Klick
Torts
The Armageddon
December 9, 2019

This exam is open book, open notes, open commercial outlines, etc. Each of the 2 questions is potentially worth the same fraction of the total score, subject to your decision for item #3. You have 4 hours to complete this exam using the law school's test taking software. Remember, you are all above average on some distribution . . . unfortunately, that can't be true on this particular one. Good luck.

1. Argue both for and against the following propositions:
    a. Entities should not be legally allowed to buy insurance against punitive damages.

For: One purpose of tort law is to induce socially efficient behavior. Generally, this is done by getting potential defendants to internalize the external effects of their behavior by setting damages equal to the external costs of a defendant's behavior. In this way, the defendant's expected costs become equivalent to society's expected costs. Punitive damages (can) serve as a damages multiplier in instances where cases are unlikely to be successfully brought even though the underlying actions of the defendant generate external costs to society (difficult to bring case; plaintiff may not always be able to identify the correct defendant; etc). By setting the damages multiplier equal to the reciprocal of the likelihood a successful case will be brought, the defendant faces to true expected social costs of his actions, which is necessary to induce efficient behavior. If the defendant is insured for the cost of punitive damages, this internalization might not take place since the defendant will not pay the punitive damages, leading to inefficient outcomes (too much risky behavior on the part of a defendant; not enough precautions taken). From a non-efficiency perspective, if punitive damages are used to punish morally blameworthy behavior, insurance seemingly undercuts that punishment function.

Against: Insurers presumably have an incentive to screen and monitor their customers. The screening function likely would lead them to not sell insurance to serial bad actors (or particularly egregious bad actors) and so the worst potential offenders likely wouldn't have insurance anyway. In any event, to remain solvent, insurers must charge premiums equal to their payouts and, so, any customer presumably does face the costs of his actions even if insured (the channel is simply through higher insurance premiums as opposed to higher damages paid). Thus, it is not likely that the efficiency effects of tort would be un-done through insurance that covers punitive damages (or any insurance, really). Further, insurers may be in a better position to develop and implement risk management strategies than individual (potential) defendants themselves due to having more data/experience, leading to even more efficient outcomes. Insurance may also reduce the likelihood that a defendant is judgement proof which might improve efficiency (since a defendant who can't pay damages won't be deterred by the prospect of larger damages).

b. Because individuals rarely buy insurance for non-economic damages (e.g., pain and suffering, loss of consortium, life insurance for non-incoming producing loved ones, etc.), tort law should not allow for these kinds of damages either.

For: If individuals choose to not insure for certain kinds of losses, it might be an indication that these losses are non-compensable (i.e., money does not have the effect of putting the person suffering the loss back in her original position utility-wise). If tort is about compensation, but these losses are (by the victim's own evaluation) non-compensable, it makes little sense to include these losses in damage calculations. Further, in contexts where liability costs are capitalized into prices (perhaps products liability), prices represent a forced bundle of the product and an implicit insurance policy. If individuals are unwilling to purchase a stand alone insurance policy for certain kinds of damages, it implies they value the insurance less than its cost (perhaps even value the insurance as being worth 0). Therefore, when such an individual buys a product with a bundled insurance policy (covering these kinds of damages), he will be subjectively worse off than he would have been had he been able to purchase the product without the bundled implicit insurance policy. Further, there will be some individuals who valued the product at an amount above the price of the product alone, but not above the price of the product when it includes the bundled insurance policy. These individuals will not purchase the product at all, lowering their utility (relative to where they would have been if they had been able to buy the product sans implicit insurance).

Against: These kinds of damages do represent utility losses (even if there are losses that cannot be compensated with money damages) and failing to include them in damages will result in a failure of the potential tortfeasor to internalize all social costs of her behavior. This will lead to the tortfeasor engaging in excessively risky behavior or investing too little in precautions (relative to the social optimum).

c. The availability of private liability insurance necessarily lessens the incentive/efficiency benefits of tort law.

