

FINAL EXAM

Instructions

DO NOT GO BEYOND THIS PAGE UNTIL THE EXAM ACTUALLY BEGINS.

THIS IS A CLOSED BOOK EXAM.

Follow the instructions from the proctor.

This exam will last 2 HOURS. Before turning in your answer, REREAD each question to be sure you haven't missed anything.

DOUBLE-SPACE your answers in the blue-book.

You are welcome to use abbreviations, but indicate what they are, *e.g.*, "Andropov (A) would sue Brezhnev (B). B may be liable to A because"

Plan on spending at least 10 minutes at the end **PROOFREADING** your answers. You may not write **ANOTHER WORD** after time is called.

Each question has been assigned a point total, and the exam as a whole has a point total of 105. Spend the amount of time on each question reflecting its relative worth.

REMEMBER THE HONOR CODE: DO NOT DO THINGS THAT TEND TO IDENTIFY YOURSELF.

GOOD LUCK!

Question 1 (55 points)

In 2002 Willis Ray McPhail, a farmer in Iowa County, Evergreen, purchased a used 1981 Deere 4440 tractor at an auction. On the morning of his death, in June 2006, the tractor would not start, due to a malfunction in its starting circuitry. Because of the urgency of getting the hay crop in, Mr. McPhail decided to bypass start the tractor as a stopgap measure; the alternative was to lose the crop. Mr. McPhail was not the first farmer to do this; significant numbers of farmers have resorted to bypass starting when the starting circuitry on their tractors failed. When a tractor's starting circuitry becomes inoperative, the tractor can still be started if the user creates a new electrical circuit that bypasses any failures in the normal circuitry. To effectuate a bypass start, the user stands on the ground near the engine and lays a screwdriver across the electrical terminals on the starter and the solenoid to close the circuit necessary for engine ignition. Mr. McPhail did this twice that morning. On his first attempt, the tractor started successfully, in neutral, but the front-end loader would not work. Mr. McPhail turned off the tractor and attempted to fix the front-end loader. Then, standing between the front and rear wheels on one side of the tractor, he attempted a second bypass start. This time, according to his employee Darrel Coffelt, the transmission engaged and the tractor suddenly lurched backward at high speed, running over Mr. McPhail. He died from the injuries later that day.

Mr. McPhail's tractor was designed with a neutral-start switch, which prevents engine ignition if the transmission is in gear. But because this switch is part of the tractor's normal starting circuitry, bypass starting the tractor also bypasses this safety mechanism. Thus, nothing in the design of the tractor protects users from the unexpected movement of the tractor if it is bypass started while in gear. In the 1970s and 1980s, Deere became aware that farmers were bypass starting their tractors, that tractors started in gear were also prone to sudden movement, and that this was leading to accidents. In response, for models manufactured after 1984, Deere began using an "Engagement Override Valve," which prevents the transmission from engaging, even if the tractor is in gear, unless the tractor's operator cycles the clutch or manually returns the tractor to neutral. For older models, Deere undertook a safety campaign, starting in 1991, to warn users of the dangers of bypass starting.

Deere first identified all of the pre-1984 models whose transmission could engage when the tractor is bypass started. For these tractors, Deere attempted to contact all known owners to educate them on the dangers of bypass starting and to install a safety kit on their tractors. The safety kits included a plastic cover for the tractor's solenoid to prevent the operator from accessing the terminals used in bypass starting, and a warning sticker to affix near the solenoid cover. The sticker is a vibrant red and contains the following words: "**DANGER**" and "**Start only from seat in park or neutral. Starting in gear kills.**" The warning also contains two cautionary depictions. One illustration, contained within a prohibitory red circle with a slash through it, shows a screwdriver being placed over a solenoid terminal. The second image depicts a person standing on the ground near the tractor and being run over because the tractor is moving forward.

