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Friday, January 18

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Continuing Legal Education Division

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Health Care Law Section

Friday, January 18

Medical Malpractice Developments

Joseph J. Tierney, Jr.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ROCK HILL DIVISION

Zekiya Knox,

Plaintiff,

v.

The United States of America; Amisub of SC, Inc., d/b/a Piedmont Medical Center; South Carolina Emergency Physicians; Jeffrey Warden, MD; Brian Fleet, PA; Piedmont General Surgery Associates, LLC; Alex Espinal, MD; Bret Garretson, MD; and Digestive Disease Associates,

Defendants.

C/A No. 0:17-cv-36-CMC

Opinion and Order Denying Defendant United States' Motion for Partial Summary Judgment on Damages (ECF No. 120)

Through this action, Zekiya Knox ("Plaintiff") seeks recovery for alleged medical malpractice by a variety of medical providers involved in her care between September 2013 and May 2014.[1] Plaintiff alleges these providers failed to properly and timely diagnose and treat her underlying condition, Crohn's disease, and that this failure led to the development of sepsis. Plaintiff further alleges various Defendants failed to properly treat her sepsis and that the collective errors led to Plaintiff's loss of three limbs. Plaintiff asserts a single claim for medical negligence

[1] Plaintiff alleges errors by each of the following Defendants: (1) her primary care provider, North Central Family Medical Clinic ("NCFMC"), for which the United States of America ("United States") is substituted as the Defendant; (2) the hospital at which she received emergency and other treatment, Amisub of S.C., Inc., d/b/a Piedmont Medical Center ("Piedmont"); (3) Piedmont emergency department medical providers Dr. Jeffrey Warden ("Dr. Warden"), Brian Fleet, PA ("Fleet"), and their employer South Carolina Emergency Physicians, LLP ("SCEP"); (4) her surgeon, Alex Espinal, MD ("Dr. Espinal"), and his employer, Piedmont General Surgery Associates, LLC; and (5) her gastroenterologist, Bret Garretson, MD ("Dr. Garretson"), and his employer Digestive Disease Associates. *See* ECF No. 88 (Second Amended Complaint).

against all Defendants, though the specifically alleged errors vary between Defendants. *See* ECF No. 88 (Second Amended Complaint).

The matter is before the court on motion of Defendant United States' for partial summary judgment on the issue of damages. ECF No. 120. The United States argues a damages limitation applies because NCFMC is a tax-exempt charitable organization providing medical care to underserved patient populations, and under South Carolina law, liability of a private charitable organization is capped at $1.2 million when physicians are involved in the alleged tort. ECF No. 120-1. Plaintiff agrees the United States is entitled to a limitation of damages, but argues there were multiple different occurrences of negligence and therefore the United States' exposure exceeds $1.2 million. ECF No. 132. In reply, the United States argues there were not multiple instances of negligence and the $1.2 million damage cap applies. ECF No. 138. For reasons set forth below, the motion is denied as the court is unable to find as a matter of law there was only one occurrence of negligence.

COMPLAINT ALLEGATIONS

Plaintiff alleges injury after abdominal pain, which she alleges was never properly treated, developed into "significant damage to her intestines and caused a life threatening infection," sepsis. ECF No. 88, Sec. Am. Compl. ¶ 37. Plaintiff originally presented to the Piedmont Emergency Room ("Piedmont ER") on September 13, 2013, complaining of persistent abdominal pain. *Id.* at ¶ 9. She was seen by Defendant Dr. Warden, who performed a physical examination and ordered lab testing, ultrasound of the lower abdomen, and CT scan. *Id.* at ¶¶ 9-11. Plaintiff was discharged from the ER with narcotic pain killers and an instruction to follow up with a gastroenterologist. *Id.* at ¶ 14. On September 19, 2013, Plaintiff was seen by Defendant Dr. Garretson, a gastroenterologist, who scheduled and conducted a colonoscopy on September 25,

2013. *Id.* at ¶¶ 15-16. Dr. Garretson was unsure if his findings represented "appendicitis or IBD" (*id.* at ¶ 16), so he referred Plaintiff to a surgeon, Defendant Dr. Espinal, that same day. *Id.* at ¶ 17. Dr. Espinal ruled out acute abdominal process and ordered a CT scan, but Plaintiff alleges she was never informed of that appointment. *Id.* at ¶¶ 18, 18.1.

The next day, September 26, Plaintiff went to see April Logan, a physician's assistant at NCFMC, a federally funded community health care center, complaining of abdominal pain. *Id.* at ¶ 19. Ms. Logan ordered an ultrasound, which was performed September 30, 2013 and showed "prominent bowel loops . . .with a somewhat thickened appearance." *Id.* at ¶¶ 19.1, 20. Ms. Logan took no action in response to this finding. *Id.* at ¶ 20. Plaintiff was next seen by Ms. Logan on January 14, 2014, for abdominal pain. *Id.* at ¶ 24. Ms. Logan referred Plaintiff back to Dr. Espinal, who saw Plaintiff in February 2014.[2] Plaintiff was prescribed prednisone at that appointment and "the records reflect there was to be an appointment scheduled with Dr. Garretson, [but] this was never made known to Ms. Knox." *Id.* at ¶ 26.

On March 21, 2014, Plaintiff returned to NCFMC complaining of abdominal pain. *Id.* at ¶ 28. The physician she saw ordered another ultrasound, which was performed on April 4, 2014, and "noted tubular structures and encouraged a CT scan." *Id.* at ¶¶ 29, 30. Plaintiff was to follow up at NCFMC on April 14 for ultrasound results, but instead returned to the Piedmont ER by ambulance that day. *Id.* at ¶ 31. Tests and examination showed an elevated white count, lower

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[2] The visit to Dr. Espinal in February 2014 appears to have been prompted by a series of telephone communications between NCFMC and Plaintiff's mother. *See* ECF No. 121-6 at 16, 17 (summary of phone messages and conversations). The first contact was apparently initiated by Ms. Logan in January 2014 after she reviewed Plaintiff's September 2013 colonoscopy results and, ultimately, led to a request by Plaintiff's mother for a referral to a surgeon to have Plaintiff's appendix removed. *Id.*

quadrant pain, and "what was then believed to be bacteria in her urine." *Id.* at ¶ 32. Dr. Warden "remarked her presentation was similar to her presentation in September," and accessed those records, but the only treatment rendered was a prescription for an antibiotic for a urinary tract infection. *Id.* at ¶¶ 33-34. Defendant Fleet, a physician's assistant in the ER, ordered an additional antibiotic after reviewing results of a vaginal culture on April 18, 2014. *Id.* at ¶ 36.

On May 4, 2014, Plaintiff returned to the Piedmont ER. *Id.* at ¶ 37. She was diagnosed with "either an infected inflamed appendix or a flare up of IBD that was never properly discovered or treated." *Id.* She went into septic shock and ultimately lost three limbs. *Id.* at ¶ 39.

STANDARD

Summary judgment should be granted if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). It is well established that summary judgment should be granted "only when it is clear that there is no dispute concerning either the facts of the controversy or the inferences to be drawn from those facts." *Pulliam Inv. Co. v. Cameo Properties*, 810 F.2d 1282, 1286 (4th Cir. 1987). The party moving for summary judgment has the burden of showing the absence of a genuine issue of material fact, and the court must view the evidence before it and the inferences to be drawn therefrom in the light most favorable to the nonmoving party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

DISCUSSION

The Federal Tort Claims Act waives the sovereign immunity of the United States for civil actions in federal court for injuries "caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment." 28 U.S.C. § 1346(b)(1). "The United States shall be liable, respecting the provisions of this title

relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances . . ." 28 U.S.C. § 2674.

The South Carolina Solicitation of Charitable Funds Act ("CFA") limits liability for injury caused by an employee of a charitable organization to "an amount not exceeding the limitations on liability imposed in the South Carolina Tort Claims Act in Chapter 78 of Title 15." S.C. Code § 33-56-180(A).[3] The South Carolina Tort Claims Act ("SCTCA") states

> (a) For any action or claim for damages brought under the provisions of this chapter, the liability shall not exceed the following limits:
>
> (1) Except as provided in Section 15-78-120(a)(3), no person shall recover in any action or claim brought hereunder a sum exceeding three hundred thousand dollars because of loss arising from a single occurrence regardless of the number of agencies or political subdivisions involved.
>
> (2) Except as provided in Section 15-78-120(a)(4), the total sum recovered hereunder arising out of a single occurrence shall not exceed six hundred thousand dollars regardless of the number of agencies or political subdivisions or claims or actions involved.
>
> (3) No person may recover in any action or claim brought hereunder against any governmental entity and caused by the tort of any licensed physician or dentist, employed by a governmental entity and acting within the scope of his profession, a sum exceeding one million two hundred thousand dollars because of loss arising from a single occurrence regardless of the number of agencies or political subdivisions involved.
>
> (4) The total sum recovered hereunder arising out of a single occurrence of liability of any governmental entity for any tort caused by any licensed physician or dentist, employed by a governmental entity and acting within the scope of his profession, may not exceed one million two hundred thousand dollars regardless of the number of agencies or political subdivisions or claims or actions involved.

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[3] The CFA also states "[a] judgment against an employee of a charitable organization may not be returned unless a specific finding is made that the employee acted in a reckless, willful, or grossly negligent manner." *Id.* The United States does not allege Plaintiff must prove gross negligence, recklessness, or willfulness on the part of the NCFMC providers, likely because the providers were not sued individually and therefore a verdict against the United States would not be "against an employee" of NCFMC.

S.C. Code Ann. § 15-78-120(a)(1-4). As defined in the SCTCA, "'occurrence' means an unfolding sequence of events which proximately flow from *a single act of negligence.*" § 15-78-30(g) (emphasis added).

"All rules of statutory construction are subservient to the one that the legislative intent must prevail if it reasonably can be discovered in the language used, and the language used must be construed in the light of the intended purpose of the statute." *Eagle Container Co., LLC v. County of Newberry,* 666 S.E.2d 892, 895 (S.C. 2008). "Legislative intent is best determined by examining the language of the statute itself." *Doe v. American Red Cross Blood Svcs.*, 377 S.E.2d 323, 437 (S.C. 1989). The legislative intent of the CFA is to "encourage the formation of charitable organizations, to promote charitable donations, and to preserve the resources of the charitable organization." *Id.*; *see also Simmons v. Toumey Regional Medical Ctr.*, 533 S.E.2d 312, 316 (S.C. 2000) ("[A] charitable institution should devote its resources to the endeavor at hand and the greater good, not to reimbursing individuals injured by the institution's negligent acts.").

Defendant United States argues it should be granted partial summary judgment on the issue of damages because the CFA limits damages against it as it assumed liability for NCFMC, "a federally funded community health center that is a tax-exempt charitable organization providing medical care to underserved patient populations." ECF No. 120-1. Plaintiff concedes the United States "is entitled to a limitation of damages and does not oppose this position," but contends there were multiple occurrences of negligence by NCFMC providers and therefore the United States' liability exceeds the damages cap of $1.2 million per occurrence. ECF No. 132. In reply, the United States argues allowing recovery to the damage cap for each alleged deviation from the standard of care would "completely eviscerate the CFA and the legislative intent to limit damages applicable to charitable organizations." ECF No. 138 at 6.

Plaintiff agrees the cap on damages in the SCTCA applies to this action through the CFA. Therefore, the only question is whether Plaintiff has alleged multiple "occurrences" of negligence so as to preclude summary judgment for the United States on this issue.

a. Multiple occurrences

Plaintiff argues different providers at NCFMC breached the "legal duty to coordinate her care" at different points in the time period between September 2013 and May 2014. ECF No. 132 at 10. She alleges negligence by April Logan, a physician's assistant[4], on September 26, 2013 for "failing to review pertinent medical records" from NCFMC visits and appointments with the gastroenterologist and general surgeon and on January 14, 2014, for failing to conduct an abdominal exam or review Plaintiff's chart; by Dr. Chua for "concluding Ms. Knox needed a gastroenterology consult but failing to follow up"; and by Dr. West who "heard Ms. Knox complain of abdominal pain but did not investigate it at all either through an exam or a review of her now extensive medical records for the same complaint." *Id.* (citing ECF No. 88, Sec. Am. Compl.). While Plaintiff does not suggest each alleged breach of the standard of care constitutes a separate occurrence, she contends the manner in which each NCFMC provider separately erred was a distinct act of negligence and thus an "occurrence" ("i.e. failure to examine v. failure to read chart v. failure to communicate with specialist"). *Id.* at 11. In support of these allegations, Plaintiff cites the expert report and deposition testimony of Dr. Carol Ann Rupe. ECF Nos. 132-7 (Rupe dep. excerpts), 132-8 (Rupe Report). Therefore, Plaintiff argues she has met her burden for purposes of defeating summary judgment. *Id.*

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[4] As Ms. Logan is a physician's assistant, not a "licensed physician," damages available for her alleged negligent acts are limited to $300,000 per occurrence.

The South Carolina Supreme Court had occasion to consider the CFA's definition of "occurrence" in *Chastain v. AnMed Health Foundation*, 694 S.E.2d 541 (S.C. 2010). In *Chastain*, a plainitff sued a charitable institution and six nurses who cared for her during her hospitalization for circulation problems. She alleged that over 2000 deviations from the standard of care led to amputation of her leg. The trial judge reduced a jury verdict to $300,000 finding "the intent of the CFA was to limit the amount of damages recoverable from a charitable organization, and to read the term 'occurrence' to include every incident where the defendant nurses violated the applicable standard of care would clearly defeat the legislature's intent...." *Id.* at 543. Alternatively, the trial judge held it was impossible to determine the number of negligent acts or negligent nurses found by the jury based on the jury charge and verdict form, and therefore only one recovery was appropriate. *Id.*

On appeal, the Supreme Court held the plaintiff failed to meet her burden of proving multiple occurrences because the jury was not asked to determine whether there was more than one occurrence, and the general verdict form only supported a single occurrence.[5] Therefore, the court found it unnecessary to address the trial judge's finding the term "occurrence" could not be read to include every incident where the nurses violated the applicable standard of care. *Id.* Instead, the court held "[i]f [plaintiff] alleges multiple occurrences, that is, that there was more than one single act of negligence from which proximately flowed an unfolding sequence of events, she bears the burden of proving each occurrence." *Id.* at 543-44.