For: Moral hazard is a standard concern when it comes to any kind of insurance. Moral hazard concerns instances where individuals do not engage in socially cost justified precautions (perhaps including the precaution of not engaging in risky behavior to begin with) because they do not bear the loss associated with their risky activities. Relative to an optimal tort system without insurance, insured tortfeasors will face worse incentives, leading to efficiency losses.

Against: Similar to the answer in 1.a above, insurance premiums will equal expected losses. Thus, if individuals engage in riskier activities, their premiums will increase by the same amount we would expect expected tort damages to increase, presumably leading to similar ultimate behavior. Further, the insurer (due to data or experience advantages) may be able to provide its customers with superior risk management advice (and incentives to follow the advice) than the customer could have developed on his own. Also, insurance may mitigate the problems that come with judgment proof defendants (who are largely immune to the deterrence effects of the tort system), leading to efficiency improvements.

2. In the 2010 Texas Supreme Court case Merck v. Garza, the court presented the facts as follows:

"Leonel Garza had a long history of heart disease. Twenty years before his death at age 71, [the Hispanic man] suffered a heart attack and four years later underwent quadruple bypass surgery to alleviate blockages in four of his coronary arteries. In the years that followed, he had one cardiac catheterization procedure that revealed additional blockages in three arteries, followed by a second such procedure that revealed severe recurrent coronary artery disease. He had a stent placed in his left main artery to increase the blood flow into his heart, but two years later was diagnosed with atherosclerotic obstructive disease and chronic venous insufficiency in his legs. He was also diagnosed with an abdominal aortic aneurysm.

Twenty-five days before his death, Garza complained to his cardiologist, Dr. Michael Evans, of intermittent numbness, pain, and weakness in his left arm. After determining that Garza was not having a heart attack, Evans ordered an ultrasound of Garza's neck to check the circulation to his brain and a stress test to check the circulation to his heart. Evans also gave him a week's supply of 25 mg Vioxx for pain relief and scheduled a follow-up visit eight days later.

When Garza returned for his appointment, Evans was out of town, and one of his partners, Dr. Juan Posada, reviewed Garza's test results with him and his wife. The stress test revealed that Garza had a stable cardiac status, and Posada noted in Garza's record that he thought Garza was on optimal medical management. However, the test did reveal some small areas of apical ischemia, meaning that a part of the tip of Garza's heart was not getting enough blood when stressed. Posada offered the possibility of a cardiac catherization to more fully investigate the cause of the apical ischemia, but Garza declined, opting to discuss the results with Evans a month later. According to Mrs. Garza, Posada gave her husband thirty additional 25 mg Vioxx pills. Seventeen days later, on April 21, 2001, Garza died while alone at his ranch near Rio Grande City, Texas. The autopsy found that the immediate cause of death was a "probable myocardial infarction" initiated at least in part by the underlying cause of "severe coronary artery disease".

Garza's statutory beneficiaries ("the Garzas") sued Merck & Co., Inc., the manufacturer of Vioxx, for products liability, alleging that the drug was defective as designed and as marketed with inadequate warnings. Merck repeatedly challenged the scientific reliability of the Garzas' evidence offered to prove that Vioxx caused Garza's death. The trial court overruled Merck's objections. The jury returned a verdict for the Garzas, awarding $7 million dollars actual damages, plus $25 million dollars in punitive damages, which the trial court reduced to the applicable statutory maximum of $750,000. Merck appealed.

The court of appeals held that the Garzas could not recover on their design-defect claim because they did not present sufficient evidence of a safer alternative design, but that they could recover on their inadequate-warning claim." Merck appealed the recovery on the inadequate warning claim to the Texas Supreme Court.