It is undisputed that this warning was present on Mr. McPhail's tractor on the morning of the accident. However, there is no evidence that a Deere representative contacted Mr. McPhail, rather than a previous owner, as part of the education component of the campaign. There were remnants of the solenoid cover in place, suggesting it had been installed at some point. But it had been broken off prior to the accident and nothing in the record indicates whether the cover was present when Mr.

McPhail bought the tractor at auction.

Two other features of the Deere 4440 are important. First, it employs a Quad-Range Transmission (QRT), which functions via a hydraulic (or "wet") clutch. When a tractor with a QRT is started, hydraulic pressure must build up within the clutch before the tractor will move, whether or not the tractor is in gear. Because of this, the tractor's engine will act as if it is in neutral for a short interval after it is started, even if it is in gear. Once the hydraulic pressure is adequate to engage the transmission, the tractor will suddenly move under full power. This is in contrast to the behavior of a manual (or "dry") clutch. If a tractor with a "dry" clutch is started while the tractor is in gear, the transmission is engaged during engine ignition. The tractor will begin to move immediately but, because the engine has not fully started, the movement is less powerful.

A second significant feature, as explained by one of Mr. McPhail's expert witnesses, is that "[t]he 'Quad-Range' transmission controls provide 'false' or 'apparent' neutral positions which can cause the operator to believe the tractor is in neutral, when it is not. The control system does not provide a positive visual or tactile indication of a true neutral position." In other words, the gear shift on this model of tractor may appear to be in neutral when in fact the tractor is in gear.

According to this same expert, the behavior of the Quad-Range Transmission masks whether the tractor is in gear. The gear selector for this model tractor could appear to be in neutral when the tractor was actually in gear. These characteristics of the tractor give rise to the inference that even an operator who takes care to ensure that the tractor is in neutral cannot be sure that unexpected movement will not occur. Mr. Coffelt testified that, after the accident, the tractor was traveling in reverse at "a pretty good rate of speed" and that he "couldn't believe it, it was going backwards instead of forwards."

The sticker affixed to Mr. McPhail's tractor warned: "**Danger. Start only from seat in park or neutral. Starting in gear kills.**" This informs a tractor's operator of the potentially lethal consequences of bypass starting a tractor in gear. However, it may also suggest that starting the tractor in neutral or park eliminates that danger. While the warning contains cautionary depictions regarding bypass starting generally and tractor motion caused by bypass starting, the warning does not caution against the possibility that even a tractor that appears to be in neutral or park may move under engine power. Indeed, by stating that "starting in gear kills," it tends to suggest that if the user is sufficiently careful in ensuring that the tractor is in park or neutral, all will be well.

You represent Mrs. McPhail, the widow of Willis McPhail. Assume that the damages would be assessed at \$1 million. Please assess her prospects for a recovery based upon product liability.

Question 2 (50 points)

You represent Dawn Porter. Dawn's husband, Leland "Lee" Porter called the office of Dr. Bernard B. Wolfberg, a physician board certified in psychiatry, on July 2, 2007, to seek an appointment. He complained generally of anxiety. Mr. Porter then met in person with Dr. Wolfberg for approximately 40 minutes on July 15, 2007, for an initial consultation. Based on this meeting, Dr. Wolfberg prescribed Prozac to Mr. Porter and advised him to come back for a follow-up visit in four weeks. Mr. Porter committed suicide on July 26, 2007, less than two weeks after beginning to take Prozac. Prozac is manufactured by Eli Lilly & Company (Lilly).

At his deposition Dr. Wolfberg testified that he generally engages in a risk-benefit analysis of a drug when prescribing it to a patient. This means he informs the patient of why he thinks the medication will be helpful and then explains any side effects that have been reported and the patient chooses whether to take the medication. However, he does not explain every potential serious side effect regardless of frequency because if he did, most patients would choose not to take the medication. Dr. Wolfberg testified that based on his experience prescribing Prozac, he felt he was familiar with the drug's risks and benefits.

