (N=12) the mean apparent oral clearance of gabapentin fell by 14% and creatinine clearance fell by 10%. Thus cimetidine appeared to alter the renal excretion of both gabapentin and creatinine, an endogenous marker of renal function. This small decrease in excretion of gabapentin by cimetidine is not expected to be of clinical importance. The effect of gabapentin on cimetidine was not evaluated.

Oral Contraceptive: Based on AUC and half-life, multiple-dose pharmacokinetic profiles of norethindrone and ethinyl estradiol following administration of tablets containing 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol were similar with and without coadministration of gabapentin (400 mg TID; N=13). The C_{max} of norethindrone was 13% higher when it was coadministered with gabapentin; this interaction is not expected to be of clinical importance.

Antacid (Maalox®): Maalox reduced the bioavailability of gabapentin (N=16) by about 20%. This decrease in bioavailability was about 5% when gabapentin was administered 2 hours after Maalox. It is recommended that gabapentin be taken at least 2 hours following Maalox administration.

Effect of Probenecid: Probenecid is a blocker of renal tubular secretion. Gabapentin pharmacokinetic parameters without and with probenecid were comparable. This indicates that gabapentin does not undergo renal tubular secretion by the pathway that is blocked by probenecid.

Drug/Laboratory Tests Interactions

Because false positive readings were reported with the Ames N-Multistix SG[®] dipstick test for urinary protein when gabapentin was added to other antiepileptic drugs, the more specific sulfosalicylic acid precipitation procedure is recommended to determine the presence of urine protein.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Gabapentin was given in the diet to mice at 200, 600, and 2000 mg/kg/day and to rats at 250, 1000, and 2000 mg/kg/day for 2 years. A statistically significant increase in the incidence of pancreatic acinar cell adenomas and carcinomas was found in male rats receiving the high dose; the no-effect dose for the occurrence of carcinomas was 1000 mg/kg/day. Peak plasma concentrations of gabapentin in rats receiving the high dose of 2000 mg/kg were 10 times higher than plasma concentrations in humans receiving 3600 mg per day, and in rats receiving 1000 mg/kg/day peak plasma concentrations were 6.5 times higher than in humans receiving 3600 mg/day. The pancreatic acinar cell carcinomas did not affect survival, did not metastasize and were not locally invasive. The relevance of this finding to carcinogenic risk in humans is unclear.

Studies designed to investigate the mechanism of gabapentin-induced pancreatic carcinogenesis in rats indicate that gabapentin stimulates DNA synthesis in rat pancreatic acinar cells *in vitro* and, thus, may be acting as a tumor promoter by enhancing mitogenic activity. It is not known whether gabapentin has the ability to increase cell proliferation in other cell types or in other species, including humans.

Gabapentin did not demonstrate mutagenic or genotoxic potential in three *in vitro* and four *in vivo* assays. It was negative in the Ames test and the *in vitro* HGPRT forward mutation assay in Chinese hamster lung cells; it did not produce significant increases in chromosomal aberrations in the *in vitro* Chinese hamster lung cell assay; it was negative in the *in vivo* chromosomal aberration assay and in the *in vivo* micronucleus test in Chinese hamster bone marrow; it was negative in the *in vivo* mouse micronucleus assay; and it did not induce unscheduled DNA synthesis in hepatocytes from rats given gabapentin.

No adverse effects on fertility or reproduction were observed in rats at doses up to 2000 mg/kg (approximately 5 times the maximum recommended human dose on a mg/m² basis).

Pregnancy

Pregnancy Category C: Gabapentin has been shown to be fetotoxic in rodents, causing delayed ossification of several bones in the skull, vertebrae, forelimbs, and hindlimbs. These effects occurred when pregnant mice received oral doses of 1000 or 3000 mg/kg/day during the period of organogenesis, or approximately 1 to 4 times the maximum dose of 3600 mg/day given to epileptic patients on a mg/m² basis. The no-effect level was 500 mg/kg/day or approximately 1/2 of the human dose on a mg/m² basis.

When rats were dosed prior to and during mating, and throughout gestation, pups from all dose groups (500, 1000 and 2000 mg/kg/day) were affected. These doses are equivalent to less than approximately 1 to 5 times the maximum human dose on a mg/m² basis. There was an increased incidence of hydronephrosis and/or hydroureter in rats in a study of fertility and general reproductive performance at 2000 mg/kg/day with no effect at 1000 mg/kg/day, in a teratology

study at 1500 mg/kg/day with no effect at 300 mg/kg/day, and in a perinatal and postnatal study at all doses studied (500, 1000 and 2000 mg/kg/day). The doses at which the effects occurred are approximately 1 to 5 times the maximum human dose of 3600 mg/day on a mg/m² basis; the no-effect doses were approximately 3 times (Fertility and General Reproductive Performance study) and approximately equal to (Teratogenicity study) the maximum human dose on a mg/m² basis. Other than hydroureter and hydronephrosis, the etiologies of which are unclear, the incidence of malformations was not increased compared to controls in offspring of mice, rats, or rabbits given doses up to 50 times (mice), 30 times (rats), and 25 times (rabbits) the human daily dose on a mg/kg basis, or 4 times (mice), 5 times (rats), or 8 times (rabbits) the human daily dose on a mg/m² basis.

In a teratology study in rabbits, an increased incidence of postimplantation fetal loss occurred in dams exposed to 60, 300, and 1500 mg/kg/day, or less than approximately ¼ to 8 times the maximum human dose on a mg/m² basis. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

To provide information regarding the effects of in utero exposure to Neurontin, physicians are advised to recommend that pregnant patients taking Neurontin enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. This can be done by calling the toll free number 1-888-233-2334, and must be done by patients themselves. Information on the registry can also be found at the website <http://www.aedpregnancyregistry.org/>.