Texas has a "Daubert-like" expert evidence standard through the *Havner* case which adds the following guidance with respect to causation when using epidemiological evidence: 1) plaintiffs must provide two independent epidemiological studies that 2) show a statistically significant

increase in the outcome at issue (so, in this case, a heart attack) for individuals taking the medication (in this case, Vioxx) at the same dose (in this case, 25 mg) and for the same duration as the plaintiff, and 3) this increase more than doubles the risk of the plaintiff's outcome. For the purposes of this question, outside of this additional guidance, assume that Texas follows the same standards as Daubert and Joiner when determining whether a trial judge can/must admit an expert's testimony.

The Garzas' medical expert relied on Merck's VIGOR study. The VIGOR study was commissioned to support Merck's FDA application to gain approval to use Vioxx to treat rheumatoid arthritis. The VIGOR clinical trial was (according to the Texas Supreme Court) "designed to compare the occurrence of [gastrointestinal] toxicity [among Vioxx users compared to those using] Naproxen, a non-selective NSAID.[1] In addition to finding a gastrointestinal benefit, VIGOR also revealed a secondary finding that patients taking Vioxx had five times the relative risk of adverse cardiovascular events as patients who took Naproxen." Also, the published study indicates that the effect is statistically significant at the conventional 5 percent level.

The sample of the VIGOR study included over 8,000 subjects, with an average age of 58. Eighty percent of the sample was female, and 12.5 percent of the sample was Hispanic. More than 80 percent of the sample had reported previously using NSAIDs regularly. In reaching the study sample, candidates were screened as follows: "Patients with rheumatoid arthritis who were at least 50 years old (or at least 40 years old and receiving long-term glucocorticoid therapy) and who were expected to require NSAIDs for at least one year were eligible. Patients were excluded if they had a history of another type of inflammatory arthritis, upper gastrointestinal surgery, or inflammatory bowel disease; an estimated creatinine clearance of 30 ml or less per minute; a positive test for fecal occult blood (this test was performed at base line in all patients); an unstable medical condition; a history of cancer or alcohol or drug abuse in the five years before the study; a history of cerebrovascular events in the two years before the study; or a history of myocardial infarction or coronary bypass in the year before the study. Patients with morbid obesity and those who required or who had been receiving treatment with aspirin, ticlopidine, anticoagulants, cyclosporine, misoprostol, sucralfate, or proton-pump inhibitors or treatment with histamine H2–receptor antagonists in prescription-strength doses were also excluded from the study. Patients enrolled in the study were not thought to require the use of these agents by their treating physicians.

The subjects were randomized between a Vioxx group and a Naproxen group, and subjects were not aware of their assigned group. The subjects in the Vioxx group received 50mg of Vioxx daily, while the Naproxen group received 1000mg of Naproxen daily. The study followed subjects until they had a documented gastric episode such as bleeding, an ulcer, etc. The study was finished after 11 months of study. The median subject was in the study for nine months.

[1] NSAIDs are a class of anti-inflammatory drugs that includes widely used products such as aspirin, ibuprofen, naproxen, etc. NSAID's are often used to treat pain, including arthritis pain, and are sometimes used to prevent heart attacks since they have the effect of thinning blood. However, NSAID's often generate gastric problems for their users (stomach pain, ulcers, bleeding in the stomach, etc.). It is estimated that 16,500 people die each year in the United States as a result of NSAID-associated gastrointestinal events and 100,000 are hospitalized for such events.

The Garzas' expert also relied on a meta-analysis performed in 2000 by Merck employee Deborah Shapiro, which combined and analyzed much of the cardiovascular data that Merck had gathered up to that point. In one arm of the analysis, Shapiro compared the relative risks of heart attack of people who had taken Vioxx to the risks of people who had taken other NSAIDs. This analysis found that patients who had taken Vioxx had a risk greater than double compared to the users of other NSAIDs. The results were statistically significant at the conventional 5 percent level. This meta-analysis combines the results of a number of different studies, with differing dosages, durations, and comparison drugs. Included in these studies was the previously mentioned VIGOR study. When the VIGOR results were removed from the meta- analysis, Shapiro found the risk of heart attack of Vioxx patients was 19% higher than the risk to individuals using NSAIDs. This risk difference was statistically significant at the conventional 5 percent level.