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[5] The court noted the jury was never instructed on the definition of occurrence, or asked to determine whether there was more than one occurrence, so the trial judge was correct in "reforming the verdict to reflect a single occurrence." *Id.* at 544.

This court agrees with the United States "occurrence" most likely could not be read to include every violation of the standard of care. However, that is not Plaintiff's position here – Plaintiff argues she has alleged separate acts of negligence by independent actors at NCFMC, not merely multiple breaches of the standard of care.

Plaintiff cites an SCTCA case, *Boiter v. South Carolina Dept. of Transp.*, for the proposition that multiple acts of negligence constitute separate occurrences under that statute. 712 S.E.2d 401 (S.C. 2011). However, *Boiter* is distinguishable on two distinct and important points: first, it does not address the CFA and the legislative intent of that statute to limit liability; and second, it discussed liability for two acts of negligence by entirely separate entities[6] with no causal connection between the two. *Id.* at 406 (distinguishing from *Chastain* on the facts and from cases in other jurisdictions "because they involve a single governmental entity which committed multiple acts of negligence" and deciding there were two occurrences "based solely on the peculiar facts of this case"). As the instant case is factually distinguishable from *Boiter*, that case does not compel a finding of multiple occurrences.

Additionally, Plaintiff cites a South Carolina circuit court case finding two occurrences under the SCTCA when two physicians working at the same facility examined a woman during childbirth and committed two separate acts of negligence in failing to timely deliver her baby. *Williamson v. South Carolina Ins. Reserve Fund*, No. 2000-CP-42-841, 2001 WL 35835128 (S.C. Com.Pl. May 8, 2001). However, on appeal, the South Carolina Supreme Court found the damages

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[6] The court did not make its decision solely on the basis of negligence by two separate departments, noting "[i]n many situations, negligent acts from more than one entity would still equal but one occurrence." *Id.* at 407. However, the number of actors is not the only difference between the instant case and *Boiter*.

cap inapplicable as it was not in effect at the time the plaintiff's claim accrued. 586 S.E.2d 115, 118 (S.C. 2003). The court explicitly declined to address the issue of number of occurrences as unnecessary because the cap did not apply. *Id.*

In this case, Plaintiff has alleged instances of distinct types of negligence by providers at NCFMC. She alleges, and includes expert testimony in support, that Ms. Logan failed to review the chart *in toto* in September 2013 and failed to perform an abdominal examination in January 2014, and that Dr. West failed to review the chart, perform an examination, and to contact the gastroenterologist or surgeon in March and April 2014.[7] She contends these separate acts of negligence took place on different dates and were unrelated to one another, and therefore Plaintiff's injury was not due to "an unfolding sequence of events which proximately flow from a single act of negligence."

The South Carolina Supreme Court has held in *Chastain* that a plaintiff who alleges multiple occurrences, that is, there was more than one single act of negligence from which proximately flowed an unfolding sequence of events, bears the burden of proving each occurrence. 694 S.E.2d at 543-44. This court is unable to find as a matter of law there was a single act of negligence here. If Plaintiff presents evidence at trial to support more than one act of negligence, the jury will be instructed on the definition of occurrence and asked to determine whether Plaintiff

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[7] Plaintiff also alleges "a different NCFMC physician (Dr. Chua) [was at fault] for concluding Ms. Knox needed a gastroenterology consult but failing to follow up," in the time period after February 2014. ECF No. 132 at 10 (citing Sec. Am. Compl. ¶ 28). Dr. Rupe's report states Dr. Tafari received and signed off on Dr. Garretson's notes in September 2013, but does not discuss Dr. Chua. The report also notes "[w]hile the providers were in the chart, that [sic] again failed to check their own records to find the consults from the gastroenterologist. If they had, they would and should have followed up with the gastroenterologist to determine the diagnosis." The excerpts of Dr. Rupe's deposition filed with the briefing of this motion do not discuss Dr. Chua.

has proven more than one occurrence. If only Ms. Logan is found to be negligent, the United States' liability would be limited to $300,000 for one occurrence or $600,000 for two occurrences. If either Dr. West or Dr. Chua is found to be negligent, but not Ms. Logan, recovery would be capped at $1.2 million for one occurrence, or $2.4 million for two. It appears the maximum potential recovery by Plaintiff from the United States is $3 million: $1.2 million for each physician's alleged negligent actions for a total of $2.4 million, plus $600,000 to encompass both alleged negligent acts by Ms. Logan.

CONCLUSION

For the reasons set forth above, Defendant United States' motion for summary judgment on the issue of damages (ECF No. 120) is denied.

IT IS SO ORDERED.

s/Cameron McGowan Currie
CAMERON MCGOWAN CURRIE
Senior United States District Judge

Columbia, South Carolina
July 3, 2018

THE STATE OF SOUTH CAROLINA
In The Supreme Court

Larry Lee Boiter, Appellant,

v.

South Carolina Department of Transportation and South Carolina Department of Public Safety, Respondents.

and

Jeannie Boiter, Appellant,

v.

South Carolina Department of Transportation and South Carolina Department of Public Safety, Respondents.

Appeal From Spartanburg County
J. Mark Hayes, II, Circuit Court Judge

Opinion No. 26981
Heard January 6, 2011 – Filed June 6, 2011

AFFIRMED IN PART AND REVERSED IN PART

James Fletcher Thompson, of Spartanburg, for Appellants.

Andrew F. Lindemann, of Davidson & Lindemann, of Columbia and Ronald H. Colvin, of Spartanburg, for Respondents.

JUSTICE HEARN: Two issues are presented in this appeal: (1) whether the two-tier statutory cap in the South Carolina Tort Claims Act is constitutional, and (2) whether two separate governmental entities' negligent acts, which resulted in severe injuries to Larry Lee and Jeannie Boiter (collectively, the Boiters) constitute one or two occurrences under the Tort Claims Act. The circuit court found the statutory caps constitutional and that only one occurrence was presented by the facts. We affirm in part and reverse in part.

FACTS

The Boiters were injured when the motorcycle they were riding collided with a car driven by Nancy Kochenower at an intersection near Inman, South Carolina. The red signal light bulbs for the road that Kochenower was traveling had burned out earlier that day. The Boiters suffered significant injuries as a result of being thrown from the

motorcycle, requiring lengthy hospital stays and incurring $888,756 in medical bills and $203,897 in lost wages. They settled with Kochenower for her policy limits of $50,000.

The Boiters filed four separate lawsuits against South Carolina Department of Transportation (SCDOT) and South Carolina Department of Public Safety (SCDPS) (collectively, Respondents), alleging negligence in their failure to prevent the accident. With respect to SCDOT, the Boiters alleged SCDOT failed to implement an appropriate re-lamping policy to replace bulbs in traffic signals before they burn out. With respect to SCDPS, the Boiters alleged that a citizen's call one hour and twenty-seven minutes prior to the accident reporting the outage should have resulted in SCDPS notifying a trooper to report to the scene and direct traffic. The negligence of both agencies is undisputed in this appeal. At trial, the jury found in favor of the Boiters and awarded them a total of 1.875 million dollars.

Thereafter, Respondents filed motions for judgment notwithstanding the verdict, a new trial, and to reduce the verdict amount pursuant to the Tort Claims Act. In response, the Boiters filed a motion challenging the constitutionality of the two-tier cap in the Tort Claims Act, and in the alternative, asserted that Respondents' negligence constituted two separate occurrences under the Act. The circuit court denied Respondents' motions for judgment notwithstanding the verdict and a new trial as well as the Boiters' motion challenging the cap's constitutionality, but the court found there was only one occurrence and granted Respondents' motion to reduce the verdict pursuant to the Act. Therefore, the Boiters' verdict was reduced to $300,000 each, for a total of $600,000. This appeal followed.

ISSUES

The Boiters raise two issues on appeal:

(1) Did the circuit court err in failing to find that the two-tier cap on damages under the Tort Claims Act is unconstitutional as a violation of equal protection?

(2) Did the circuit court err in failing to find that two separate occurrences gave rise to the Boiters' injuries?

ANALYSIS

I. CONSTITUTIONALITY OF CAP

Section 15-78-120 of the South Carolina Code (2005) states the following, in pertinent part:

(1) Except as provided in Section 15-78-120(a)(3), no person shall recover . . . a sum exceeding three hundred thousand dollars because of loss arising from a single occurrence regardless of the number of agencies or political subdivisions involved.

(2) Except as provided in Section 15-78-120(a)(4), the total sum recovered hereunder arising out of a single occurrence shall not exceed six hundred thousand dollars regardless of the number of agencies or political subdivisions or claims or actions involved.

(3) No person may recover in any action or claim . . . caused by the tort of any licensed physician or dentist, employed by a governmental entity and acting within the scope of his profession, a sum exceeding one million two hundred thousand dollars because of loss arising from a single occurrence . . . .

(4) The total sum recovered hereunder arising out of a single occurrence of liability of any governmental entity for any tort caused by any licensed physician or dentist, employed by a governmental entity and acting within the scope of his profession, may not exceed one million two hundred thousand dollars regardless of the number of agencies or political subdivisions or claims or actions involved.

Therefore, a two-tier statutory cap on damages exists based on who allegedly committed the act. For state-employed physicians and dentists, the cap is 1.2 million dollars per person and per occurrence. For all other state entities, the cap is $300,000 per person and $600,000 per occurrence. The Boiters allege this disparate treatment based solely on the identity of the tortfeasor violates their constitutional right to equal protection of the laws.

Because no fundamental right has been infringed, we focus our analysis on the rational basis test. See Wright v. Colleton County School Dist., 301 S.C. 282, 291, 391 S.E.2d 564, 570 (1990). Under this framework, the Equal Protection Clause is satisfied if: (1) the classification bears a reasonable relation to the legislative purpose sought to be effected; (2) the members of the class are treated alike under similar circumstances and conditions; and (3) the classification rests on some reasonable basis. Samson v. Greenville Hospital System, 295 S.C. 359, 368 S.E.2d 665 (1988). "Those attacking the validity of legislation [under the rational basis test of the Equal Protection Clause] have the burden to negate every conceivable basis which might support it." Lee v. SC Dept. of Natural Resources, 339 S.C. 463, 470 n.8, 530 S.E.2d 112, 115 n.8 (2000) (citing to Fed'l Commc'ns Comm'n v. Beach Comm'n, Inc., 508 U.S. 307 (1993)). The Boiters argue the two-tier cap's different treatment of injured plaintiffs based on the identity of the tortfeasor does not have a rational basis sufficient to withstand constitutional scrutiny. Respondents counter that this Court has consistently upheld the constitutionality of the monetary caps, and the Boiters have not put forth sufficient evidence to depart from this precedent.

This Court has upheld the constitutionality of the statutory caps in three prior cases. In Wright, the Court upheld the general existence of statutory caps. Wright, 301 S.C. at 292, 391 S.E.2d at 570. There, a child was injured while working with a product on the school district's premises. Id. at 284, 391 S.E.2d at 566. Wright, who was the child's mother, and the child filed actions against the school district, among other entities. See id. The circuit court granted judgment to Wright and the child in the amount of

$750,000. Id. at 285, 391 S.E.2d at 566. Wright and the child appealed, arguing numerous constitutional challenges, including equal protection. See id. at 290, 391 S.E.2d at 569. This Court upheld the constitutionality of the statute, finding:

The limitation on damages as set forth in the statute bears a reasonable relationship to the legislative objectives as expressed in Section 15-78-20(a) of relieving the government from hardships of unlimited and unqualified liability and preserving the finite assets of governmental entities which are needed for an effective and efficient government. The limitations set forth in the statute rest on a reasonable basis and are not arbitrary in that the legislature has balanced the needs for services and demand for reasonable taxes against the fair reimbursement of injured tort victims. Finally, we find that the damage limitation provisions apply to similar plaintiffs in a similar manner.

Id. at 291, 391 S.E.2d at 570.

In Foster v. South Carolina Department of Highways & Public Transportation, 306 S.C. 519, 413 S.E.2d 31 (1992), the Court had an opportunity to examine the two-tier cap at issue in this case. Foster sued the Highway Department after she was involved in a car accident, claiming the Highway Department failed to give proper warning of a low shoulder and failed to maintain the highway. Foster was awarded three million dollars, and the circuit court reduced the verdict amount to $250,000. Id. at 522, 413 S.E.2d at 33-34. Foster appealed, claiming the two-tier cap was unconstitutional as a violation of her right to equal protection. Id.

This Court found Foster, as the party asserting the unconstitutionality of the statute, failed to meet her burden of proof to show that the classification was arbitrary and without any reasonable basis. See id. at 526-27, 413 S.E.2d at 36. The Court noted that it affords great deference to a legislative classification and will uphold a classification if it is "not plainly arbitrary and there is any reasonable hypothesis to support it." Id. at 526, 413 S.E.2d at 36. In finding against Foster, we said, "The fact that the classification results in some inequity does not render it in violation of the Constitution." Id. at 527, 413 S.E.2d at 36 (citing State v. Smith, 271 S.C. 317, 247 S.E.2d 331 (1978)). The Court also articulated a specific basis found in the statute for the two tiers: "These higher limits and mandated coverages are recognition by the General Assembly of significantly higher damages in cases of medical malpractice." In regards to Foster's burden of proof, the Court instructed,

Foster must offer evidence that the legislative finding of higher awards in actions of medical malpractice was unfounded and thus no rational basis for the classification existed. She has not met her burden of proof by the bare assertion that her damages are as high as damages that might be assessed against a physician or dentist.

Id.