Use in Nursing Mothers

Gabapentin is secreted into human milk following oral administration. A nursed infant could be exposed to a maximum dose of approximately 1 mg/kg/day of gabapentin. Because the effect on the nursing infant is unknown, Neurontin should be used in women who are nursing only if the benefits clearly outweigh the risks.

Pediatric Use

Safety and effectiveness of Neurontin (gabapentin) in the management of postherpetic neuralgia in pediatric patients have not been established.

Effectiveness as adjunctive therapy in the treatment of partial seizures in pediatric patients below the age of 3 years has not been established (see CLINICAL PHARMACOLOGY, Clinical Studies).

Geriatric Use

The total number of patients treated with Neurontin in controlled clinical trials in patients with postherpetic neuralgia was 336, of which 102 (30%) were 65 to 74 years of age, and 168 (50%) were 75 years of age and older. There was a larger treatment effect in patients 75 years of age and older compared with younger patients who received the same dosage. Since gabapentin is almost exclusively eliminated by renal excretion, the larger treatment effect observed in patients ≥75 years may be a consequence of increased gabapentin exposure for a given dose that results from an age-related decrease in renal function. However, other factors cannot be excluded. The types and incidence of adverse events were similar across age groups except for peripheral edema and ataxia, which tended to increase in incidence with age.

Clinical studies of Neurontin in epilepsy did not include sufficient numbers of subjects aged 65 and over to determine whether they responded differently from younger subjects. Other reported

clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and dose should be adjusted based on creatinine clearance values in these patients (see CLINICAL PHARMACOLOGY, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION sections).

ADVERSE REACTIONS

Postherpetic Neuralgia

The most commonly observed adverse events associated with the use of Neurontin in adults, not seen at an equivalent frequency among placebo-treated patients, were dizziness, somnolence, and peripheral edema.

In the 2 controlled studies in postherpetic neuralgia, 16% of the 336 patients who received Neurontin and 9% of the 227 patients who received placebo discontinued treatment because of an adverse event. The adverse events that most frequently led to withdrawal in Neurontin[®]-treated patients were dizziness, somnolence, and nausea.

Incidence in Controlled Clinical Trials

Table 3 lists treatment-emergent signs and symptoms that occurred in at least 1% of Neurontin-treated patients with postherpetic neuralgia participating in placebo-controlled trials and that were numerically more frequent in the Neurontin group than in the placebo group. Adverse events were usually mild to moderate in intensity.

TABLE 3. Treatment-Emergent Adverse Event Incidence in Controlled Trials in Postherpetic Neuralgia (Events in at least 1% of Neurontin[®]-Treated Patients and Numerically More Frequent Than in the Placebo Group)

Body System/ Preferred Term	Neurontin [®] N=336 %	Placebo N=227 %
<u>Body as a Whole</u>		
Asthenia	5.7	4.8
Infection	5.1	3.5
Headache	3.3	3.1
Accidental injury	3.3	1.3
Abdominal pain	2.7	2.6
<u>Digestive System</u>		
Diarrhea	5.7	3.1
Dry mouth	4.8	1.3
Constipation	3.9	1.8
Nausea	3.9	3.1
Vomiting	3.3	1.8
Flatulence	2.1	1.8
<u>Metabolic and Nutritional Disorders</u>		
Peripheral edema	8.3	2.2
Weight gain	1.8	0.0
Hyperglycemia	1.2	0.4
<u>Nervous System</u>		
Dizziness	28.0	7.5
Somnolence	21.4	5.3
Ataxia	3.3	0.0
Thinking abnormal	2.7	0.0
Abnormal gait	1.5	0.0
Incoordination	1.5	0.0
Amnesia	1.2	0.9
Hypesthesia	1.2	0.9
<u>Respiratory System</u>		
Pharyngitis	1.2	0.4
<u>Skin and Appendages</u>		
Rash	1.2	0.9
<u>Special Senses</u>		
Amblyopia ^a	2.7	0.9
Conjunctivitis	1.2	0.0
Diplopia	1.2	0.0
Otitis media	1.2	0.0

^a Reported as blurred vision

Other events in more than 1% of patients but equally or more frequent in the placebo group included pain, tremor, neuralgia, back pain, dyspepsia, dyspnea, and flu syndrome.

There were no clinically important differences between men and women in the types and incidence of adverse events. Because there were few patients whose race was reported as other than white, there are insufficient data to support a statement regarding the distribution of adverse events by race.

Epilepsy

The most commonly observed adverse events associated with the use of Neurontin in combination with other antiepileptic drugs in patients >12 years of age, not seen at an equivalent frequency among placebo-treated patients, were somnolence, dizziness, ataxia, fatigue, and nystagmus. The most commonly observed adverse events reported with the use of Neurontin in combination with other antiepileptic drugs in pediatric patients 3 to 12 years of age, not seen at an equal frequency among placebo-treated patients, were viral infection, fever, nausea and/or vomiting, somnolence, and hostility (see WARNINGS, Neuropsychiatric Adverse Events).

Approximately 7% of the 2074 patients >12 years of age and approximately 7% of the 449 pediatric patients 3 to 12 years of age who received Neurontin in premarketing clinical trials discontinued treatment because of an adverse event. The adverse events most commonly associated with withdrawal in patients >12 years of age were somnolence (1.2%), ataxia (0.8%), fatigue (0.6%), nausea and/or vomiting (0.6%), and dizziness (0.6%). The adverse events most commonly associated with withdrawal in pediatric patients were emotional lability (1.6%), hostility (1.3%), and hyperkinesia (1.1%).

Incidence in Controlled Clinical Trials

Table 4 lists treatment-emergent signs and symptoms that occurred in at least 1% of Neurontin-treated patients >12 years of age with epilepsy participating in placebo-controlled trials and were numerically more common in the Neurontin group. In these studies, either Neurontin or placebo was added to the patient's current antiepileptic drug therapy. Adverse events were usually mild to moderate in intensity.