The Garzas also rely on the APPROVe study. The APPROVe study followed 2500 patients who were randomized between a group receiving a daily 25mg dose of Vioxx and a group receiving a placebo. The mean age of the sample was 59, and the sample was 84 percent white (no information is provided about the races of the remaining 16 percent of the sample). Sixty-two percent of the sample was male. The study followed the subjects for three years.

The APPROVe study found an overall risk among the Vioxx group that was slightly more than double the risk found among the placebo group for APTC (Antiplatelet Trialists' Collaboration criteria) events, a category of events which includes "the combined incidence of death from cardiovascular, hemorrhagic, and unknown causes; of nonfatal myocardial infarction; and of nonfatal ischemic and hemorrhagic stroke."

Cardiovascular Thrombotic Events, a narrower category that still contained myocardial infarction, were also studied. The APPROVe study found a risk among the Vioxx group that was 92 percent higher than that found among the placebo group and the difference in the risk faced by the two groups was statistically significant at the conventional 5 percent level. The study noted that at the halfway point of the three-year study, there was no statistically significant difference in the risk of Cardiovascular Thrombotic Events between the two groups.

Merck argues that the trial court erred in finding that the Garzas had met their burden under *Havner* and, therefore, the defense should have prevailed on the inadequate warning claim.

a. Given the description of the evidence and the description of *Havner* (including the description of *Havner* as *Daubert*-like), provide Merck's argument.

   Under *Havner*, to demonstrate causation with epidemiological evidence, plaintiffs must provide two independent studies that demonstrate a statistically significant increase in the outcome at issue for individuals taking the same medication, at the same dose, and for the same duration as the victim, and the increase must represent at least a doubling of the likelihood the underlying adverse condition.

   Mr. Garza died of myocardial infarction (i.e., a heart attack). The plaintiff's theory suggests that Vioxx caused the heart attack. Mr. Garza was prescribed (and we presume he took) 25 mg of Vioxx per day for approximately 25 days. The plaintiff must provide two independent studies where it is shows that individuals taking 25 mg of Vioxx per day for

25 days had at least twice the risk of myocardial infarction compared to individuals who did not take Vioxx at all, and this estimated risk difference must be statistically significant. In addition to the *Havner* requirements, *Daubert* principles require that the studies are methodologically sound or reliable and that the studies are relevant to the facts of the case.

The plaintiff offers three studies: Vigor, the Shapiro meta-analysis, and APPROVe. On *Havner* and *Daubert* grounds, each of these studies is problematic.

Vigor: Although the study did examine Vioxx, the subjects of the study were administered 50 mg of Vioxx daily, an amount that is twice as large as the amount taken by Mr. Garza. Further, the median subject in the study took the medicine for 9 months, whereas Mr. Garza took Vioxx for less than a month. These distinctions specifically violate the *Havner* requirement that the dosage and duration used in the studies be the same as the dosage and duration observed for the victim. Under more general *Daubert* principles, these differences undercut the relevance of the studies for the victim's case. Beyond these obvious concerns, the sample of the Vigor study was not comparable to Mr. Garza (the sample was 80 percent female; few Hispanics were in the sample; the sample was screened so as to avoid individuals with serious cardiac conditions; etc) which undermines its relevance under *Daubert*. It also should not be ignored that because the control group in Vigor was taking Naproxen, which has an independent protective effect against heart attacks, it cannot be ruled out that the increased "cardiovascular" events observed in the Vioxx group arose not because the subjects were taking Vioxx but because they were not taking Naproxen. Because the study does not rule out this possibility (e.g., by having a third group of subjects who took neither Vioxx nor Naproxen but rather a placebo), it provides no evidence that Vioxx caused any increase in cardiovascular events. Lastly, the Vigor study is inapt because it focuses on the broader category of cardiovascular events rather than Mr. Garza's specific adverse event (infarction).