Sixteen years after Foster, this Court decided Giannini v. South Carolina Department of Transportation, 378 S.C. 573, 664 S.E.2d 450 (2008). There, a car hydroplaned and

crossed into the other lane of traffic, striking two cars; one person was killed and two others suffered serious bodily injuries. Id. at 578, 664 S.E.2d at 452. After citing to both Wright and Foster, this Court found the "[l]egislature's aggregate limitation on liability is supported by a rational basis such that there is no equal protection violation." Id. at 584, 664 S.E.2d at 456. This Court noted the legislation was in line with the purposes of preserving finite governmental assets and treating similar plaintiffs in a similar manner. See id. This Court then cited to cases from other jurisdictions which have also held that general liability caps do not violate equal protection. See id. at 585, 664 S.E.2d at 456 (citing Wilson v. Gipson, 753 P.2d 1349 (Ok. 1988) and Lee v. Colorado Dep't of Health, 718 P.2d 221 (Colo. 1986)).

With these three cases in mind, we now turn to the Boiters' argument. At the hearing before the circuit court on the constitutionality of the two-tier system, the Boiters produced substantial evidence in the form of national and state studies designed to establish that there is no empirical evidence to justify the difference in the respective caps. The Boiters submitted the following in support of the cap's unconstitutionality: (1) Three U.S. Department of Justice Bulletins detailing the number of trials and verdicts in large counties for civil cases, tort cases, and medical malpractice cases; (2) U.S. Department of Justice report on Medical Malpractice Insurance Claims in Seven States[1]; (3) South Carolina Legislative Audit Council Report in 2000 and 2004, reviewing the Medical Malpractice Compensation Fund; (4) SCDOT and SCDPS budgets for 2007- 2008; and (5) correspondence from the State Budget and Control Board, Boiters' counsel, and Respondents' counsels regarding the above reports. The Boiters argue that consistent with the degree of proof suggested by the Court in Foster, they introduced sufficient evidence to demonstrate the constitutional infirmity in the two-tier system. However, even taking all of their evidence into account, it cannot overcome the great deference this Court must give to the General Assembly's stated classification. Under settled principles, we will sustain such classifications if any reasonable hypothesis exists to support them. Samson, 295 S.C. at 367, 368 S.E.2d at 665; Foster, 306 S.C. at 526, 413 S.E.2d at 36.

Two reasonable hypotheses exist in the code to substantiate section 15-78-120: (1) relieving the government from the hardships of unlimited liability; and (2) furthering accountable and competent healthcare while promoting affordable medical liability insurance. S.C. Code Ann. § 15-78-20(a), (g) (2005). The evidence submitted by the Boiters before the circuit court does not overcome these two reasonable hypotheses, and we are not persuaded that the General Assembly's two-tier classification is arbitrary or without rational basis. Moreover, our precedent in this area, although perhaps not as compelling from a factual or evidentiary standpoint as this case, convinces us that the Boiters' constitutional challenge should be denied. Therefore, we find that the two-tier cap meets the rational basis test, and we affirm the circuit court's finding of constitutionality.

II. OCCURRENCE

The Boiters argue that the circuit court erred in failing to find two separate occurrences in the two separate acts of negligence committed by SCDOT and SCDPS. We agree.

Under Section 15-78-30(g) of the South Carolina Code (2005), "occurrence" is defined as an "unfolding sequence of events which proximately flow from a single act of negligence." In its order denying the Boiters' arguments that there were two separate occurrences, the circuit court stated:

The Plaintiffs present a logical argument as to the statutory construction of the term 'occurrence,' but under the facts of this case, where the jury's verdict has to be read as finding both Defendants as concurrently at fault in bringing about the damages to the Plaintiffs, the definition of occurrence limits the award to the statutory cap.

We disagree and find the facts here present a classic case of two occurrences.

Questions of statutory construction are a matter of law. Charleston County Parks & Recreation Comm'n v. Somers, 319 S.C. 65, 67, 459 S.E.2d 841, 843 (1995). "All rules of statutory construction are subservient to the one that the legislative intent must prevail if it reasonably can be discovered in the language used, and the language must be construed in the light of the intended purpose of the statute." Sumter Police Dep't v. Blue Mazda Truck, 330 S.C. 371, 375, 498 S.E.2d 894, 896 (Ct. App. 1998). "In construing statutory language, the statute must be read as a whole, and sections which are part of the same general statutory law must be construed together and each one given effect." TNS Mills, Inc. v. S.C. Dep't of Revenue, 331 S.C. 611, 620, 503 S.E.2d 471, 476 (1998).

Only one appellate case[2] in South Carolina has considered the issue of occurrence under section 15-78-30. In Chastain v. AnMed Health Foundation, 388 S.C. 170, 694 S.E.2d 541 (2010), the plaintiff suffered severe and permanent injuries as a result of the poor care given to her by six nurses at AnMed, a charitable institution. Id. at 171-72, 694 S.E.2d at 542. The jury returned a general verdict against AnMed for 2.2 million dollars, and the trial judge reduced it to the $300,000 statutory cap based on his finding of one occurrence. Id. at 172-73, 694 S.E.2d at 542-43. In affirming the verdict reduction, this Court noted that the burden to prove more than one occurrence rested on the plaintiff and that from the general verdict rendered, it was impossible to conclude that the jury had found more than one occurrence. Id. at 174, 695 S.E.2d at 543. Because the facts presented here are so different than those involved in Chastain, that case provides little guidance to us.

Cases from other jurisdictions are similarly inapposite because they involve a single governmental entity which committed multiple acts of negligence, a completely different situation than the one before us. See Tex. Dep't of Mental Health & Mental Retardation v. Petty By & Through Kauffman, 848 S.W.2d 680 (Tex. 1992) (one occurrence after department committed multiple acts of negligence); Folz v. State, 797 P.2d 246 (N.M. 1990) (negligence by highway department which resulted in truck striking five separate vehicles in collision was only one occurrence under statute); cf. Brooks v. Memphis &

Shelby County Hosp. Auth., 717 S.W.2d 292 (Tenn. App. 1986) (finding two occurrences when one employee negligently let patient fall off stretcher and a second employee negligently gave an overdose of medication, resulting in patient's death). Accordingly, we determine the issue before us based solely on the peculiar facts of this case.

In order to determine the number of occurrences, the Boiters urge this Court to focus on the number of negligent acts; in contrast, Respondents contend we should look to the number of injuries caused by those acts. The circuit court specifically found in its order that "each of [the Respondents] committed a separate wrongful act that led to the damages," and that "[t]he wrongful acts [of Respondents] were separate and distinct." Nevertheless, the circuit court found that each act of negligence was "a part of the same 'unfolding sequence of events' that resulted in the Boiters' damages." Therefore, the circuit court accepted Respondents' argument and equated occurrence with the number of injuries sustained by the Boiters. While we do not adopt a bright-line test based on the existence of multiple acts of negligence, we find the circuit court erred in tying the number of occurrences to the number of injuries sustained by the Boiters.

We are persuaded that two independent and separate acts of negligence occurred here – one by SCDOT and one by SCDPS. There is no indication that the Respondents' actions combined to form a single act of negligence. Unlike the situation presented in Chastain, we have two separate and distinct acts of negligence involving two separate and distinct entities together with separate verdicts against each of them. As found by the jury, SCDOT was negligent in not having a re-lamping policy in place, and SCDPS was negligent in not following its own policy to notify a SCDOT technician when a light had burned out. Based on the facts presented here, we cannot see how SCDOT's negligent act "unfolded" into SCDPS' negligent act. SCDPS only became involved due to a citizen call regarding the burned-out light bulb; SCDOT never called SCDPS regarding the light, and SCDPS never informed SCDOT about the citizen call. We can find no causal connection between the actions of SCDOT and SCDPS; had the jury not found SCDOT negligent, the verdict against SCDPS could still stand, and the converse is also true. Therefore, we do not believe that these two separate and independent acts of negligence constituted an unfolding sequence of events which injured the Boiters.

Respondents cite to language found in section 15-78-120(2),[3] arguing that it demonstrates the General Assembly's recognition that the number of governmental entities involved in a particular occurrence does not increase the statutory limits on liability. While we do not disagree with Respondents' view, we do not believe this ends the inquiry. In many situations, negligent acts from more than one entity would still equal but one occurrence. However, under these facts, there were two separate entities which committed two separate and independent acts of negligence, and we do not believe the General Assembly's intent was to limit recovery in such situations based on there being only one occurrence. Accordingly, we hold each Respondent's act of negligence was a separate occurrence entitling the Boiters to a combined verdict of 1.2 million dollars, and we reverse the circuit court.

CONCLUSION

We hold that the two-tier statutory cap on damages is constitutional against an equal protection challenge. However, we also hold that more than one occurrence existed in this situation. Therefore, we affirm in part and reverse in part the circuit court's order.

TOAL, C.J., BEATTY and KITTREDGE, JJ., concur. PLEICONES, J., concurring in part and dissenting in part in a separate opinion.

JUSTICE PLEICONES: I concur in part and dissent in part. I agree with the majority that the differential caps created by the Tort Claims Act (TCA) are constitutional. I disagree, however, with the majority's conclusion that there was more than one occurrence here. I would therefore affirm the circuit court's order.

In my opinion, the majority errs when it focuses on the number of acts of negligence rather than on the TCA's definition of occurrence: "an unfolding sequence of events which proximately flow from a single act of negligence." S.C. Code Ann. § 15-78-30(g) (2005). Under the TCA, an occurrence is not defined by the number of individual acts of negligence, nor does it require, as would the majority, a "causal connection" between these independent acts. Here, appellants' theory was that as the result of the SCDOT's negligent failure to have a replacement bulb policy a traffic light was not functioning properly, and when a concerned citizen notified SCDPS of the dangerous situation, that agency negligently failed to send a trooper to the scene to direct traffic. This unfolding sequence of events proximately led to the accident and appellants losses.

In my view, an occurrence is not defined by the number of agencies involved, or by the acts of negligence committed, nor by temporal proximity. Instead, the occurrence ends when the unfolding sequence of events is broken by an unnatural or intervening cause. Here, there was no such break, and thus appellants each suffered only one compensable loss as the result of a single occurrence.

I would affirm.

[1] South Carolina was not one of the seven states discussed in this report.

[2] In Williamson v. South Carolina Insurance Reserve Fund, two different physicians examined a mother during childbirth and failed to take necessary steps, at different times during the delivery, to prevent harm to the child. See 355 S.C. 420, 422, 586 S.E.2d 115, 116 (2003). The circuit court found two occurrences had been established for purposes of the Tort Claims Act because neither doctor's actions was the result of the other's. See id. at 423, 586 S.E.2d at 116. On appeal, this Court declined to address whether two occurrences existed. See id. at 426, 586 S.E.2d at 118.

[3] The subsection notes that liability is limited to $600,000 regardless of the number of agencies or political subdivisions involved.

948 F.Supp.2d 577
United States District Court, D. South Carolina, Beaufort Division.

Diane S. BOYLE, as Personal Representative of the Estate of John Francis Boyle, Plaintiff,
v.
UNITED STATES of America, Defendant.

Civil Action No. 9:09–939–SB.
|
Aug. 7, 2012.

Synopsis

Background: Estate of kidney transplant patient brought action against the United States pursuant to the Federal Tort Claims Act (FTCA), alleging the patient died of Tacrolimus toxicity and kidney failure due to the negligent, careless, and reckless filling and dispensing of the patient's medication by employees at a naval hospital pharmacy.

Following a non-jury trial, the District Court, Sol Blatt Jr., Senior District Judge, held that patient's estate, and patient's surviving spouse and children all constituted claimants under the South Carolina Noneconomic Damage Awards Act.

Ordered accordingly.

Attorneys and Law Firms

***577** Carl H. Jacobson, Jonathan F. Krell, Uricchio Howe Krell Jacobson Toporek Theos and Keith, Charleston, SC, for Plaintiff.

***578** Lee Ellis Berlinsky, U.S. Attorneys Office, Charleston, SC, for Defendant.

FINDINGS OF FACT AND CONCLUSIONS OF LAW AS TO DAMAGES

SOL BLATT JR., Senior District Judge.

This matter came before the Court for a non-jury trial on the Plaintiff's action brought against the United States of America pursuant to the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b) and 2671–80 (hereinafter referred to as "the FTCA").[1] Carl Jacobson and Jonathan Krell represented the Plaintiff at trial, and Lee Berlinsky represented the Defendant. On March 9, 2012, 948 F.Supp.2d 570, 2012 WL 8303337 (D.S.C.2012), the Court issued its findings of fact and conclusions of law as to liability, and the Court incorporates herein those findings of fact and conclusions of law. On March 20, 2012, the Court held a hearing on the issue of damages.

In its March 9th findings of fact and conclusions of law, the Court found that the Plaintiff met her burden of proof to establish the Defendant's liability. Specifically, the Court found it more likely than not that the Beaufort Naval Hospital mis-filled John Francis Boyle's (hereinafter referred to as "Mr. Boyle" or "the decedent") 0.5–milligram Prograf[2] prescription in December of 2005, and that instead of dispensing 180 0.5–milligram Prograf capsules, the Beaufort Naval Hospital negligently dispensed 180 5–milligram capsules of Prograf. (Entry 59 at 3, ¶ 11.) The Court also found from what it deemed to be the more credible evidence that Mr. Boyle's hospitalizations on February 2, 2006, February 19, 2006, and March 19, 2006, more likely than not occurred at least in part because Mr. Boyle was taking an improper daily dose of Prograf due to the December 2005 mis-fill. (*Id.* at 4, ¶ 13.) Therefore, the Court found that the Defendant breached the standard of care and that the breach proximately caused Mr. Boyle's Prograf toxicity, thereby contributing to his death. (*Id.* at 8, ¶ 9.)