The prescriber should be aware that these figures, obtained when Neurontin was added to concurrent antiepileptic drug therapy, cannot be used to predict the frequency of adverse events in the course of usual medical practice where patient characteristics and other factors may differ from those prevailing during clinical studies. Similarly, the cited frequencies cannot be directly compared with figures obtained from other clinical investigations involving different treatments, uses, or investigators. An inspection of these frequencies, however, does provide the prescribing physician with one basis to estimate the relative contribution of drug and nondrug factors to the adverse event incidences in the population studied.

TABLE 4. Treatment-Emergent Adverse Event Incidence in Controlled Add-On Trials In Patients >12 years of age (Events in at least 1% of Neurontin patients and numerically more frequent than in the placebo group)

Body System/ Adverse Event	Neurontin ^a N=543 %	Placebo ^a N=378 %
<u>Body As A Whole</u>		
Fatigue	11.0	5.0
Weight Increase	2.9	1.6
Back Pain	1.8	0.5
Peripheral Edema	1.7	0.5
<u>Cardiovascular</u>		
Vasodilatation	1.1	0.3
<u>Digestive System</u>		
Dyspepsia	2.2	0.5
Mouth or Throat Dry	1.7	0.5
Constipation	1.5	0.8
Dental Abnormalities	1.5	0.3
Increased Appetite	1.1	0.8
<u>Hematologic and Lymphatic Systems</u>		
Leukopenia	1.1	0.5
<u>Musculoskeletal System</u>		
Myalgia	2.0	1.9
Fracture	1.1	0.8
<u>Nervous System</u>		
Somnolence	19.3	8.7
Dizziness	17.1	6.9
Ataxia	12.5	5.6
Nystagmus	8.3	4.0
Tremor	6.8	3.2
Nervousness	2.4	1.9
Dysarthria	2.4	0.5
Amnesia	2.2	0.0
Depression	1.8	1.1
Thinking Abnormal	1.7	1.3
Twitching	1.3	0.5
Coordination Abnormal	1.1	0.3
<u>Respiratory System</u>		
Rhinitis	4.1	3.7
Pharyngitis	2.8	1.6
Coughing	1.8	1.3
<u>Skin and Appendages</u>		
Abrasion	1.3	0.0
Pruritus	1.3	0.5

TABLE 4. Treatment-Emergent Adverse Event Incidence in Controlled Add-On Trials In Patients >12 years of age (Events in at least 1% of Neurontin patients and numerically more frequent than in the placebo group)

Body System/ Adverse Event	Neurontin ^a N=543 %	Placebo ^a N=378 %
<u>Urogenital System</u>		
Impotence	1.5	1.1
<u>Special Senses</u>		
Diplopia	5.9	1.9
Amblyopia ^b	4.2	1.1
<u>Laboratory Deviations</u>		
WBC Decreased	1.1	0.5

^a Plus background antiepileptic drug therapy

^b Amblyopia was often described as blurred vision.

Other events in more than 1% of patients >12 years of age but equally or more frequent in the placebo group included: headache, viral infection, fever, nausea and/or vomiting, abdominal pain, diarrhea, convulsions, confusion, insomnia, emotional lability, rash, acne.

Among the treatment-emergent adverse events occurring at an incidence of at least 10% of Neurontin-treated patients, somnolence and ataxia appeared to exhibit a positive dose-response relationship.

The overall incidence of adverse events and the types of adverse events seen were similar among men and women treated with Neurontin. The incidence of adverse events increased slightly with increasing age in patients treated with either Neurontin or placebo. Because only 3% of patients (28/921) in placebo-controlled studies were identified as nonwhite (black or other), there are insufficient data to support a statement regarding the distribution of adverse events by race.

Table 5 lists treatment-emergent signs and symptoms that occurred in at least 2% of Neurontin-treated patients age 3 to 12 years of age with epilepsy participating in placebo-controlled trials and were numerically more common in the Neurontin group. Adverse events were usually mild to moderate in intensity.

TABLE 5. Treatment-Emergent Adverse Event Incidence in Pediatric Patients Age 3 to 12 Years in a Controlled Add-On Trial (Events in at least 2% of Neurontin patients and numerically more frequent than in the placebo group)

Body System/ Adverse Event	Neurontin ^a N=119 %	Placebo ^a N=128 %
<u>Body As A Whole</u>		
Viral Infection	10.9	3.1
Fever	10.1	3.1
Weight Increase	3.4	0.8
Fatigue	3.4	1.6
<u>Digestive System</u>		
Nausea and/or Vomiting	8.4	7.0
<u>Nervous System</u>		
Somnolence	8.4	4.7
Hostility	7.6	2.3
Emotional Lability	4.2	1.6
Dizziness	2.5	1.6
Hyperkinesia	2.5	0.8
<u>Respiratory System</u>		
Bronchitis	3.4	0.8
Respiratory Infection	2.5	0.8

^a Plus background antiepileptic drug therapy

Other events in more than 2% of pediatric patients 3 to 12 years of age but equally or more frequent in the placebo group included: pharyngitis, upper respiratory infection, headache, rhinitis, convulsions, diarrhea, anorexia, coughing, and otitis media.

Other Adverse Events Observed During All Clinical Trials

Clinical Trials in Adults and Adolescents (Except Clinical Trials in Neuropathic Pain)

Neurontin has been administered to 4717 patients >12 years of age during all adjunctive therapy clinical trials (except clinical trials in patients with neuropathic pain), only some of which were placebo-controlled. During these trials, all adverse events were recorded by the clinical investigators using terminology of their own choosing. To provide a meaningful estimate of the proportion of individuals having adverse events, similar types of events were grouped into a smaller number of standardized categories using modified COSTART dictionary terminology. These categories are used in the listing below. The frequencies presented represent the proportion of the 4717 patients >12 years of age exposed to Neurontin who experienced an event of the type cited on at least one occasion while receiving Neurontin. All reported events are included except those already listed in Table 4, those too general to be informative, and those not reasonably associated with the use of the drug.