Regarding his understanding of the risks associated with Prozac, he further testified:

Q: Up through and including today, have you read any literature that discusses whether SSRI's¹ may have a role in worsening depression or the emergence of suicidality in adult populations?

A: I just said I didn't think that it had. I don't remember any specific articles about that, to tell you the truth.

....

Q: Do you recall as you sit here today what the label for Prozac said in July of 2007 about the risk for suicide or suicidalities?

A: I do not recall.

Q: When did you first become aware of the concerns about suicidality and SSRI's in any particular patient group?

A: In the last year or two.

Q: And I know you don't treat children-

A: Correct.

Q:-or adolescents. So you weren't aware of any of the discussions or any of the literature or any publications that were discussing this issue throughout the nineties or early 2000?

A: I didn't pay attention, no.

....

Q: So I guess I'm unclear then because I think it's fair to say that the question of Prozac or SSRI-induced suicidality is not a new one, and it's been in the literature for a little while, in the nineties and two thousands.

And you didn't read any of that?

A: Originally, I remember Prozac, there were some lawsuits against Prozac by the Scientologists, and they were dismissed. And the literature at that time said there was really no connection between suicide and Prozac. And since then anything that's come up, there's nothing-nothing I've read that I can remember that made me believe that there was an increase in suicide, suicidality with Prozac in adults.

....

Q: Have you ever heard any reference to a small vulnerable subpopulation of people

¹Selective serotonin reuptake inhibitors (SSRIs) describe a class of antidepressants including Prozac, Paxil, and Zoloft, among others.

that may be at particular risk for increased suicidality as a result of the use of an SSRI?

A: Beyond children and adolescents?

Q: Beyond children.

A: I don't remember that.

....

Q: Are you aware of the various public health advisories that have been issued regarding the same topic of SSRI-induced suicide, not only in children, but also in the adult population, that has been issued by the FDA in 2009?

A: No, I'm not aware of that.

Q: So, I guess, to be clear on this, in 2007 were you aware of concerns about a link between Prozac and suicidality in adult population?

A: With OCD [obsessive compulsive disorder]?

Q: In general.

A: No, I wasn't.

Q: What about for major depressive disorder?

A: I don't know if I was or not.

Q: Okay. Fair enough. Anxiety?

A: I wasn't aware of that.

Regarding his practice of prescribing Prozac, he testified:

Q: Is there anything about your prescribing practice for Prozac that has changed between July of 2007 and the present?

A: No.

Q: Has the information that you provide a patient when you counsel them regarding Prozac at the time you prescribe it, has that information changed since July of 2007?

A: No.

Q: Do you believe that if you were to counsel a patient now who you were initiating on 20 milligrams of Prozac daily that your counseling would be similar to the counseling you would have provided Lee Porter back in July of 2007?

A: Yes, I think so.

He further testified:

Q: Based on the having read the 2009 PDR [Physicians Desk Reference] version of the Prozac package insert, is there anything in that package insert that makes you believe if you had read that same information in July of 2007, you would have decided to not prescribe Prozac for Lee Porter?

A: No. There's nothing there that would have made me not prescribe Prozac for Lee Porter.

....

Q: Sitting here today, January 12th, 2009, knowing that Lee Porter ultimately took his own life, do you still consider your decision to prescribe Prozac for him on July

15th, 2007, to be an appropriate decision?

A: Yes.

Dr. Wolfberg also testified that he carefully considered so-called "black box" warnings on prescription drugs but would still continue to prescribe the drug for patients depending on the nature of the problem. He would be more concerned about the risk if it occurred in more than one out of a thousand patients. It would be important to him if the number was one in fifty. He further stated:

Q: And, I guess, let me be specific then, in fairness. If there was a black box warning that said there's been an identified association between some type of medication and suicide or increased suicidal thoughts or suicidality, would you warn your patients about that?

A: If they had-if that-if that warning was specific to the diagnosis that they had, yes.

Q: And what if it was a generalized type warning, that we've identified this issue with the use of these medications as a class, let's say? Would your answer be the same?