Despite the foregoing, the Court also found that at some point between the December 2005 mis-fill and his final hospitalization, Mr. Boyle should have recognized that the bottle of 0.5–milligram Prograf capsules actually contained 5–milligram capsules, based on factors such as his familiarity with the medication and the differing characteristics of the dosages, including size, color, and markings. (*Id.* at 9, ¶ 11, 12.) Thus, in addition to finding that the Defendant was negligent, the Court also found that Mr. Boyle was negligent by failing to recognize the mis-fill at some point between December 2005 and his subsequent hospitalizations. (*Id.*, ¶ 13.) Ultimately, the Court attributed twenty-five percent of the fault to Mr. Boyle. (*Id.*)

*579 *FINDINGS OF FACT* [3]

1. Mr. Boyle was born on July 3, 1934, and he was seventy-one years old at the time of his death on April 28, 2006.

2. In the mid-nineties, Mr. Boyle began suffering from renal disease secondary to autosomal dominant polycystic kidney disease.

3. In November of 2000, Mr. Boyle received a kidney transplant, and his medical records indicate that he was mostly stable from the time of his transplant until February of 2006.

4. Mr. Boyle graduated from college in 1956 and went to work in the New York City Police Department, where he worked for thirty years, in addition, Mr. Boyle was in the New York National Guard and Army Reserve for thirty years.

5. Diane S. Boyle ("Diane") was born on December 17, 1935, and she met Mr. Boyle when she was eighteen or nineteen years old. They married when she was twenty-three years old, and together they had two children, Julie Boyle Mecca ("Julie") and John C. Boyle ("John").

6. At the time of Mr. Boyle's death, Diane and Mr. Boyle had been married for forty-seven years, and from the evidence presented, it appears that they had a very loving and happy relationship. Diane testified that Mr. Boyle was a great husband, the love of her life, her best friend, and her spiritual partner.

7. When Mr. Boyle was twenty-seven years old, Diane gave birth to a daughter, Julie. According to Julie, it was a "great family." Julie lived under the same roof with her parents until she got married at age twenty-six. In addition, her father's line of work influenced her to go work for the Department of Probation and for the District Attorney's Office. Julie particularly enjoyed it when her father spent time with her and her three children. In all, it appears from the evidence presented that Julie had a close, loving relationship with her father.

8. When Mr. Boyle was thirty years old, Diane gave birth to a son, John. In addition to being his father's namesake, John followed his father's footsteps into the police academy and the national guard. From all accounts John and his father had a close relationship; they participated in joint athletic activities and enjoyed family vacations and outings. John lived at home until he entered the police academy at age twenty-one, and even after he moved out of the house, he continued to see his father at least twice a week. John had plans to eventually move to Hilton Head to spend more time with his parents. As with Julie, it appears from the evidence that John had a close, loving relationship with his father.

9. Mr. Boyle and his family lived in one home in New York until 1995 when he and his wife moved to Hilton Head, South Carolina.

10. Mr. Boyle was an active member of both his family and his community. He was involved with his church and he served as the financial secretary and chief recruiter for the Knights of Columbus.

11. At the time of his death, Mr. Boyle was receiving police retirement income from his employment with the New York City Police Department, military retirement income, and Social Security benefits. In 2005, the last full year before his death, Mr. Boyle received approximately $44,050.00 in police retirement income, approximately $16,096.00 in military retirement income, and $17,054.00 in Social Security benefits.

*580 *CONCLUSIONS OF LAW*

1. This case involves claims based on the South Carolina statutes for a "survival right of action," S.C. Code Ann. § 15–5–90, and for "wrongful act causing death," S.C. Code Ann. § 15–51–10.

2. Section 15–5–90 of the South Carolina Code (sometimes referred to as the "survival statute") provides in pertinent part: "Causes of action for and in respect to ... any and all injuries to the person or to personal property shall survive both to and against the personal or real representative, as the case may be, of a deceased person .... any law or rule to the contrary not withstanding." S.C. Code Ann. § 15–5–90.

3. Thus, the "survival statute provides that a cause of action for injuries to a person shall survive the person's death, with damages recoverable by the legal representative of the deceased." *Smalls v. South Carolina*

Dept. of Educ., 339 S.C. 208, 216, 528 S.E.2d 682, 686 (Ct.App.2000).

4. In a survival action, the legal representative of the deceased may recover damages for the deceased's conscious pain and suffering and medical expenses. *See Baker v. Sanders,* 301 S.C. 170, 391 S.E.2d 229 (1990) (finding that the South Carolina Tort Claims Act does not preclude a survival action for conscious pain and suffering and medical expenses when an injured person later dies as a result of the tortious conduct).

5. In addition, pursuant to section 15–5–100 of the South Carolina Code, funeral expenses are recoverable in a survival action. S.C. Code Ann. § 15–5–100.

6. Next, section 15–51–10 (sometimes referred to as the "wrongful death statute") provides;

> Whenever the death of a person shall be caused by the wrongful act, neglect or default of another and the act, neglect or default is such as would, if death had not ensued, have entitled the party injured to maintain an action and recover damages in respect thereof, the person who would have been liable, if death had not ensued, shall be liable to an action for damages, notwithstanding the death of the person injured, although the death shall have been caused under such circumstances as made the killing in law a felony....

S.C. Code Ann. § 15–51–10.

7. Section 15–51–20 outlines the beneficiaries of a wrongful death action, stating:

> Every such action shall be for the benefit of the wife or husband and child or children of the person whose death shall have been so caused, and, if there be no such wife, husband, child, or children, then for the benefit of the parent or parents, and if there be none such, then for the benefit of the heirs of the person whose death shall have been so caused. Every such action shall be brought by or in the name of the executor or administrator of such person.

Id. at § 15–51–20.

8. In a wrongful death action in South Carolina, the damages recoverable by the statutory beneficiaries of the decedent include (1) pecuniary loss, (2) mental shock and suffering, (3) wounded feelings, (4) grief and sorrow, (5) loss of companionship, and (6) deprivation of the use and comfort of the intestate's society. *Knoke v. South Carolina Dept. of Parks, Recreation & Tourism,* 324 S.C. 136, 141, 478 S.E.2d 256, 258 (1996). "In a wrongful death case, the question of damages is not directed toward the value of the human life that was lost, but rather the damages sustained by the beneficiaries as a result of the death." *Self v. Goodrich,* 300 S.C. 349, 351, 387 S.E.2d 713, 714 (Ct.App.1989).

9. This case also involves application of the South Carolina Noneconomic Damage ***581** Awards Act of 2005. Specifically, section 15–32–220 provides:

> (A) In an action on a medical malpractice claim when final judgment is rendered against a single health care provider, the limit of civil liability for noneconomic damages of the health care provider **is limited to an amount not to exceed three hundred fifty thousand dollars as for each claimant, regardless of the number of separate causes of action on which the claim is based,** except as provided in subsection (E). [4]

S.C. Code Ann. § 15–32–220(A) (emphasis added).

10. Here, the parties dispute how the Court should construe the term "claimant" in section 15–32–220(A). Specifically, the Plaintiff urges the Court to find four claimants in this case: (1) the estate of Mr. Boyle in the survival action; (2) Diane Boyie in the wrongful death action; (3) Julie Boyle Mecca in the wrongful death action; and (4) John C. Boyle in the wrongful death action. In

contrast, the government argues that there is only one claimant in this case: the patient, Mr. Boyle.

11. Section 15–32–210(2) of the South Carolina Code (titled "Definitions") states that **" '[c]laimant' means the person suffering personal injury."** *Id.* at § 15–32–210(2) (emphasis added).

12. Subsection (11) then defines "[p]ersonal injury" as the following: "injuries to the person **including, but not limited to, bodily injuries, mental distress or suffering, loss of wages, loss of service, loss of consortium, wrongful death, survival, and other noneconomic damages and actual economic damages.**" *Id.* at § 15–32–210(11) (emphasis added).

13. "Personal injury action" is defined as "an action for personal injury, including a wrongful death action pursuant to Sections 15–51–10 through 15–51–60 and a survival action pursuant to Section 15–5–90." *Id.* at § 15–32–210(12).

14. Subsection (9) provides that "[n]oneconomic damages" means "nonpecuniary damages arising from pain, suffering, inconvenience, physical impairment, disfigurement, mental anguish, emotional distress, loss of society and companionship, loss of consortium, injury to reputation, humiliation, other nonpecuniary damages, and any other theory of damages including, but not limited to, fear of loss, illness, or injury." *Id.* at § 15–32–210(9).

15. Although there is little guidance on how to construe the term "claimant" other than the statutory language itself, the Plaintiff provided the Court with a copy of an order issued on March 25, 2009, by South Carolina Circuit Court Judge John C. Hayes, III.[5] In his order, Judge Hayes discusses the Noneconomic Damages Awards Act of 2005 and states:

> The phrase "for each claimant" makes clear that the caps apply separately to each claimant. Therefore, if the caps apply separately for each claimant, it becomes necessary for a jury to award damages separately to each claimant.
>
> In addition, it is conceivable that a jury could determine that one claimant deserves a larger damage award than another claimant. For example, in a case where a mother and father are suing for the wrongful death of their child, a jury ***582** could award more damages to the mother than the father because the mother was more directly involved in the caring and support of each child.
>
> *Wilson v. Amisub of South Carolina, Inc., et al.,* Civil Action No. 06–CP–46–2891, Order dated March 25, 2009, Exhibit A at 4.

16. Ultimately, after a great deal of consideration, the Court agrees with the Plaintiff that this case involves four claimants rather than just one. Stated simply, the Court believes that the statutory language, including the definitions set forth above, requires such a finding. First, the statute makes clear that the number of causes of action is irrelevant. *See* S.C. Code Ann. § 15–32–220(A). Moreover, the statute caps damages for "each claimant" and not "the claimant." *Id.* Although claimant means "*the* person suffering personal injury," *id.* at § 15–32–210(2) (emphasis added), the definition of personal injury makes clear that not only does Mr. Boyle (or more accurately, his estate) qualify as a claimant pursuant to the survival statute, but also, Diane, Julie, and John each qualify as claimants pursuant to the wrongful death statute, as they each suffered personal injury, which is defined to include (and not limited to) "mental distress or suffering, loss of wages, loss of service, loss of consortium, wrongful death, survival, and other noneconomic damages and actual economic damages." *Id.* at § 15–32–210(11).

17. Having resolved the foregoing issue, the Court next determines the decedent's life expectancy. According to South Carolina Code Section 19–1–500, Mr. Boyle's life expectancy was an additional twelve years (12.01 years, in fact, which would have carried Mr. Boyle to age 83.82).

18. However, Dr. Michael P. Mayes, who personally treated Mr. Boyle from September 23, 2004, until January of 2006, testified that based on his medical history Mr. Boyle likely would have lived another eight to ten years if not for the apparent Prograf overdose.

19. In contrast, the government's expert witness in the field of nephrology and transplant medicine, Dr. Anil Chandraker, who did not treat Mr. Boyle, testified that Mr. Boyle likely would have lived another five years.

20. After thoroughly considering the evidence and testimony presented, the Court finds itself more persuaded by Dr. Mayes' testimony than by Dr. Chandraker's,

particularly in light of the fact that Dr. Mayes actually treated Mr. Boyle over a period of time. However, the Court notes that Dr. Chandraker presented compelling testimony regarding life expectancy studies of individuals with kidney transplants, and based in part on that information, the Court accepts the lower end of Dr. Mayes' suggested life expectancy rather than the middle or higher end. Therefore, the Court finds that Mr. Boyle had a life expectancy of eight years.

Damages in the Survival Action

21. After consideration, the Court finds that **Diane Boyle, the duly-appointed personal representative of the estate of Mr. Boyle, is entitled to $319,412.17 in economic damages in the survival action,** which consists of the following:

a. $3,952.10 for Mr. Boyle's hospitalization at the Hilton Head Regional Medical Center on February 2, 2006;

b. $37,410.83 for Mr. Boyle's hospitalization at the Hilton Head Regional Medical Center on February 19, 2006;

c. $22,305.40 for Mr. Boyle's hospitalization at the Hilton Head Regional Medical Center on March 19, 2006;

d. $202,131.34 for Mr. Boyle's hospitalization at Emory University Hospital;

***583** e. $49,259.00 for Mr. Boyle's treatment at the Emory Clinic; and

f. $4,353.50 in funeral expenses;

22. The estate of Mr. Boyle is entitled to recover for the non-economic damages suffered by Mr. Boyle between the time of the mis-fill on December 6, 2005, until the date of his death on April 28, 2006, to the extent that those non-economic damages are attributable to the mis-fill.

23. The Plaintiff presented evidence showing that, towards the end of Mr. Boyle's life, he suffered from diarrhea, acute renal failure, respiratory failure, volume overload, difficulty moving, and cellulitis, among other things. At one point, in a matter of three weeks, Mr. Boyle gained twenty-five to thirty pounds due to fluid retention. Mr. Boyle was hospitalized for a total of thirty-nine days between December 6, 2005, and April 28, 2006, and he was intubated and on a respirator for three weeks. Even after being taken off the intubator and put into hospice care, Mr. Boyle was on a morphine drip for twelve days. In all, the Court has no doubt that Mr. Boyle experienced a great deal of pain and suffering, for which the Court believes **the estate of Mr. Boyle is entitled to recover $250,000.00 in noneconomic damages in the survival action.**

Damages in the Wrongful Death Action

24. Diane Boyle, as a surviving spouse, and Julie and John, as surviving children, are the beneficiaries in the wrongful death action. The Court has carefully considered evidence in the record, including the testimony of the beneficiaries, and it is clear that they suffered a difficult loss.

25. With respect to the economic damages suffered by Diane Boyle, the Plaintiff presented the testimony and expert report of Dr. Oliver G. Wood, Jr., dated February 7, 2011. In this report, Dr. Wood used a life expectancy of nine years (the average of the eight-to-ten-year range testified to by Dr. Mayes) and came up with a total amount of economic loss of $501,148.00.