Events are further classified within body system categories and enumerated in order of decreasing frequency using the following definitions: frequent adverse events are defined as

those occurring in at least 1/100 patients; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients.

Body As A Whole: *Frequent:* asthenia, malaise, face edema; *Infrequent:* allergy, generalized edema, weight decrease, chill; *Rare:* strange feelings, lassitude, alcohol intolerance, hangover effect.

Cardiovascular System: *Frequent:* hypertension; *Infrequent:* hypotension, angina pectoris, peripheral vascular disorder, palpitation, tachycardia, migraine, murmur; *Rare:* atrial fibrillation, heart failure, thrombophlebitis, deep thrombophlebitis, myocardial infarction, cerebrovascular accident, pulmonary thrombosis, ventricular extrasystoles, bradycardia, premature atrial contraction, pericardial rub, heart block, pulmonary embolus, hyperlipidemia, hypercholesterolemia, pericardial effusion, pericarditis.

Digestive System: *Frequent:* anorexia, flatulence, gingivitis; *Infrequent:* glossitis, gum hemorrhage, thirst, stomatitis, increased salivation, gastroenteritis, hemorrhoids, bloody stools, fecal incontinence, hepatomegaly; *Rare:* dysphagia, eructation, pancreatitis, peptic ulcer, colitis, blisters in mouth, tooth discolor, perlèche, salivary gland enlarged, lip hemorrhage, esophagitis, hiatal hernia, hematemesis, proctitis, irritable bowel syndrome, rectal hemorrhage, esophageal spasm.

Endocrine System: *Rare:* hyperthyroid, hypothyroid, goiter, hypoestrogen, ovarian failure, epididymitis, swollen testicle, cushingoid appearance.

Hematologic and Lymphatic System: *Frequent:* purpura most often described as bruises resulting from physical trauma; *Infrequent:* anemia, thrombocytopenia, lymphadenopathy; *Rare:* WBC count increased, lymphocytosis, non-Hodgkin's lymphoma, bleeding time increased.

Musculoskeletal System: *Frequent:* arthralgia; *Infrequent:* tendinitis, arthritis, joint stiffness, joint swelling, positive Romberg test; *Rare:* costochondritis, osteoporosis, bursitis, contracture.

Nervous System: *Frequent:* vertigo, hyperkinesia, paresthesia, decreased or absent reflexes, increased reflexes, anxiety, hostility; *Infrequent:* CNS tumors, syncope, dreaming abnormal, aphasia, hypesthesia, intracranial hemorrhage, hypotonia, dysesthesia, paresis, dystonia, hemiplegia, facial paralysis, stupor, cerebellar dysfunction, positive Babinski sign, decreased position sense, subdural hematoma, apathy, hallucination, decrease or loss of libido, agitation, paranoia, depersonalization, euphoria, feeling high, doped-up sensation, psychosis; *Rare:* choreoathetosis, orofacial dyskinesia, encephalopathy, nerve palsy, personality disorder, increased libido, subdued temperament, apraxia, fine motor control disorder, meningismus, local myoclonus, hyperesthesia, hypokinesia, mania, neurosis, hysteria, antisocial reaction.

Respiratory System: *Frequent:* pneumonia; *Infrequent:* epistaxis, dyspnea, apnea; *Rare:* mucositis, aspiration pneumonia, hyperventilation, hiccup, laryngitis, nasal obstruction, snoring, bronchospasm, hypoventilation, lung edema.

Dermatological: *Infrequent:* alopecia, eczema, dry skin, increased sweating, urticaria, hirsutism, seborrhea, cyst, herpes simplex; *Rare:* herpes zoster, skin discolor, skin papules, photosensitive reaction, leg ulcer, scalp seborrhea, psoriasis, desquamation, maceration, skin nodules, subcutaneous nodule, melanosis, skin necrosis, local swelling.

Urogenital System: *Infrequent:* hematuria, dysuria, urination frequency, cystitis, urinary retention, urinary incontinence, vaginal hemorrhage, amenorrhea, dysmenorrhea, menorrhagia,

breast cancer, unable to climax, ejaculation abnormal; *Rare*: kidney pain, leukorrhea, pruritus genital, renal stone, acute renal failure, anuria, glycosuria, nephrosis, nocturia, pyuria, urination urgency, vaginal pain, breast pain, testicle pain.

Special Senses: *Frequent*: abnormal vision; *Infrequent*: cataract, conjunctivitis, eyes dry, eye pain, visual field defect, photophobia, bilateral or unilateral ptosis, eye hemorrhage, hordeolum, hearing loss, earache, tinnitus, inner ear infection, otitis, taste loss, unusual taste, eye twitching, ear fullness; *Rare*: eye itching, abnormal accommodation, perforated ear drum, sensitivity to noise, eye focusing problem, watery eyes, retinopathy, glaucoma, iritis, corneal disorders, lacrimal dysfunction, degenerative eye changes, blindness, retinal degeneration, miosis, chorioretinitis, strabismus, eustachian tube dysfunction, labyrinthitis, otitis externa, odd smell.

Clinical trials in Pediatric Patients With Epilepsy

Adverse events occurring during epilepsy clinical trials in 449 pediatric patients 3 to 12 years of age treated with gabapentin that were not reported in adjunctive trials in adults are:

Body as a Whole: dehydration, infectious mononucleosis

Digestive System: hepatitis

Hemic and Lymphatic System: coagulation defect

Nervous System: aura disappeared, occipital neuralgia

Psychobiologic Function: sleepwalking

Respiratory System: pseudocroup, hoarseness

Clinical Trials in Adults With Neuropathic Pain of Various Etiologies

Safety information was obtained in 1173 patients during double-blind and open-label clinical trials including neuropathic pain conditions for which efficacy has not been demonstrated. Adverse events reported by investigators were grouped into standardized categories using modified COSTART IV terminology. Listed below are all reported events except those already listed in Table 3 and those not reasonably associated with the use of the drug.