A: No.

With respect to his specific treatment of Mr. Porter, Dr. Wolfberg testified:

Q: Doctor, in looking back at your treatment of Lee Porter in July of 2007, sitting here today knowing that he did go on to commit suicide, do you still consider your treatment to have been appropriate?

A: Yes.

Q: In looking back at your treatment of Lee and your notes for Lee and knowing that he ultimately committed suicide in late July of 2007, is there anything that you believe you would do now differently than you had done then?

A: Well, if I forecast-you mean if I-I don't understand the question.

Q: Sure. I recognize that you couldn't have seen into the future that he committed suicide and that you can't go back and redo anything.

But I'm just wondering if, based on what you know today in terms of your additional training and experience that you've received since Lee was a patient of yours, if there's anything that you, looking back today, believe you would have done differently than you did back in July of 2007?

A: Not being-not foretelling the future, no, not-I know he committed suicide now. But at the time, if I didn't know he was going to commit suicide, I would have done the exact same thing. If I knew he was going to commit suicide, I would put him in the hospital that minute.

Q: Right. But, of course, he didn't ever tell you-

A: Never told me.

Q: He never reported to you that he had any suicidal thoughts .

A: None.

Q: And he never reported to you that he had any suicidal plans.

A: None.

Q: And if he had, you would have taken different action.

A: Correct.

Q: On July 15th of 2007, did you consider Lee Porter to be at risk for suicide?

A: No.

Q: If there had been a warning back in July of 2007 regarding SSRI's or Prozac and suicide, would you have considered Lee to be at risk for-such that that warning would apply in your risk-benefit analysis for prescribing Prozac for Lee?

A: Are you saying the warning is for obsessive-compulsive disorder or are you saying that warning is for major depressive disorder?

Q: Just for the use of the medication in general.

A: Is there such a warning?

Q: I'm not asking about a particular warning now. But if there had been such a warning then, can you-maybe a better way for me to ask you this question is: Sitting here-well, let me back up.

There's a statement in the prescribing information for Prozac now that says: There's been a longstanding concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients.

And first let me just ask you: Over the years have you read or heard that there may be some concern about antidepressants having a role in inducing the worsening of depression and the emergence of suicidality in certain patients?

A: In certain patients, I think so.

Q: And would that statement, if you had read it back in July of 2007, have caused you to decide not to prescribe Prozac for Lee Porter?

A: No. It would not have prevented me from prescribing it.

Q: In other words, you had evaluated Lee Porter specifically for suicidality; correct?

A: Correct.

Q: And determined that he wasn't suicidal?

A: Correct.

Q: And then you had intended to follow up with him four weeks later; correct?

A: Correct.

At the time Prozac was prescribed to Mr. Porter in 2007, the package insert for Prozac contained the following warning:

Suicide-The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy.... Because of well-established comorbidity between [obsessive compulsive disorder] and depression ..., the same precautions observed when treating patients with depression should be observed when treating patients with OCD....

A physician expert that Dawn has consulted, Dr. Joseph Glenmullen, stated in his expert report that "[s]ince Lee's death, in recent years, the [Food & Drug Administration] and pharmaceutical industry have warned doctors and the public that antidepressants may make patients suicidal, especially in the period shortly after starting the drugs." The Food & Drug Administration warnings recommend

that patients who are started on antidepressant therapy should be observed for unusual changes in behavior. The Food & Drug Administration notes that such side effects could include: "anxiety, agitation, panic attacks, insomnia, irritability, hostility, akathisia (severe restlessness), hypomania, and mania." The current Prozac warnings describe these side effects. There is some evidence that in December 2008, two scientists employed by Lilly, working with a group from Harvard University, concluded that there is a "small vulnerable subpopulation" of patients who are at risk for Prozac-induced suicidality.

Please evaluate Dawn's prospects for a product liability claim against Lilly. Assume that if she were able to recover her damages would be \$1 million.