26. The Court has great respect for Dr. Wood's calculations; however, the Court is not fully convinced by these calculations for various reasons including the following. First, Dr. Wood relied on a life expectancy of nine years whereas this Court has found Mr. Boyle's life expectancy to be eight years. Second, Dr. Wood included a $12,000 variable supplement to Mr. Boyle's police retirement income as a yearly supplement without knowing whether the supplement was tied to market conditions or whether the supplement was to continue every year of Mr. Boyle's retirement. (*See* Entry 57 at 74–75.) Third, it is not clear whether the surviving spouse benefit that Diane Boyle receives ($11,076 per year as of the time of trial) comes from a collateral or a noncollateral source because the evidence does not indicate with any certainty whether or not Mr. Boyle's military pension was reduced actuarially to provide for the benefit.

I. ***The Surviving Spouse's Damages***

27. Ultimately, having started by considering Dr. Wood's computation of $501,148.00, and having considered certain factors that negatively affect that computation (such as the Court's finding of a reduced life expectancy as

well as the other concerns outlined in paragraph 25), the Court finds, based on all of the evidence presented, that **Diane Boyle is entitled to recover $375,000.00 in economic damages in the wrongful death action.**

28. Next, the Court finds that Diane, who has undoubtedly suffered a great loss, is entitled to **recover $400,000.00 in noneconomic damages in the wrongful death action.**

584 II.** ***The Surviving Children's Damages

29. Next, the Court finds that Julie and John, the surviving children of Mr. Boyle who also have suffered from the loss of their father, are **each entitled to $200,000.00 in noneconomic damages in the wrongful death action.**

CONCLUSION

Based on the foregoing, it is hereby

ORDERED that

(1) Diane Boyle, as the duly-appointed personal representative of the estate of Mr. Boyle, is entitled to $319,412.17 in economic damages and $250,000.00 in noneconomic damages in the survival action, to be reduced by twenty-five percent, which amounts to $239,559.13 in economic damages and $187,500.00 in noneconomic damages, together totaling **$427,059.13.**

(2) Diane Boyle, as the surviving spouse of Mr. Boyle, is entitled to $375,000.00 in economic damages and $400,000.00 in noneconomic damages in the wrongful death action, to be reduced by twenty-five percent, which amounts to $281,250.00 in economic damages and $300,000.00 in noneconomic damages, together totaling **$581,250.00.**

(3) Julie Boyle, as a surviving child of Mr. Boyle, is entitled to $200,000.00 in noneconomic damages in the wrongful death action, to be reduced by twenty-five percent, for a total of **$150,000.00.**

(4) John Boyle, as a surviving child of Mr. Boyle, is entitled to $200,000.00 in noneconomic damages in the wrongful death action, to be reduced by twenty-five percent, for a total of **$150,000.00.**

Altogether the total judgment in this case amounts to **$1,308,309.13.**

IT IS FURTHER ORDERED that the judgment shall bear the current statutory legal rate of interest from the date of the judgment until it is satisfied.

IT IS SO ORDERED.

EXHIBIT A

STATE OF SOUTH CAROLINA

IN THE COURT OF COMMON PLEAS

C.A. No.: 06–CP–46–2891

COUNTY OF YORK

Robin R. Wilson and Brice R. Wilson Individually and as Personal Representatives for the Estate of Sierra R. Wilson,

Plaintiffs,

vs.

ORDER

Amisub of South Carolina, Inc., d/b/a Piedmont Healthcare System and Piedmont Medical Center, and James R. Granger, III, M.D.,

Defendants.

This matter comes before the Court on five post-trial motions made by Defendant Amisub of South Carolina, Inc., d/b/a Piedmont ***585** Healthcare System and Piedmont Medical Center ("the Hospital"). This medical malpractice case was tried to verdict in front of the undersigned in York, South Carolina, during the February 9, 2009, Term of Common Pleas Court. Plaintiffs were awarded a total verdict in the amount of $4,405,000.00.[1] Plaintiffs were represented by Kenneth Suggs, Esq. and Gerald Jowers, Esq. Defendant Hospital was represented by William Gunn, Esq., and Defendant James R. Granger, III, M.D. ("Dr. Granger") was represented by Ashby Davis, Esq. and Collie Lehn, Esq. A hearing was heard on the motions in Union, South Carolina, by the undersigned on March 16, 2009. Plaintiff was represented by Kenneth Suggs, Esq., the Hospital was represented by William Gunn, Esq., and Ashby Davis, Esq. represented Dr. Granger. For the below reasons, the Court denies the Hospital's motions.

Motion for New Trial Based on the Thirteenth Juror Doctrine

In *Youmans ex rel. Elmore v. S.C. Dept. of Transp.,* 380 S.C. 263, 272, 670 S.E.2d 1, 5 (Ct.App.2008), the Court of Appeals recently explained the purposes of the thirteenth juror doctrine:

> The thirteenth juror doctrine is a vehicle by which the trial court may grant a new trial absolute when he finds that the evidence does not justify the verdict. This ruling has also been termed granting a new trial upon the facts. The effect is the same as if the jury failed to reach a verdict. The judge as the thirteenth juror "hangs" the jury. (*citing Folkens v. Hunt,* 300 S.C. 251, 254–55, 387 S.E.2d 265, 267 (1990)).

The *Youmans* Court also made clear that "[t]he 'thirteenth juror' doctrine is not used when the trial judge has found the verdict was inadequate or unduly liberal and, therefore, is not a vehicle to grant a new trial *nisi additur.*" *Bailey v. Peacock,* 318 S.C. 13, 14–15, 455 S.E.2d 690, 692 (1995). *Youmans* at 273, 670 S.E.2d 1.

This Court finds that the evidence presented at trial justifies the verdict and that the verdict is neither inconsistent nor a reflection of confusion by the jury. The interpretation and reporting of both the fetal monitor strips and the complete blood count (CBC) test formed the basis for Plaintiffs' theory of negligence. Plaintiffs' expert, Dr. Jeffery King, testified that the fetal monitor strips showed recurrent late decelerations, a sign, according to him, indicating placental insufficiency. While Defendants' witnesses and expert witnesses offered a different interpretation of the fetal monitor strips, it was for the jury to decide the weight and credibility to give to the differing testimony.

Similarly, it was for the jury to decide the weight and credibility to give to the testimony regarding the CBC test. Dr. Granger testified that he could not remember whether he had the CBC test results on November 16, 2003, but that this did not impact his treatment of Mrs. Wilson. Moreover, Dr. Granger's expert, Dr. Robert Arnett, testified that obstetricians may rely on the information given to them by nurses—in this case, the results from the fetal monitor and CBC tests—and that to do so is not a deviation from the standard of care. Based on this and other evidence and testimony offered at trial, the jury had

enough evidence to reach a verdict against the Hospital but not against Dr. Granger ***586** and such a verdict is justified by the evidence and is not inconsistent or illogical.

Motion for New Trial Based on the Verdict Form

Under Rule 59(a), SCRCP, a "new trial may be granted to all or any of the parties and on all or part of the issues (1) in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the State ...". The Hospital bases its first motion for new trial on the grounds that the Court erred in providing separate lines on the verdict form for Robin Wilson and Brice Wilson in the wrongful death cause of action. Instead, the Hospital argues the Court should have submitted a form with one line letting the probate court divide any verdict between the co-personal representatives.

Using separate lines on the verdict form complies with the South Carolina wrongful death statute and the statute regarding caps on noneconomic damages.[2] Section 15–51–40 of the wrongful death statute says that "the jury may give damages ... as they may think proportioned to the injury resulting from the death to the parties *respectively* for whom and for whose benefit such action shall be brought." S.C. Code Ann. § 15–51–40 (Rev. 2005) (emphasis added). That the legislature chose to use the word "respectively" indicates its desire to separate the amount of damages according to each claimant. *See Matter of Decker,* 322 S.C. 215, 219, 471 S.E.2d 462, 463 (1995) ("A statute should be so construed that no word, clause, sentence, provision or part shall be rendered surplusage, or superfluous ....") (citation omitted).

In addition, the statute dealing with caps on noneconomic damages, section 15–32–220(a), says

> [i]n an action on a medical malpractice claim when final judgment is rendered against a single health care provider, the limit of civil liability for noneconomic damages of the health care provider is limited to an amount not to exceed three hundred fifty thousand dollars *for each claimant,* regardless of the number of separate causes of action on which the claim is based, except as provided in subsection (E).

S.C. Code Ann. § 15–32–220(a) (Supp.2008) (emphasis added). The phrase "for each claimant" makes clear that the caps apply separately to each claimant. Therefore, if the caps apply separately for each claimant, it becomes necessary for a jury to award damages separately to each claimant.

In addition, it is conceivable that a jury could determine that one claimant deserves a larger damage award than another claimant. For example, in a case where a mother and father are suing for the wrongful death of their child, a jury could decide to award more damages to the mother than the father because the mother was more directly involved in the caring and support of the child. Such a possibility makes separate lines on a verdict form for each claimant appropriate and necessary.

*587 Motion for New Trial Based on the Court's Note to the Jury

The Hospital also argues the Court should grant a new trial because the Court erred in its response to a request from the jury to rehear the testimony of Nurse Lisa Reynolds and, instead, wrote a note to the jury answering its question.[3] In support of its argument, the Hospital cites Article V, § 21 of the South Carolina Constitution, which says that "[j]udges shall not charge juries in respect to matters of fact, but shall declare the law."

This Court does not believe its handling of the jury's question regarding Nurse Reynolds' testimony constitutes grounds for a new trial. The Court gave a completely accurate response to the question asked and only responded to the question asked. More importantly, the Court's response did not comment on the facts but, rather, simply stated what Nurse Reynolds had said. It would have been unfair to the Plaintiff to direct the jury to other testimony because such an emphasis from the Court might have been misconstrued by the jury.

Article V, § 21 of the Constitution deals with jury charges not responses to jury questions. If this Court were to apply Article V, § 21 as narrowly as the Hospital seems to want, then a judge would not be allowed to comment on a question from the jury requesting pens and paper

because such a comment would not deal with the law. Such a result is neither required nor contemplated under our Constitution.

The undersigned has adopted the philosophy/practice of responding to jury questions with specificity. That is, the jury poses a question, the Court answers *that* question. For the Court to broaden the jury's inquiry would, in the undersigned's opinion, interject the trial judge into the jury's analysis and deliberations. The Court would in essence be saying "well, you asked this, but don't you think you should consider this other thing also?" The undersigned believes to broaden the answer to a question beyond the question itself places the judge in the jury room as a thirteenth juror.

Finally, this Court's ruling on the jury's note must be considered in light of Rule 61, SCRCP. Rule 61 says that "... no error or defect in any ruling or order or anything done or omitted by the court ... is ground for granting a new trial ... unless refusal to take such action appears to the court inconsistent with substantial justice." Rule 61, SCRCP. Writing a completely accurate response to a jury's question is not inconsistent with substantial justice and did not prejudice the Hospital.

Motion for New Trial or in the Alternative New Trial *Nisi* (Excessive Verdict)

The Hospital makes its last motion for new trial on the grounds that the total verdict of $4,405,000.00 was excessive and based upon arbitrariness, capriciousness, passion, prejudice, or other considerations not found in the evidence. The Court disagrees.

"A new trial absolute should be granted only if the verdict is so grossly excessive that it shocks the conscience of the court and clearly indicates the amount of the verdict was the result of caprice, passion, prejudice, partiality, corruption, or other improper motive" *Knoke v. S.C. Dept. of* ***588** *Parks, Recreation, and Tourism,* 324 S.C. 136, 141, 478 S.E.2d 256, 258 (1996) (citations omitted). "[T]he circuit court alone has the power to grant a new trial *nisi* when it finds the amount of the verdict to be merely inadequate or excessive. *McCourt by and through McCourt v. Abernathy,* 318 S.C. 301, 308, 457 S.E.2d 603, 607 (1995). "Compelling reasons, however, must be given to justify invading the jury's province in this manner." *Bailey v. Peacock,* 318 S.C. 13, 14, 455 S.E.2d 690, 691 (1995)." *RRR, Inc. v. Toggas,* 378 S.C. 174, 183, 662 S.E.2d 438, 442–43 (Ct.App.2008).

The verdict in this case does not shock the conscience of the Court, and the verdict is not excessive. The decedent, Sierra Wilson, lived with substantial pain and suffering that supports a verdict in her survival action of $2,405,000.00 for her medical expenses and pain and suffering. Part of her pain and suffering included the seizures she experienced when she was only six hours old; kidney failure; the numerous operations she had; and the fact that she suffered from cerebral palsy. While the Defendants may disagree as to the cause and culpability of these problems, the jury returned a verdict against the Hospital and the Court must analyze the reasonableness and excessiveness of the verdict in light of the jury's determination of negligence.

Similarly, the jury's award of $1,000,000.00 each to Robin and Brice Wilson in their wrongful death action is not excessive and does not shock the conscience of the court. The jury's award was reasonable based on the evidence and testimony presented at trial regarding Robin and Brice's pain and suffering, including the fact that Sierra is the only child that Robin and Brice will be capable of having together since Robin was sterilized when Sierra was born.

Motion to Alter or Amend the Judgment by Reducing the Verdict

Pursuant to Rule 59(e), SCRCP, the Hospital moves the court to alter or amend the judgment by reducing the verdict. This issue is affected by the Court's ruling on Plaintiffs' motion regarding the constitutionality of the statutory caps on non-economic damages in medical malpractice causes of action. Based on the Order issued by this Court this date, the Court finds the statutory caps constitutional and reduces the verdict in accordance with § 15–32–220(A)–(F).

The caps require reducing each of the Wilson's award to $350,000.00 and then increasing or decreasing that amount based on the Consumer Price Index formula set forth in § 15–32–220(F). The Chief Economist at the State of South Carolina Board of Economic Advisors has informed the parties that applying subsection (F)

increases the caps to $386,650.00. Therefore, Robin Wilson's wrongful death verdict is reduced to $386,650.00 and Brice Wilson's wrongful death verdict is reduced to $386,650.00.