Events are further classified within body system categories and enumerated in order of decreasing frequency using the following definitions: frequent adverse events are defined as those occurring in at least 1/100 patients; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients.

Body as a Whole: *Infrequent*: chest pain, cellulitis, malaise, neck pain, face edema, allergic reaction, abscess, chills, chills and fever, mucous membrane disorder; *Rare*: body odor, cyst, fever, hernia, abnormal BUN value, lump in neck, pelvic pain, sepsis, viral infection.

Cardiovascular System: *Infrequent*: hypertension, syncope, palpitation, migraine, hypotension, peripheral vascular disorder, cardiovascular disorder, cerebrovascular accident, congestive heart failure, myocardial infarction, vasodilatation; *Rare*: angina pectoris, heart failure, increased capillary fragility, phlebitis, thrombophlebitis, varicose vein.

Digestive System: *Infrequent*: gastroenteritis, increased appetite, gastrointestinal disorder, oral moniliasis, gastritis, tongue disorder, thirst, tooth disorder, abnormal stools, anorexia, liver

function tests abnormal, periodontal abscess; *Rare*: cholecystitis, cholelithiasis, duodenal ulcer, fecal incontinence, gamma glutamyl transpeptidase increased, gingivitis, intestinal obstruction, intestinal ulcer, melena, mouth ulceration, rectal disorder, rectal hemorrhage, stomatitis.

Endocrine System: *Infrequent*: diabetes mellitus.

Hemic and Lymphatic System: *Infrequent*: ecchymosis, anemia; *Rare*: lymphadenopathy, lymphoma-like reaction, prothrombin decreased.

Metabolic and Nutritional: *Infrequent*: edema, gout, hypoglycemia, weight loss; *Rare*: alkaline phosphatase increased, diabetic ketoacidosis, lactic dehydrogenase increased.

Musculoskeletal: *Infrequent*: arthritis, arthralgia, myalgia, arthrosis, leg cramps, myasthenia; *Rare*: shin bone pain, joint disorder, tendon disorder.

Nervous System: *Frequent*: confusion, depression; *Infrequent*: vertigo, nervousness, paresthesia, insomnia, neuropathy, libido decreased, anxiety, depersonalization, reflexes decreased, speech disorder, abnormal dreams, dysarthria, emotional lability, nystagmus, stupor, circumoral paresthesia, euphoria, hyperesthesia, hypokinesia; *Rare*: agitation, hypertonia, libido increased, movement disorder, myoclonus, vestibular disorder.

Respiratory System: *Infrequent*: cough increased, bronchitis, rhinitis, sinusitis, pneumonia, asthma, lung disorder, epistaxis; *Rare*: hemoptysis, voice alteration.

Skin and Appendages: *Infrequent*: pruritus, skin ulcer, dry skin, herpes zoster, skin disorder, fungal dermatitis, furunculosis, herpes simplex, psoriasis, sweating, urticaria, vesiculobullous rash; *Rare*: acne, hair disorder, maculopapular rash, nail disorder, skin carcinoma, skin discoloration, skin hypertrophy.

Special Senses: *Infrequent*: abnormal vision, ear pain, eye disorder, taste perversion, deafness; *Rare*: conjunctival hyperemia, diabetic retinopathy, eye pain, fundi with microhemorrhage, retinal vein thrombosis, taste loss.

Urogenital System: *Infrequent*: urinary tract infection, dysuria, impotence, urinary incontinence, vaginal moniliasis, breast pain, menstrual disorder, polyuria, urinary retention; *Rare*: cystitis, ejaculation abnormal, swollen penis, gynecomastia, nocturia, pyelonephritis, swollen scrotum, urinary frequency, urinary urgency, urine abnormality.

Postmarketing and Other Experience

In addition to the adverse experiences reported during clinical testing of Neurontin, the following adverse experiences have been reported in patients receiving marketed Neurontin. These adverse experiences have not been listed above and data are insufficient to support an estimate of their incidence or to establish causation. The listing is alphabetized: angioedema, blood glucose fluctuation, breast hypertrophy, erythema multiforme, elevated liver function tests, fever, hyponatremia, jaundice, movement disorder, Stevens-Johnson syndrome.

Adverse events following the abrupt discontinuation of gabapentin have also been reported. The most frequently reported events were anxiety, insomnia, nausea, pain and sweating.

DRUG ABUSE AND DEPENDENCE

The abuse and dependence potential of Neurontin has not been evaluated in human studies.

OVERDOSAGE

A lethal dose of gabapentin was not identified in mice and rats receiving single oral doses as high as 8000 mg/kg. Signs of acute toxicity in animals included ataxia, labored breathing, ptosis, sedation, hypoactivity, or excitation.

Acute oral overdoses of Neurontin up to 49 grams have been reported. In these cases, double vision, slurred speech, drowsiness, lethargy and diarrhea were observed. All patients recovered with supportive care.

Gabapentin can be removed by hemodialysis. Although hemodialysis has not been performed in the few overdose cases reported, it may be indicated by the patient's clinical state or in patients with significant renal impairment.

DOSAGE AND ADMINISTRATION

Neurontin is given orally with or without food. Patients should be informed that, should they break the scored 600 or 800 mg tablet in order to administer a half-tablet, they should take the unused half-tablet as the next dose. Half-tablets not used within several days of breaking the scored tablet should be discarded.

If Neurontin dose is reduced, discontinued or substituted with an alternative medication, this should be done gradually over a minimum of 1 week (a longer period may be needed at the discretion of the prescriber).

Postherpetic Neuralgia

In adults with postherpetic neuralgia, Neurontin therapy may be initiated as a single 300-mg dose on Day 1, 600 mg/day on Day 2 (divided BID), and 900 mg/day on Day 3 (divided TID). The dose can subsequently be titrated up as needed for pain relief to a daily dose of 1800 mg (divided TID). In clinical studies, efficacy was demonstrated over a range of doses from 1800 mg/day to 3600 mg/day with comparable effects across the dose range. Additional benefit of using doses greater than 1800 mg/day was not demonstrated.