Shapiro meta-analysis: First, because the meta-analysis (basically a quantitative summary of studies) includes the Vigor study, it cannot be used as an "independent" study as required in *Havner*. If the Vigor component is dropped from the meta-analysis, the increased risk of heart attack associated with Vioxx is an increase of only 19 percent, well short of *Havner's* required doubling (i.e., a 100 percent increase). Further, in order to meet *Havner's* and *Daubert's* requirements, it would be necessary to ensure that each of the other studies included in the meta-analysis satisfied the specific requirements of same dosage and duration as well as the more general relevance requirements (i.e., are the characteristics of the samples used in the studies sufficiently similar to Mr. Garza in terms of age, sex, ethnicity, health history, etc.).

APPROVe: Although this study examines a dosage that is the same as Mr. Garza's, the duration is significantly longer (3 years). Further, when the more narrow category of adverse outcomes is examined, the increase in risk (92 percent) falls short of *Havner's* required doubling. Beyond this, even this more narrow category includes more adverse outcomes than just infarction, and so the study may overstate the actual increase of Mr. Garza's specific cause of death. Additionally, the characteristics of the sample do not match Mr. Garza, as the sample is primarily white and much younger than Mr. Garza.

Because none of the offered studies satisfies the *Havner* requirements, it is clear that the plaintiff has not met its burden to produce two independent studies showing a statistically significant doubling of the risk of developing the plaintiff's condition.

b. Given the description of the evidence and the description of *Havner* (including the description of *Havner* as *Daubert*-like), provide the Garzas' argument that it was proper to allow them to prevail on the inadequate warning claim.

The defense argues for an untenable interpretation of the *Havner* requirements. The purpose of *Havner* is to require that the underlying studies are relevant to the case at hand. While the defense suggests that the study duration must literally equal the duration of use of the plaintiff, such a reading cannot stand. If a study examined a single month of usage, would it be reasonable to exclude it because Mr. Garza did not even last a month? If a study showed a large increase in death of Vioxx users after only two weeks, would the court require studies that continued exposing people to a fatal risk through Mr. Garza's 25 day duration? Of course not. The purpose of the similar duration language is to direct the court to insist on relevant studies, but such relevance determinations are necessarily judgement calls to be left to a trial judge. The trial judge in this case clearly accepted that the plaintiff's studies were relevant to Mr. Garza's situation. A similar argument can be made with respect to dosage. If a study had examined the use of 25.1111 mg per day, clearly it would still be relevant. Absent any scientific evidence that the difference between dosages is material, it is clear that a trial judge can make a judgment regarding the comparability of dosages. Again, the mandate in *Havner* is a mandate for relevance, not literal equality. Any other reading would be ridiculous.

Likewise, it is a judgement call regarding how precisely to define the relevant adverse event. Categories can be drawn ridiculously broadly (deaths from any cause) or ridiculously narrowly (deaths from myocardial infarction on a Saturday in years where the Ravens beat the Giants in the Super Bowl). There may be medical or scientific reasons why some levels of aggregation make sense while others do not, but absent such clear criteria, it is up to the trial court's discretion to make this judgment. Similarly, *Havner's* doubling requirement should not be interpreted overly literally. A rule that a study showing a 99.999% increase doesn't make the cut, while one showing a 100.00000001% increase does is nonsensical. Again, the *Havner* requirement merely instructs a judge to require a substantial increase in risk, but how substantial should be left to the trial judge's discretion.

Clearly, there is a body of evidence consistently demonstrating that the use of Vioxx elevates cardio-vascular risk significantly and substantially. This body of evidence is methodologically sound and examines situations that are very similar to Mr. Garza's. The trial court accepted that the plaintiff met its burden, and the defense has presented no medical evidence that the deviations between the underlying studies and Mr. Garza's experience were clinically relevant.

c. Relative to *Daubert*, argue the pros and cons of *Havner's* additional criteria for determining the adequacy of epidemiological evidence.