Wherefore, the Hospital's Motion for New Trial Based on the Thirteenth Juror Doctrine is DENIED; the Hospital's Motions for New Trial Based on the Verdict Form and the Court's Note to the Jury are DENIED; the Hospital's Motion for New Trial or in the Alternative New Trial *Nisi* is DENIED; and the Hospital's Motion to Alter or Amend the Judgment by Reducing the Verdict is GRANTED.

IT IS SO ORDERED.

John C. Hayes, III

Presiding Judge

***589** March 29th, 2009

York, South Carolina

All Citations

948 F.Supp.2d 577

Footnotes

1 The Plaintiff filed her amended complaint on April 13, 2009, alleging that her husband died of Tacrolimus toxicity and kidney failure due to the negligent, careless, and reckless filling and dispensing of her husband's medication by employees at the Beaufort Naval Hospital Pharmacy. (Entry 1 at 2.)

2 Following his transplant, Mr. Boyle was prescribed Tacrolimus (available under the brand name “Prograf”), which is an immunosuppressant medication that helps prevent a person's immune system from rejecting a transplanted organ. Prograf is available for oral administration as capsules in the following dosages: 0.5 milligram, 1 milligram, or 5 milligrams. The colors and sizes of 0.5–milligram capsules, 1–milligram capsules, and 5–milligram capsules are different, and they are distinguishable by sight. In addition, each capsule contains a marking identifying the dosage. Prograf is considered a narrow therapeutic index medication, which means there is a small margin of error in dosing and significant toxicity can result from a minor overdose.

3 To the extent that the Court has made “findings of fact” that would be better expressed as “conclusions of law,” and vice versa, each category is expressly incorporated into the other.

4 Subsection (F) includes a built-in inflation valve tied to the Consumer Price Index. *See* S.C. Code Ann. § 15–32–220(F). Taking into consideration this built-in inflation valve, the current maximum amount recoverable is $415,055.00.

5 Because it is not entirely clear from the docket whether a copy of this order was formally filed with one of the Plaintiff's briefs or memoranda, the Court attaches a copy of the order hereto as Exhibit A.

1 The jury found Dr. Granger not liable. The Plaintiffs have moved this Court to declare the statutory cap on noneconomic damages unconstitutional. That motion is not addressed in this Order.

2 The statute regarding noneconomic damages, section 15–32–220, was enacted by 2005 Act No. 32, which says “this act takes effect July 1,2005, for causes of action arising after July 1, 2005.” Therefore, the caps do not apply to the damages awarded in Sierra Wilson's survival action because that action arose on November 18, 2003. Assuming for the moment that they are constitutional, the caps do apply to the wrongful death claim, which arose in February 2008; therefore, this Court must comply with the language in that section.

3 The jury's question was “[m]ay we hear Ms. Reynolds' testimony of what she reported to the doctor about the NST/CST results?” The Court's response was “[w]e have examined the testimony of Ms. Reynolds and she testified that she could not recall what she reported to Dr. Granger.”

Chastain v. AnMed

THE STATE OF SOUTH CAROLINA
In The Supreme Court

Phillip Chastain, as Personal Representative of the Estate of Ruth Chastain Appellant,

v.

AnMed Health Foundation, a/k/a Anderson Area Medical Center, Inc., Jennifer Wright, RN, Cindy Wilson, RN, Janet Kincaid, RN, Marilyn Crawford, RN, Kris Burris, RN and Kristina Goldsmith, RN, Respondents.

Appeal from Anderson County
Alison Renee Lee, Circuit Court Judge

Opinion No. 26829
Heard April 7, 2010 – Filed June 14, 2010

AFFIRMED

Joseph G. Wright, III, and Chad A. McGowan, both of McGowan, Hood and Felder, of Anderson, and F. Patrick Hubbard, of Columbia, for Appellant.

Andrew F. Lindemann, of Davidson & Lindemann, of Columbia, Attorney General Henry Dargan McMaster, and Assistant Deputy Attorney General J. Emory Smith, both of Columbia, and V. Clark Price and Fred W. Suggs, III, both of Greenville, for Respondents.

PER CURIAM: Appellant Ruth Chastain appeals orders reducing her verdict against respondent AnMed to $300,000 pursuant to a statutory cap and upholding the constitutionality of that cap. On appeal, she challenges the decision to reduce the verdict and also argues that the statutory caps violate several constitutional provisions. We affirm.

FACTS

Appellant was hospitalized for circulatory problems at AnMed where she was under the care of the six defendant nurses. Appellant's left leg was eventually amputated while she was at AnMed,[1] and she developed a sacral pressure sore. Appellant's condition worsened, and at her family's request she was transferred to another medical facility shortly after her pressure sore was surgically debrided at AnMed. When appellant arrived at the second facility her extremely large infected sore was classified as Stage

IV, the most severe stage. Appellant remained at the second facility for eight and a half months, and then spent the next 316 days in other medical facilities.

Appellant brought this medical malpractice suit against AnMed, a charitable institution, and the six nurses. The jury returned a verdict for appellant against AnMed for $2.2 million dollars, and found appellant was 30% at fault. Since the jury found none of the nurses guilty of "reckless, wilful, or grossly negligent" care, they were not found individually liable. See S.C. Code Ann. § 33-56-180(A) (2006) (employee of charitable organization individually liable only for gross negligence).

The trial judge reduced the jury verdict to $1.54 million to reflect appellant's contributory negligence. AnMed moved to reduce the verdict to $300,000 pursuant to a statutory cap. Appellant opposed the motion, arguing the cap did not apply and/or that such a reduction would be unconstitutional. The trial judge granted AnMed's motion and reduced the verdict to $300,000. After appellant's post-trial motion was denied, she filed this appeal.

AnMed is a charitable organization under the "South Carolina Solicitation of Charitable Funds Act," S.C. Code Ann. §§ 33-56-10 to -200 (2006) (CFA). Section 33-56-180(A) provides:

A person sustaining an injury or dying by reason of the tortious act of commission or omission of an employee of a charitable organization, when the employee is acting within the scope of his employment, may recover in an action brought against the charitable organization only the actual damages he sustains in an amount not exceeding the limitations on liability imposed in the South Carolina Tort Claims Act in Chapter 78 of Title 15. An action against the charitable organization pursuant to this section constitutes a complete bar to any recovery by the claimant, by reason of the same subject matter, against the employee of the charitable organization whose act or omission gave rise to the claim unless it is alleged and proved in the action that the employee acted in a reckless, willful, or grossly negligent manner, and the employee must be joined properly as a party defendant. A judgment against an employee of a charitable organization may not be returned unless a specific finding is made that the employee acted in a reckless, willful, or grossly negligent manner. If the charitable organization for which the employee was acting cannot be determined at the time the action is instituted, the plaintiff may name as a party defendant the employee, and the entity for which the employee was acting must be added or substituted as party defendant when it reasonably can be determined.

Under the Tort Claims Act (TCA), recovery for an individual plaintiff is limited to $300,000 per occurrence, unless the tort-feasor is a licensed physician or dentist in which case the cap for an individual plaintiff is $1.2 million per occurrence. S.C. Code Ann. §§ 15-78-120(a)(1) and (a)(3) (2005). "Occurrence" is defined in the TCA as "an unfolding sequence of events which proximately flow from a single act of negligence." § 15-78-30(g).

ISSUES

1) Did the trial judge err in reducing the verdict from $1.54 million to $300,000?
2) Does the statutory limitation on appellant's recovery violate the equal protection clauses, the right to trial by jury, the right to a speedy remedy, or the constitutional requirement of separation of powers?

ANALYSIS

1. Verdict Reduction

The trial judge reduced appellant's recovery to $300,000, finding there was only one "occurrence" and thus § 15-78-120(a)(1) operated to reduce the award pursuant to § 33-56-180(A) ("actual damages…in an amount not exceeding the limitations on liability imposed in [§ 15-78-120]"). The trial judge reasoned the intent of the CFA was to limit the amount of damages recoverable from a charitable organization, and that to read the term "'occurrence' to include every incident where the defendant nurses violated the applicable standard of care[2] would clearly defeat the legislature's [intent]. . . . " Alternatively, the judge held that based on the jury charge and verdict form, it was impossible to determine the number of negligent acts or negligent nurses found by the jury and thus only one recovery was appropriate.

On appeal, appellant challenges both grounds. We find it necessary to uphold only one ground in order to affirm the trial judge's decision to reduce the verdict. E.g., South Carolina Dist. Council of Assemblies of God v. River of Life Internat'l Worship Center, 372 S.C. 581, 643 S.E.2d 104 (Ct. App. 2007). We hold that the general jury verdict supports the trial judge's decision, and affirm.

In her post-trial order, the judge gave as one reason for reducing appellant's award the impossibility of determining from the jury instruction and verdict forms whether the jury found one or more than one nurse had rendered negligent care to appellant. Thus, she held, it was impossible to conclude that the jury had found more than one occurrence. Appellant now contends that AnMed bore the burden of proving there was only one occurrence. We disagree.

Just as in any tort action, a CFA plaintiff bears the burden of proof. If she alleges multiple occurrences, that is, that there was more than one single act of negligence from which proximately flowed an unfolding sequence of events, she bears the burden of proving each occurrence. Here, the jury was never instructed on the definition of occurrence nor was it asked to determine whether there was more than one occurrence, either in the instructions or in its verdict. The trial judge correctly reformed this verdict to reflect a single occurrence.

2. Constitutional Challenges

Appellant contends that application of the $300,000 cap to her recovery violates the equal protection clauses of the state and federal constitutions, her right to trial by jury,[3] her right to a speedy remedy,[4] and the constitutional requirement of separation of powers.[5] We granted appellant's petition to argue against certain precedents which have decided these issues adversely to her position. After careful consideration, we adhere to those precedents and affirm the trial court's ruling upholding the cap's constitutionality pursuant to Doe v. Am. Red Cross Blood Servs., 297 S.C. 430, 377 S.E.2d 323 (1984) (upholding predecessor charitable immunity statutory cap against equal protection challenge); Wright v. Colleton County Sch. Dist., 301 S.C. 282, 391 S.E.2d 564 (1990) (rejecting equal protection, jury trial, speedy remedy, and separation of powers challenges to TCA caps); Foster v. S.C. Dep't of Highways & Pub. Transp., 306 S.C. 519, 413 S.E.2d 31 (1992) (differential medical caps constitutional); Giannini v. S.C. Dep't of Transp., 378 S.C. 573, 664 S.E.2d 450 (2008) (limits on recovery for governmental tort victims do not violate equal protection).

Conclusion

The circuit court's orders reducing appellant's verdict to $ 300,000 and denying appellant's constitutional challenges are

AFFIRMED.

TOAL, C.J., PLEICONES, BEATTY, KITTREDGE and HEARN, JJ., concur.

[1] Her right leg had been amputated above the knee in 1996.

[2] Appellant's expert testified to 2,372 deviations from the standard of care.

[3] S.C. Const. art I, § 14.

[4] S.C. Const. art. I, § 9.

[5] S.C. Const. art. I, § 8.

142 S.W.3d 880
Missouri Court of Appeals,
Western District,
En Banc.

Clarence COOK, et al., Respondents,
v.
Joseph NEWMAN, M.D., et al., Appellants,
Alan Buchele M.D. and Alan Buchele M.D., P.C., Defendants.

No. WD 62634.
|
July 27, 2004.
|
Motion for Rehearing and/or Transfer to Supreme Court Denied Aug. 31, 2004.
|
Application for Transfer Denied Sept. 28, 2004.

Synopsis

Background: Patient's relatives brought medical malpractice action against doctors and medical clinic. The Circuit Court, Jackson County, Justine Elisa Del Muro, J., entered judgment on jury verdicts in favor of relatives, and doctors and clinic appealed.

Holdings: The Court of Appeals, Robert G. Ulrich, J., held that:

[1] even though patient's surviving husband and two children were entitled to recover damages for her wrongful death, together they were considered one "plaintiff" within meaning of statute providing that, in any action against a health care provider for damages for personal injury or death arising out of the rendering of or the failure to render health care services, no "plaintiff" shall recover more than three hundred fifty thousand dollars per occurrence for noneconomic damages from any one defendant;

[2] there were two "occurrences" within meaning of statute, and these two occurrences were the separate and distinct acts of negligence of the two doctors; and

[3] medical clinic and doctors each constituted a separate "defendant" within meaning of statute.

Reversed and remanded.

West Headnotes (30)

[1] Appeal and Error
Statutory or legislative law

The interpretation of a statute is a question of law, and therefore, appellate review is de novo.

2 Cases that cite this headnote

[2] Statutes
Language and intent, will, purpose, or policy

Statutes
Plain Language;Plain, Ordinary, or Common Meaning

The primary rule in statutory construction is to ascertain the intent of the legislature from the language used, to give effect to that intent if possible, and to consider the words in their plain and ordinary meaning.

5 Cases that cite this headnote

[3] Statutes
What constitutes ambiguity;how determined

When the legislative intent cannot be ascertained from the language of the statute, by giving it its plain and ordinary meaning, the statute is considered ambiguous.

2 Cases that cite this headnote

[4] Statutes

What constitutes ambiguity;how determined

"Ambiguity," in context of statutory interpretation, means duplicity, indistinctness or uncertainty of meaning of an expression.

Cases that cite this headnote

[5] **Statutes**

Clarity and Ambiguity;Multiple Meanings

The issue is not whether a particular word in a statute, considered in isolation, is ambiguous, but, rather, whether the statute itself is ambiguous.

1 Cases that cite this headnote

[6] **Statutes**

Context

The meaning of a particular word must be considered in the context of the entire statute in which it appears.

1 Cases that cite this headnote

[7] **Statutes**

Clarity and Ambiguity;Multiple Meanings

Only when a statute is ambiguous can the rules of statutory construction be applied.

Cases that cite this headnote

[8] **Statutes**

Purpose and intent;determination thereof

In construing an ambiguous statute, the ultimate guide is the intent of the legislature.