Epilepsy

Neurontin is recommended for add-on therapy in patients 3 years of age and older. Effectiveness in pediatric patients below the age of 3 years has not been established.

Patients >12 years of age: The effective dose of Neurontin is 900 to 1800 mg/day and given in divided doses (three times a day) using 300 or 400 mg capsules, or 600 or 800 mg tablets. The starting dose is 300 mg three times a day. If necessary, the dose may be increased using 300 or 400 mg capsules, or 600 or 800 mg tablets three times a day up to 1800 mg/day. Dosages up to 2400 mg/day have been well tolerated in long-term clinical studies. Doses of 3600 mg/day have also been administered to a small number of patients for a relatively short duration, and have been well tolerated. The maximum time between doses in the TID schedule should not exceed 12 hours.

Pediatric Patients Age 3–12 years: The starting dose should range from 10-15 mg/kg/day in 3 divided doses, and the effective dose reached by upward titration over a period of approximately 3 days. The effective dose of Neurontin in patients 5 years of age and older is

25–35 mg/kg/day and given in divided doses (three times a day). The effective dose in pediatric patients ages 3 and 4 years is 40 mg/kg/day and given in divided doses (three times a day) (see CLINICAL PHARMACOLOGY, Pediatrics.) Neurontin® may be administered as the oral solution, capsule, or tablet, or using combinations of these formulations. Dosages up to 50 mg/kg/day have been well-tolerated in a long-term clinical study. The maximum time interval between doses should not exceed 12 hours.

It is not necessary to monitor gabapentin plasma concentrations to optimize Neurontin therapy. Further, because there are no significant pharmacokinetic interactions among Neurontin and other commonly used antiepileptic drugs, the addition of Neurontin does not alter the plasma levels of these drugs appreciably.

If Neurontin is discontinued and/or an alternate anticonvulsant medication is added to the therapy, this should be done gradually over a minimum of 1 week.

Dosage in Renal Impairment

Creatinine clearance is difficult to measure in outpatients. In patients with stable renal function, creatinine clearance (C_{Cr}) can be reasonably well estimated using the equation of Cockcroft and Gault:

$$\begin{aligned} &\text{for females } C_{Cr} = (0.85)(140 - \text{age})(\text{weight}) / [(72)(S_{Cr})] \\ &\text{for males } C_{Cr} = (140 - \text{age})(\text{weight}) / [(72)(S_{Cr})] \end{aligned}$$

where age is in years, weight is in kilograms and S_{Cr} is serum creatinine in mg/dL.

Dosage adjustment in patients ≥ 12 years of age with compromised renal function or undergoing hemodialysis is recommended as follows (see dosing recommendations above for effective doses in each indication).

TABLE 6. Neurontin® Dosage Based on Renal Function

Renal Function Creatinine Clearance (mL/min)	Total Daily Dose Range (mg/day)	Dose Regimen (mg)				
≥ 60	900-3600	300 TID	400 TID	600 TID	800 TID	1200 TID
>30-59	400-1400	200 BID	300 BID	400 BID	500 BID	700 BID
>15-29	200-700	200 QD	300 QD	400 QD	500 QD	700 QD
15 ^a	100-300	100 QD	125 QD	150 QD	200 QD	300 QD

Post-Hemodialysis Supplemental Dose (mg)^b

Hemodialysis	125 ^b	150 ^b	200 ^b	250 ^b	350 ^b
--------------	------------------	------------------	------------------	------------------	------------------

^a For patients with creatinine clearance < 15 mL/min, reduce daily dose in proportion to creatinine clearance (e.g., patients with a creatinine clearance of 7.5 mL/min should receive one-half the daily dose that patients with a creatinine clearance of 15 mL/min receive).

^b Patients on hemodialysis should receive maintenance doses based on estimates of creatinine clearance as indicated in the upper portion of the table and a supplemental post-hemodialysis dose administered after each 4 hours of hemodialysis as indicated in the lower portion of the table.

The use of Neurontin in patients < 12 years of age with compromised renal function has not been studied.

Dosage in Elderly

Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and dose should be adjusted based on creatinine clearance values in these patients.

HOW SUPPLIED

Neurontin (gabapentin) capsules, tablets and oral solution are supplied as follows:

100 mg capsules;

White hard gelatin capsules printed with “PD” on one side and “Neurontin/100 mg” on the other; available in:

Bottles of 100: N 0071-0803-24

Unit dose 50’s: N 0071-0803-40

300 mg capsules;

Yellow hard gelatin capsules printed with “PD” on one side and “Neurontin/300 mg” on the other; available in:

Bottles of 100: N 0071-0805-24

Unit dose 50’s: N 0071-0805-40

400 mg capsules;

Orange hard gelatin capsules printed with “PD” on one side and “Neurontin/400 mg” on the other; available in:

Bottles of 100: N 0071-0806-24

Unit dose 50’s: N 0071-0806-40

600 mg tablets;

White elliptical film-coated scored tablets debossed with “NT” and “16” on one side; available in:

Bottles of 100: N 0071-0513-24

800 mg tablets;

White elliptical film-coated scored tablets debossed with “NT” and “26” on one side; available in:

Bottles of 100: N 0071-0401-24

250 mg/5 mL oral solution;

Clear colorless to slightly yellow solution; each 5 mL of oral solution contains 250 mg of gabapentin; available in:
Bottles containing 470 mL: N0071-2012-23

Storage (Capsules)

Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature].

Storage (Tablets)

Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature].

Storage (Oral Solution)

Store refrigerated, 2°-8°C (36°-46°F)

Rx only

Distributed by: _____

A Parke-Davis

Division of Pfizer Inc, NY, NY 10017

LAB-0106-9.1

Revised April 2009

Exhibit F



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF STEELTON

SAM SHIELDS;

Plaintiff,

GD No.: 15-008771

v.