Daubert **recognizes that the determination of whether a study is good or not (or relevant or not) cannot be reduced to cookbook approach. Further, it recognizes that even scientific consensus is unlikely to provide an uncontroversial guide (and may be particularly unhelpful when asked whether a study is "close enough" to the legally relevant facts of the case). This leaves a presumption that courts will need to make some judgements about whether an expert's testimony is likely to be helpful to a jury. On the other hand, judges are not trained in most scientific fields, and so their unguided judgment may itself be unreliable. Daubert attempts to balance these issues by providing some general guidance (methodological reliability and relevance), some specific aspirations (theories should be falsifiable and, ideally, should be tested), as well as some practical clues (peer review is good, all things equal; etc).**

Havner **adds to the practical clues. By requiring same drug, dosage, and duration, the rule is telling judges that these things are almost always going to be relevant, if not crucial, for epidemiological relevance. By focusing on statistical significance, the rule is highlighting for judges that there is a lot of randomness in the world, and, therefore, it is useful to provide at least some filtering of random associations. Because statistical significance itself is a pretty low bar, the requirement of two studies further filters out random associations (as long as the studies are independent; if they are not, perhaps no additional filtering is being done).**

The requirement for a doubling of the risk, at first glance, seems pretty arbitrary. Isn't a 50 percent increase in risk quite a lot? If you are really trying to screen out cases, why not require a tripling, quadrupling, etc? Perhaps more than the other requirements, this one seems pretty heavy handed, especially given its arbitrariness. That said, there is a bit of a rationale here (though that rationale itself may be based on arbitrary assumptions). If 20 people out of 100 in the non-drug taking population have heart attacks, and 20 out of a hundred in the drug taking population likewise have heart attacks, it would be weird to say (just based on this information) that the drug seems to increase heart attacks. If 21 out of 100 had heart attacks among the drug users, we might think that maybe there's an association (though we might also think it's just a random blip). If 30 had heart attacks, maybe we're less likely to think it's a random blip, but we still face a dilemma. If a plaintiff is a drug taker and has a heart attack, is he more likely to be 1 of the 20 of the drug takers who might have had a heart attack even if he hadn't taken the drug (surely there are some people like this since we know the non drug takers have heart attacks too) or 1 of the extra 10 who represent the "additional" heart attacks observed among the drug takers? We can't know the answer to this, but probabilistically, it is 2 to 1 that he is in the former group than the latter. That is, he is NOT "more likely that not" to have had a heart attack because he took the drug. If, instead, 40 out of 100 drug users had heart attacks, that ratio becomes 1 to 1, and if any more than 40 in the drug group have heart attacks, the ratio now implies our particular plaintiff is more likely in the group of "extra" heart attacks than he is in the group of "normal" (i.e., would have been expected even if drugs have no effect on heart attacks) heart attack havers. That is, "more likely than not" requires more than a doubling of the risk of the drug users as compared to those not using drugs. In effect, ***Havner*** **is providing judges with the translation of the legal more likely than not standard into statistical terms (so although still an arbitrary standard, it is one we accept in tort generally).**

If one believes judges are not well equipped to make scientific determinations, this extra practical guidance may be welcome and may make legal determinations more predictable. However, there is nothing magical about these hints. One well done paper may have more evidentiary value than two less well done papers and a strict interpretation of *Havner* would make it less likely that a court would make the "correct" determination in such a situation. Strict interpretation of dosage and duration requirements may lead a judge to ignore the need for clinical determinations about the relevance of differences on these attributes.

3. Choose one of the questions (1 or 2) to count double, or choose to have the two questions weighted equally (i.e., I multiply the points for both of the questions by 1.5). If you do not make your choice clear, I will choose the least advantageous option (i.e., the option that provides you with the fewest points) for you.