Cases that cite this headnote

[9] **Health**

Wrongful death

Even though patient's surviving husband and two children were entitled to recover damages for her wrongful death, together they were considered one "plaintiff" within meaning of statute providing that, in any action against a health care provider for damages for personal injury or death arising out of the rendering of or the failure to render health care services, no "plaintiff" shall recover more than three hundred fifty thousand dollars per occurrence for noneconomic damages from any one defendant. V.A.M.S. § 538.210.

Cases that cite this headnote

[10] **Statutes**

Construction based on multiple factors

Statutes

In general;factors considered

Statutes

Extrinsic Aids to Construction

Statutes

Contemporary and Historical Circumstances

Statutes

History of statute

Only when a statute's language is ambiguous or uncertain or if its plain meaning would lead to an illogical result will extrinsic matters, such as the statute's history, surrounding circumstances and objectives to be accomplished through the statute, be considered.

Cases that cite this headnote

[11] **Health**

Statutory Limits on Damages Awards

With the enactment of statute directing that no medical malpractice plaintiff shall recover more than a limited amount per occurrence for noneconomic damages, the legislature intended to impose a specific limitation on tort claims against health care providers to temper the high cost of health care. V.A.M.S. § 538.210.

Cases that cite this headnote

[12] **Statutes**

Similar or related statutes

A presumption exists that the legislature acts with the knowledge of statutes involving similar or related subject matters.

Cases that cite this headnote

[13] Statutes

Prior or existing law in general

Presumably, legislature is aware of the state of the law at the time it enacts a statute.

1 Cases that cite this headnote

[14] Health

Wrongful death

There were two "occurrences" within meaning of statute providing that, in any action against health care provider for damages for personal injury or death arising out of rendering of or failure to render health care services, no plaintiff shall recover more than three hundred fifty thousand dollars per "occurrence" for noneconomic damages from any one defendant, and these two occurrences were the separate and distinct acts of negligence of the two doctors; each act was independent act of negligence committed by each doctor that contributed to cause patient's death, and each doctor was a defendant within meaning of statute. V.A.M.S. § 538.210.

Cases that cite this headnote

[15] Statutes

Legislative Construction

When the legislature enacts a statute referring to terms that have had other judicial or legislative meanings attached to them, a presumption exists that it acts with knowledge of that judicial or legislative action.

Cases that cite this headnote

[16] Damages

Mode of estimating compensatory damages in general

The term "occurrence," as used in instruction for personal and property damages, refers to the defendant's wrongful act. MAI No. 4.01.

Cases that cite this headnote

[17] Health

Wrongful death

Medical clinic and doctors each constituted a separate "defendant" within meaning of statute providing that, in any action against a health care provider for damages for personal injury or death arising out of the rendering of or the failure to render health care services, no plaintiff shall recover more than three hundred fifty thousand dollars per occurrence for noneconomic damages from any one defendant; legislature did not intend for health care provider to include its employed physicians for purposes of defining "defendant" under noneconomic damages cap statute. V.A.M.S. § 538.210.

1 Cases that cite this headnote

[18] Statutes

Construing together;harmony

One rule of statutory construction is that the provisions of a statute are not read in isolation but construed together, and if reasonably possible, the provisions are harmonized with each other.

Cases that cite this headnote

[19] Statutes

Similarity or difference

Presumably, a word has the same meaning in every place used within a statute.

2 Cases that cite this headnote

[20] Statutes

Similarity or difference

When different terms are used in different subsections of a statute, presumably, the legislature intended the terms to have different meaning and effect.

3 Cases that cite this headnote

[21] Statutes

Giving effect to entire statute and its parts;harmony and superfluousness

Presumably, the legislature intends that every word, clause, sentence, and provision of a statute have effect.

3 Cases that cite this headnote

[22] Statutes

Giving effect to entire statute and its parts;harmony and superfluousness

A presumption exists that the legislature does not insert idle verbiage or superfluous language in statute.

4 Cases that cite this headnote

[23] Health

Statutory Limits on Damages Awards

Legislature did not intend the term "employees" to include physicians as that term was used in statute limiting noneconomic damages recoverable in tort action against defendant based on improper health care and defining "defendant" as any other health care provider having the legal capacity to sue and be sued and who is not included in other subdivisions, including "employees" of any health care providers who are insured under the health care provider's professional liability insurance policy; in other words, legislature did not intend for health care provider to include its employed physicians for purposes of defining "defendant" under noneconomic damages cap statute. V.A.M.S. § 538.210, subd. 2.

2 Cases that cite this headnote

[24] Health

Wrongful death

Applicable noneconomic damages cap amount in medical malpractice case was $547,000, which was the cap amount in effect at time of trial; noneconomic damages cap statute was not amended between time of negligent acts that caused patient's death and time of trial, statute provided cap on noneconomic damages in malpractice action and for yearly increase or decrease in cap amount in accordance with economic index, malpractice cause of action arose after enactment of statute, and thus, in sense that legislature did not enact a statute during life of this cause of action, constitutional article providing that no ex post facto law nor law impairing obligations of contracts nor retrospective in its operation shall be enacted was inapplicable. V.A.M.S. Const. Art. 1, § 13; V.A.M.S. § 538.210.

1 Cases that cite this headnote

[25] Statutes

Power to enact;validity

The underlying repugnance to the retrospective application of laws is that an act or transaction, to which certain legal effects were ascribed at the time they transpired, should not, without cogent reasons, thereafter be subject to a different set of effects which alter the rights and liabilities of the parties thereto.

Cases that cite this headnote

[26] Statutes

Language and Intent;Express Provisions

Statutes

Effect on substantive rights

Statutory provisions that are substantive are generally presumed to operate prospectively unless the legislative intent that they be given retroactive operation clearly appears from the express language of the act or by necessary or unavoidable implication, and "substantive law" creates, defines and regulates rights.

4 Cases that cite this headnote

[27] Statutes

Remedies and Remedial Statutes

Statutes

Procedural Statutes

Statutory provisions that are remedial or procedural operate retrospectively unless the legislature expressly states otherwise, and "procedural law" prescribes a method of enforcing rights or obtaining redress for their invasion.

3 Cases that cite this headnote

[28] **Statutes**

Effect on substantive rights

Statutes

Procedural Statutes

The distinction between substantive law and procedural law is that substantive law relates to the rights and duties giving rise to the cause of action, while procedural law is the machinery used for carrying on the suit, for purposes of principle that substantive statutory provisions operate prospectively and procedural provisions operate retrospectively.

3 Cases that cite this headnote

[29] **Statutes**

Prospective or Retroactive Construction

When determining whether statute applies retrospectively, it is not sufficient merely to label certain consequences as substantive and others as procedural; notions of justice and fair play in a particular case are always germane.

Cases that cite this headnote

[30] **Health**

Statutory Limits on Damages Awards

Statutory noneconomic damages cap for actions against a health care provider was enacted to maintain the integrity of health care for all Missourians by limiting the liability of health care providers for noneconomic damages caused by their acts of medical malpractice. V.A.M.S. § 538.210.

Cases that cite this headnote

Attorneys and Law Firms

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Before JOSEPH M. ELLIS, C.J., HAROLD L. LOWENSTEIN, ROBERT G. ULRICH, PAUL M. SPINDEN, JAMES M. SMART, JR., EDWIN H. SMITH, VICTOR HOWARD, THOMAS H. NEWTON, RONALD R. HOLLIGER, LISA WHITE HARDWICK, JJ., and WILLIAM E. TURNAGE, SR. J.

Opinion

ROBERT G. ULRICH, Judge.

Joseph Newman, M.D., Walter Dandridge, Jr., M.D., and Joplin Surgical Associates, Inc. ("JSA")(collectively "Appellants") appeal the trial court's amended judgment entered upon jury verdict in favor of Clarence Cook, Clarence Cook, Jr., and Eugenia White (collectively "Respondents") in the amount of $7,281,886.30 in this medical malpractice action. This appeal involves section 538.210, [1] which limits the recovery for noneconomic damages from a defendant ("cap"). Appellants claim that the trial court erred in calculating the number of statutory caps on noneconomic damages to be applied in the case. Appellants also claim that the trial court erred in applying the cap amount in effect at the time of trial rather than the cap amount in effect at the time of the occurrence. The judgment of the trial court is reversed, and the case is remanded with directions.

Facts

In July 2000, Respondents filed this medical malpractice action against Appellants for the wrongful death of Ruth Cook, their spouse and mother. They alleged that Ms. Cook underwent a laparoscopic cholecystectomy on April 6, 1998, and that as a result of Dr. Newman's and Dr. Dandridge's negligent care of her, she developed symptoms of peritonitis and died on June 17, 1998. [2]

The verdict director against Dr. Newman and JSA directed the jury to find for Respondents if it believed:

> First, either:
>
> defendant Joseph Newman, M.D. injured Ruth Cook's duodenum while performing a laparoscopic cholecystectomy on April 6, 1998, or,
>
> defendant Joseph Newman, M.D. failed to inspect and test for injury to Ruth Cook's duodenum during the laparoscopic cholecystectomy on April 6, 1998, or,
>
> ***885** defendant Joseph Newman, M.D. failed to timely repair Ruth Cook's duodenum after the laparoscopic cholecystectomy on April 6, 1998, or
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> defendant Joseph Newman, M.D. failed to adequately repair Ruth Cook's duodenum during the surgery performed on April 7, 1998, or
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> defendant Joseph Newman, M.D. failed to order diagnostic testing to determine the adequacy of the April 7, 1998 repair, or,
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> defendant Joseph Newman, M.D. failed to reoperate on Ruth Cook after April 7, 1998.

Furthermore, to return a verdict for Respondents, the jury was required to find that Dr. Newman was negligent in any one or more of the respects submitted and that such negligence directly caused or directly contributed to cause the death of Ruth Cook.

The verdict director against Dr. Dandridge and JSA directed the jury to find for Respondents if it believed:

> First, defendant Walter C. Dandridge, M.D. failed to test or reoperate or recommend reoperation or testing to determine the adequacy of the April 7, 1998 repair on April 16th, or April 25th, or April 26th, or May 14th, or May 15th, or June 2nd, or June 9th, or June 14th, 1998, when he provided care to Ruth Cook.

Furthermore, to return a verdict for Respondents, the jury was required to find that Dr. Dandridge was negligent in any one or more of the respects submitted and that such negligence directly caused or directly contributed to cause the death of Ruth Cook.

The jury returned verdicts in favor of Respondents on the claim against Dr. Newman and JSA and on the claim against Dr. Dandridge and JSA. It awarded Respondents past economic damages in the amount of $717,886.31 and past and future noneconomic damages in the amount of $7,282,113.69 for total damages in the amount of $8,000,000. The trial court entered judgment in favor of Respondents in accordance with the jury's verdict.

Thereafter, Appellants filed their motion for judgment notwithstanding the verdict or, in the alternative, for new trial or, in the alternative, to modify the judgment. In their post-trial motion, Appellants contended, in pertinent part, that the judgment amount should be reduced to $1,230,886.31 to reflect the sum of the economic damages assessed by the jury together with one cap amount for noneconomic damages pursuant to section 538.210. They argued that the appropriate maximum awarded for noneconomic damages should be calculated on the basis that the three persons joining in the wrongful death action constitute one plaintiff; only one occurrence was determined by the jury, that being the death of Ruth Cook; Dr. Newman, Dr. Dandridge, and JSA constitute one defendant as the term "defendant" is defined in section 538.210; and the applicable cap amount for events that occurred in 1998 is $513,000. Appellants attached to their post-trial motion an affidavit of Dr. Newman stating that at all times referenced in the petition, JSA was a Missouri corporation; at all such times, JSA was engaged in the business of providing health care services, by and through licensed medical practitioners (including Dr. Newman and Dr. Dandridge); at all times from April 6, 1998, Dr. Newman and Dr. Dandridge were employed by JSA; and at all times from April 6, 1998, Dr. Newman and Dr. Dandridge were insured under a professional liability insurance policy issued to JSA.

Following a hearing on the post-trial motion, the trial court entered an order ***886** declaring that each of the three persons joining in the wrongful death action constitute a plaintiff as that term is used in section 538.210; cap amounts shall be awarded for two occurrences because the jury returned verdicts against Dr. Newman and JSA and against Dr. Dandridge and JSA for separate and distinct acts of negligence; JSA, Dr. Newman, and Dr. Dandridge constitute separate defendants under section

538.210; and the applicable cap amount is $547,000, the amount in effect at the time of the verdict, which was greater than the cap amount at the time of the occurrences for which suit was filed. The court, therefore, concluded that Respondents shall collect noneconomic damages equal to twelve cap amounts. The same day, the trial court entered its amended judgment reducing noneconomic damages to $6,564,000 for total damages in the amount of $7,281,886.30. It also allocated the proceeds of the judgment after attorneys' fees and expenses at 50% to Clarence Cook, 25% to Clarence Cook, Jr., and 25% to Eugenia White. This appeal by Drs. Newman and Dandridge and JSA followed.