DR. CHRIS CONDON, M.D.;

Defendant.

JURY INSTRUCTIONS

BELIEVABILITY OF WITNESSES GENERALLY

As judges of the facts, you decide the believability of the witnesses' testimony. This means that you decide the truthfulness and accuracy of each witness's testimony and decide whether to believe all, or part, or none of that witness's testimony. The following are some of the factors that you may and should consider when determining the believability of the witnesses and their testimony:

- a. How well could each witness see, hear or know the things about which he or she testified?
- b. How well could the witness remember and describe those things?
- c. Was the ability of the witness to see, hear, know, remember, or describe those things affected by age or by any physical, mental or intellectual deficiency?
- d. Did the witness testify in a convincing manner? How did the witness look, act and speak while testifying?
- e. Was the testimony uncertain, confused, self- contradictory or presented in an evasive manner?
- f. Did the witness have any interest in the outcome of the

case, or any bias, or any prejudice, or any other motive that might have affected his or her testimony?

g. Was a witness's testimony contradicted or supported by other witnesses' testimony or other evidence?

h. Does the testimony make sense to you?

i. If you believe some part of the testimony of a witness to be inaccurate, consider whether that inaccuracy cast doubt upon the rest of that same witness's testimony. This may depend on whether the inaccuracy is in an important matter or in a minor detail.

j. You should also consider any possible explanation for the inaccuracy. Did the witness make an honest mistake or simply forget, or was there a deliberate attempt to present false testimony?

k. If you find that a witness intentionally lied about a significant fact that may affect the outcome of the trial, you may, for that reason alone, choose to disbelieve the rest of that witness's testimony. But, you are not required to do so.

l. As you decide the believability of each witness's testimony, you will at the same time decide the believability of other witnesses and other evidence in the case.

m. If there is a conflict in the testimony, you must decide which, if any, testimony you believe is true.

As the only judges of believability and facts in this case, you, the jurors, are responsible to give the testimony of every witness, and all the other evidence, whatever credibility and weight you think it is entitled to receive.

EXPERT TESTIMONY

During the trial you have heard testimony from both *fact* witnesses and *expert* witnesses. To assist juries in deciding cases such as this one, involving scientific, technical or other specialized knowledge beyond that possessed by a layperson, the law allows an expert witness with special education and experience to present opinion testimony.

An expert witness gives his or her *opinion*, to a reasonable degree of professional certainty, based upon the assumption of certain facts. You do not have to accept an expert's opinion just because he or she is considered an expert in his or her field.

In evaluating an expert witness's testimony and in resolving any conflicting expert witness's testimony, you should consider the following:

- a. The witness's knowledge, skill, experience, training and education;
- b. Whether you find that the facts the witness relied upon in reaching his or her opinion are accurate; and,
- c. All the believability factors I have given to you.

EXPERT OPINION – BASIS FOR OPINION GENERALLY

In general, the opinion of an expert has value only when you accept the facts upon which it is based. This is true whether the facts are assumed hypothetically by the expert, or they come from the expert's personal knowledge, from some other proper source, or from some combination of these.

WEIGHING CONFLICTING EXPERT TESTIMONY

In resolving any conflict that may exist in the testimony of expert witnesses, you are entitled to weigh the opinion of one expert against that of another. In doing this, you should consider the relative qualifications and reliability of the expert witnesses, as well as the reasons for each opinion and the facts and other matters upon which it was based.

CONFLICTING TESTIMONY

You may find inconsistencies *within* the testimony of a single witness, or conflicts *between* the testimony of several witnesses. Conflicts or inconsistencies do not necessarily mean that a witness intentionally lied. Sometimes two or more persons witnessing the

same incident see, hear, or remember it differently. Sometimes a witness remembers incorrectly or forgets. If the testimony of a witness seems inconsistent within itself, or if the testimony given by several witnesses conflicts, you should try to *reconcile* the differences. If you cannot reconcile the differences, you must then decide which testimony, if any, you believe.

DIRECT AND CIRCUMSTANTIAL EVIDENCE

The evidence presented to you may be either *direct* or *circumstantial evidence*. *Direct evidence* is testimony about what a witness personally saw, heard, or did. *Circumstantial evidence* is testimony about one or more facts that logically leads you to believe the truth of another fact. You should consider both *direct* and *circumstantial* evidence in reaching your verdict. You may decide the facts in this case based upon circumstantial evidence alone.

NEGLIGENCE – DEFINITION

In this case you must decide whether the Defendant was negligent. I will now explain what negligence is. A person must act in a reasonably careful manner to avoid injuring others. The care required varies according to the circumstances and the degree of danger at a particular time. You must decide how a reasonably careful person would act under the circumstances established by the evidence in this case. A person who does something a reasonably careful person would not do under the circumstances is negligent. A person also can be negligent by failing to act. A person who fails to do something a reasonably careful person would do under the circumstances is negligent.

ISSUE IN THE CASE

The issues you must decide, in accordance with the law as I give it to you, are:

1. Was Dr. Condon negligent?
2. Was Dr. Condon's negligent conduct a factual cause in bringing about the harm to Sam Shields?

BURDEN OF PROOF

In civil cases, the Plaintiff has the burden of proving his claims.

The Plaintiff must prove his or her claims by a legal standard called "a preponderance of the evidence." Preponderance of the evidence means the claim is more likely true than not.

If, after considering all the evidence, you find the Plaintiff's claims are more likely true than not, you must find for the Plaintiff.

Think about an ordinary balance scale with a pan on each side to hold objects. Imagine using the scale as you deliberate in the jury room. Place all the evidence favorable to the Plaintiff in one pan. Place all evidence favorable to the Defendant in the other. If the scales tip, even slightly, to the Plaintiff's side, then, you must find for the Plaintiff. If, however, the scales tip even slightly on the Defendant's side, or if the two sides balance, then you must find for the Defendant.

In this case, the Plaintiff has the burden of proving the following claims:

- a. The Defendant was negligent; and,
- b. The Defendant's negligence was a factual cause in bringing about the harms/damages.

FACTUAL CAUSE

In order for Plaintiff to recover in this case, Defendant's negligent conduct must have been a factual cause in bringing about harm. Conduct is a factual cause of harm

when the harm would not have occurred absent the conduct. To be a factual cause, the conduct must have been an actual, real factor in causing the harm, even if the result is unusual or unexpected. A factual cause cannot be an imaginary or fanciful factor having no connection or only an insignificant connection with the harm.

To be a factual cause, Defendant's conduct need not be the only factual cause. The fact that some other causes concur with the negligence of the Defendant in producing an injury does not relieve the defendant from liability as long as his or her own negligence is a factual cause of the injury.

CONCURRING CAUSES

Sometimes a person's negligent conduct combines with other people's conduct to cause harm.

When a defendant's negligent conduct combines with the conduct of other persons, the defendant is legally responsible if his or her negligent conduct was one of the factual causes of the harm.

In such a case, Defendant is fully responsible for the harm suffered by Plaintiff regardless of the extent to which Defendant's conduct contributed to the harm.

COMPARATIVE NEGLIGENCE

Defendant claims that Plaintiff was negligent and Plaintiff's negligence was a factual cause of Plaintiff's injury. Defendant has the burden of proving by a fair preponderance of the evidence that Plaintiff was negligent and that the Plaintiff's negligence was a factual cause of the plaintiff's harm. Plaintiff does not have the burden to prove he was *not* negligent. The burden is not on Plaintiff to prove his or her freedom

from negligence. You must determine whether Defendant has proven that Plaintiff, under all the circumstances, failed to use reasonable care for his or her own protection.

VIOLATION OF STATUTE - NEGLIGENCE PER SE

The law provides that Dr. Condon is obligated to follow and abide by certain state and federal regulations pertaining to patient care Dr. Condon must provide. The statute at issue requires Dr. Condon to act as follows:

A. 75 Steelton Statutes § 5.71

In addition to use by the Department of Transportation, these physical and mental criteria shall be used by physicians, chiropractors, CRNPs and physician assistants in conducting physical examinations of applicants for learner's permits and driver's licenses and by physicians and other persons authorized to diagnose and treat disorders and disabilities covered in this chapter in determining whether a person examined by the provider should be reported to the Department as having a disorder affecting the ability of the person to drive safely.

B. 75 Steelton Statutes § 5.81

Seizure—A paroxysmal disruption of cerebral function characterized by altered consciousness, altered motor activity or behavior identified by a licensed physician as inappropriate for the individual.

Seizure disorder—Condition in which an individual has experienced a single seizure of electrically diagnosed epilepsy, or has experienced more than one seizure not including seizures resulting from an acute illness, intoxication, metabolic disorder, or trauma.

C. 75 Steelton Statutes § 5.87

A person who has a seizure disorder will not be qualified to drive unless a licensed physician reports that the person has been free from seizure for at least six (6) months immediately preceding, with or without medication. A person will not be disqualified if the person has experienced only auras during that period. Every provider who treats a person who has experienced a single seizure shall provide a report to the Department of Transportation which shall constitute cause for the Department of Transportation to immediately suspend that individual's drivers' license until the person is able to undergo an examination prescribed and conducted by a Department of

Transportation physician.

Sam Shields claims that Dr. Condon violated these statutes. If you find that Dr. Condon violated these statutes, you must find that Dr. Condon was negligent.

If you find that Dr. Condon did not violate these statutes, then you must still decide whether Dr. Condon was negligent because Dr. Condon failed to act as a reasonably careful person would under the circumstances established by the evidence in this case.

DEPOSITION TESTIMONY

The testimony of a witness, who for some proper reason cannot be present to testify in person, may be presented in this form. Such testimony is given under oath and in the presence of attorneys for the parties, who question the witness. A court reporter takes down everything that is said and then transcribes the testimony. The use of videotape permits you to see and hear the witness as he appeared and testified under questioning by counsel. This form of testimony is entitled to neither more nor less consideration by the jury because of the manner of its submission.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF STEELTON

SAM SHIELDS;

Plaintiff,

GD No.: 16-008771

v.

CHRIS CONDON, MD;

Defendant.

VERDICT FORM

You must decide whether any party was negligent and whether that negligence was a factual cause of injury.

I will now read you the questions on the verdict form that you must answer to arrive at a proper verdict:

Question 1:

Was Chris Condon, MD negligent? Please answer:

Yes___ No___

If you answer Question 1 "Yes," go to Question 2.

If you answer Question 1 "No," Sam Shields cannot recover and you should not answer any further questions. Tell the court officer you have reached a verdict.

Question 2:

Was the negligence of Chris Condon, MD a factual cause of any harm to Sam Shields?

Yes___ No___

If you answer Question 2 "Yes," go to Question 3.

If you answer Question 2 "No," Sam Shields cannot recover and you should not answer any further questions. Please tell the court officer you have reached a verdict.

Question 3:

Was Sam Shields negligent?

Yes___ No___

If you answer Question 3 “Yes,” go to Question 4.

If you answer Question 3 “No,” go to Question 6.

Question 4:

Was Sam Shields’s negligence a factual cause of any harm to Sam Shields?

Yes___ No___

If you answer Question 4 “Yes,” go to Question 5.

If you answer Question 4 “No,” go to Question 6.

Question 5:

Taking the combined negligence that was a factual cause of any harm to Sam Shields as 100 percent, what percentage of that negligence do you attribute to Sam Shields and what percentage do you attribute to Chris Condon, MD?

Percentage of negligence attributable to Sam Shields: _____%

Percentage of negligence attributable to Chris Condon, MD: _____%

Total 100%

If you have found Sam Shields’s percentage is greater than 50 percent, Sam Shields cannot recover and you should not answer any other questions. Please tell the court officer you have reached a verdict.