Standard of Review

[1] [2] [3] [4] [5] [6] [7] [8] Appellants' appeal asserts that the trial court misinterpreted and misapplied section 538.210. The interpretation of a statute is a question of law; therefore, appellate review is de novo. *Knob Noster Educ. v. Knob Noster R–VIII Sch. Dist.,* 101 S.W.3d 356, 360 (Mo.App. W.D.2003). The primary rule in statutory construction is to ascertain the intent of the legislature from the language used, to give effect to that intent if possible, and to consider the words in their plain and ordinary meaning. *Landman v. Ice Cream Specialties, Inc.,* 107 S.W.3d 240, 251 (Mo. banc 2003), *overruled on other grounds by Hampton v. Big Boy Steel Erection,* 121 S.W.3d 220 (Mo. banc 2003). When the legislative intent cannot be ascertained from the language of the statute, by giving it its plain and ordinary meaning, the statute is considered ambiguous. *Stotts v. Progressive Classic Ins. Co.,* 118 S.W.3d 655, 664 (Mo.App. W.D.2003)(*quoting Ozark Wholesale Beverage Co. v. Supervisor of Liquor Control,* 80 S.W.3d 491, 497 (Mo.App. W.D.2002)). Ambiguity means "duplicity, indistinctness or uncertainty of meaning of an expression." *J.B. Vending Co. v. Dir. of Revenue,* 54 S.W.3d 183, 188 (Mo. banc 2001)(quoting *Lehr v. Collier,* 909 S.W.2d 717, 721 (Mo.App. S.D.1995)). "The issue is not whether a particular word in a statute, considered in isolation, is ambiguous, but whether the statute itself is ambiguous." *Id.* at 187. Thus, the meaning of a particular word must be considered in the context of the entire statute in which it appears. *Id.* Only when a statute is ambiguous can the rules of statutory construction be applied. *Stotts,* 118 S.W.3d at 664 (quoting *Ozark Wholesale Beverage,* 80 S.W.3d at 497). "In construing an ambiguous statute, the ultimate guide is the intent of the legislature." *Long v. Interstate Ready–Mix, L.L.C.,* 83 S.W.3d 571, 577 (Mo.App. W.D.2002)(quoting *Lincoln Indus., Inc. v. Dir. of Revenue,* 51 S.W.3d 462, 465 (Mo. banc 2001)).

Plaintiffs

[9] In the first point addressed in this appeal,[3] Appellants claim that the trial court erred in determining that Clarence Cook, Clarence Cook, Jr., and Eugenia White each constitute a plaintiff for purposes of applying the statutory cap for noneconomic damages under section 538.210. They contend that all the wrongful death claim beneficiaries constitute a ***887** single plaintiff within the meaning of section 538.210.

Section 538.210.1 provides:

> In any action against a health care provider for damages for personal injury or death arising out of the rendering of or the failure to render health care services, no plaintiff shall recover more than three hundred fifty thousand dollars per occurrence for noneconomic damages from any one defendant as defendant is defined in subsection 2 of this section.

Chapter 538 does not, however, define the term "plaintiff." Respondents argue that the term should, therefore, be construed according to its plain and ordinary meaning citing *Wright v. Barr,* 62 S.W.3d 509, 536 (Mo.App. W.D.2001).

In *Wright,* Virginia Wright filed a medical malpractice action against a physician and his cardiology practice after the physician's alleged negligent treatment of her atrial fibrillation causing her to suffer a stroke. *Id.* at 515. Her husband sued for loss of consortium. *Id.* The jury returned a verdict in favor of the Wrights. *Id.* at 523. One issue on appeal was the number of plaintiffs for purposes of the statutory noneconomic damages cap, section 538.210. The physician and cardiology practice urged that because Mr. Wright's consortium claim was derivative of Mrs. Wright's claim, the Wrights collectively constituted one plaintiff under section 538.210. *Id.* at 535.

This court found that the term "plaintiff" was unambiguous, meaning a person who brings a lawsuit or a party who complains or sues in a civil action; therefore, looking for the definition of "plaintiff" beyond the plain and ordinary meaning of the statute was unnecessary. *Id.* at 536. Because Mr. Wright's claim of loss of consortium was a separate personal injury claim from his wife's negligence claim, this court found that Mr. Wright was a second plaintiff. *Id.* at 537. This case, however, is distinguishable from *Wright.* Unlike *Wright,* the underlying action in this case is a wrongful death action. Under the wrongful death statute, the surviving spouse, children, parents, or others named in the statute may sue for damages for the wrongful death of the decedent. § 537.080.1. Only one action, however, may be brought under section 537.080 against any one defendant for the death of any one person. § 537.080.2. Thus, the term "plaintiff" in section 538.210 is ambiguous when considered in the context of a wrongful death action.

[10] **[11]** Only when a statute's language is ambiguous or uncertain or if its plain meaning would lead to an illogical result will extrinsic matters, such as the statute's history, surrounding circumstances and objectives to be accomplished through the statute, be considered. *Riordan v. Clark,* 67 S.W.3d 610, 613 (Mo.App. W.D.2001)(quoting *Riordan v. Clark,* 8 S.W.3d 182, 184 (Mo.App. W.D.1999)); *Wright,* 62 S.W.3d at 536. Accordingly, the legislature's intent in adopting section 538.210 is considered. The Supreme Court held in *Mahoney v. Doerhoff Surgical Services, Inc.,* 807 S.W.2d 503, 507 (Mo. banc 1991), that Chapter 538 is "a legislative response to the public concern over the increased cost of health care and the continued integrity of that system of essential services." With the enactment of section 538.210, which directs that "no plaintiff shall recover more than" a limited amount per occurrence for noneconomic damages, the legislature intended to impose a specific limitation on tort claims against health care providers to temper the high cost of health care. *Burns v. Elk River Ambulance, Inc.,* 55 S.W.3d 466, 486 (Mo.App. S.D.2001).

***888** **[12]** **[13]** Additionally, a presumption exists that the legislature acts with the knowledge of statutes involving similar or related subject matters. *Id.* Presumably, it is also aware of the state of the law at the time it enacts a statute. *Id.* At the time Chapter 538 was enacted, the wrongful death statute identified those persons entitled to sue and recover damages for a wrongful death, namely the surviving spouse, children, parents, or others named in the statute. § 537.080.1. It provided, however, that "[o]nly one action may be brought under this section against any one defendant for the death of any one person." § 537.080.2. Thus, the wrongful death statute provided that any one plaintiff could settle the claim for damages or maintain such suit and recover such damages without joinder therein by any other person entitled to recover damages, § 537.095.1, and that a recovery by any one plaintiff shall be apportioned by the court according to the laws of descent or in proportion to the losses suffered by each person entitled to share in the proceeds. § 537.095.2. In interpreting these statutes, the Missouri Supreme Court has said, "The wrongful death statute creates but one indivisible cause of action which remains the same whether enforceable by the surviving spouse, by the minor child or children, or by the others named in the statute." *Nelms v. Bright,* 299 S.W.2d 483, 487 (Mo. banc 1957). Knowing that the wrongful death statute created an indivisible cause of action enforceable by one or more persons, the legislature chose not to increase the noneconomic damages cap where more than one person brings a wrongful death action.

Such was the analysis in *Burns v. Elk River Ambulance, Inc.,* 55 S.W.3d 466, 486–87 (Mo.App. S.D.2001), where the Southern District applied one statutory cap for noneconomic damages even though two people were entitled to recover for the wrongful death of the decedent, his mother and father. After discussing the legislature's intent in adopting various provisions of Chapter 538 and the wrongful death statute and case law interpreting it, the Southern District explained:

> If Plaintiff's argument [that two caps should have been applied] is accepted, a widow could sue for her husband's death and recover a separate cap for herself and each of the couple's six children. This interpretation does not further the legislative goal of harnessing increasing health care costs nor does it square with the legislature's awareness of the application of § 537.080 when chapter 538 was enacted.

Id.

In this case, even though Ms. Cook's surviving husband and two children are entitled to recover damages for her wrongful death, together they are considered one plaintiff for the purposes of section 538.210. The point is granted. [4]

Occurrences

[14] In the second point addressed in this appeal, Appellants claim that the trial ***889** court erred in determining that each of the separate and distinct acts of negligence of Dr. Newman and Dr. Dandridge found by the jury constituted a distinct actionable occurrence for purposes of section 538.210. Again, section 538.210.1 provides:

> In any action against a health care provider for damages for personal injury or death arising out of the rendering of or the failure to render health care services, no plaintiff shall recover more than three hundred fifty thousand dollars *per occurrence* for noneconomic damages from any one defendant as defendant is defined in subsection 2 of this section. (emphasis added).

Appellants contend that the term "occurrence" refers to the injurious consequences of acts, i.e. the wrongful death of Ruth Cook, rather than the acts themselves; therefore, the noneconomic damages maximum should have been calculated on the basis of a single occurrence.

The term "occurrence" as used in section 538.210.1 is not defined. And the meaning of "occurrence" as used in section 538.210.1 is not clear and unambiguous. *Scott v. SSM Healthcare St. Louis,* 70 S.W.3d 560, 570 (Mo.App. E.D.2002). The term could plausibly be interpreted as either the harm plaintiff has sustained or the act of medical negligence causing that harm. *Id.* The statutory meaning must, therefore, be construed with the aid of rules of construction. *Id.*

Appellant's contention that the term "occurrence" refers to the injurious consequences of acts was expressly rejected in *Scott v. SSM Healthcare St. Louis,* 70 S.W.3d 560 (Mo.App. E.D.2002). In *Scott,* plaintiff filed a medical malpractice action against a hospital asserting vicarious liability based on the conduct of two of its physicians for injuries suffered when a sinus infection was misdiagnosed and spread to his brain. *Id.* at 563. In particular, plaintiff alleged that one physician misread a CT scan and the other physician failed to instruct plaintiff to return to the hospital emergency room after being discharged. *Id.* After a jury verdict in favor of plaintiff, the defendant hospital argued that under section 538.210, a single statutory cap on noneconomic damages applied. *Id.* at 564. The trial court, however, rejected the hospital's argument determining that two statutory noneconomic damage caps applied in the case because "there were two separate occurrences of malpractice in the instant case, each of which contributed to cause [plaintiff's] injuries ... and each of which could support the application of a statutory damage cap." *Id.*

On appeal, the trial court's application of two statutory caps was affirmed. *Id.* at 571. The Eastern District interpreted the term "occurrence" as used in the context of section 538.210 as a singular wrongful act sued upon, not the receipt of injury by the plaintiff. *Id.* (citing *Romero v. United States,* 865 F.Supp. 585 (E.D.Mo.1994)). It explained that had the legislature intended one damages cap to apply regardless of the number of occurrences of medical malpractice by a single defendant, "the clearest and most unambiguous way for the legislature to have expressed such an intent would have been to simply leave the words 'per occurrence' out of the statute entirely." *Id.* "If that had indeed been the legislative intent, then using the words 'per occurrence' would amount to mere surplusage which added nothing at all to the intended statutory meaning." *Id.* Presumably, the legislature does not insert superfluous language in a statute. *Id.*

[15] **[16]** An interpretation of the term "occurrence" as a wrongful act sued upon rather than a resulting injury or death is also consistent with other statutory law. When the legislature enacts a statute referring ***890** to terms that have had other judicial or legislative meanings attached to them, a presumption exists that it acts with knowledge of that judicial or legislative action. *Leiser v. City of Wildwood,* 59 S.W.3d 597, 603 (Mo.App. E.D.2001). The medical malpractice statute of limitations, section 516.105, utilizes the term "occurrence" to describe the alleged negligent act upon which a suit can be brought. It provides that "[a]ll actions against physicians, hospitals ... for damages for malpractice, negligence, error or mistake

related to health care shall be brought within two years from the date of *occurrence of the act of neglect complained of* ....” § 516.105 (emphasis added). Similarly, Missouri's Wrongful Death Act contemplates the term “occurrence” to mean the wrongful act sued upon. Section 537.080.1 provides, “Whenever *the death of a person results from any* act, conduct, *occurrence,* transaction, or circumstance which, if death had not ensued, would have entitled such person to recover damages in respect thereof, the person or party who, or the corporation which, would have been liable if death had not ensued shall be liable in an action for damages ....” (emphasis added). *See also* § 537.085 (In a wrongful death action, “the defendant may plead and prove as a defense any defense which the defendant would have had against the deceased in an action based upon the same act, conduct, *occurrence,* transaction, or circumstance *which caused the death of the deceased* ....”) (emphasis added). Finally, an interpretation of the term “occurrence” as a wrongful act sued upon rather than a resulting injury or death is also consistent with MAI 4.01 and cases analyzing it. The instruction for personal and property damages provides, in pertinent part:

> If you find in favor of plaintiff, then you must award plaintiff such sum as you believe will fairly and justly compensate plaintiff for any damages you believe plaintiff sustained as a direct result of the occurrence mentioned in the evidence.

MAI 4.01. The term “occurrence” in the instruction refers to the defendant's wrongful act. *Smith v. Courter,* 575 S.W.2d 199, 204 (Mo.App.1978); *Nelson v. R.H. Macy & Co.,* 434 S.W.2d 767, 774 (Mo.App.1968).

In this case, Respondents submitted separate verdict directors against Dr. Newman and JSA and Dr. Dandridge and JSA for each doctor's individual acts of negligence. The jury found in favor of Respondents on the claim against Dr. Newman and JSA and on the claim against Dr. Dandridge and JSA. Thereafter, the trial court applied two statutory caps for the two occurrences or acts of negligence found by the jury.

Appellants argue that because the claimed negligent acts or omissions of the two physicians were submitted in the disjunctive and the trial court could not and did not make a finding as to which disjunctive submission was actually true and because the verdict director for both doctors included an allegation that each doctor failed to test the adequacy of the April 7, 1998, repair, [5] the jury possibly found only one occurrence in the case. This argument, however, is meritless. First, even if the jury did find that each doctor negligently failed to test the adequacy of the April 7, 1998, repair, each act was an independent act of negligence committed by each doctor that contributed to cause the death of Ms. Cook. Second, as discussed in the next point, each doctor was a defendant for purposes of section 538.210. The trial court, therefore, did not err in concluding that there were two occurrences ***891** in this case, the separate and distinct acts of negligence of Drs. Newman and Dandridge. The point is denied.

Defendants

[17] Appellants next claim that the trial court erred in determining that Dr. Newman, Dr. Dandridge, and JSA each constitute a defendant for purposes of applying the noneconomic damages cap of section 538.210. Section 538.210.1 provides, in pertinent part, that no plaintiff shall recover more than a limited amount per occurrence for noneconomic damages “from any one defendant as defendant is defined in subsection 2 of this section”

Subsection 2 of section 538.210 defines “defendant” as:

(1) A hospital as defined in chapter 197, RSMo, and its employees and physician employees who are insured under the hospitals professional liability insurance policy or the hospital's self-insurance maintained for professional liability purposes;

(2) A physician, including his nonphysician employees who are insured under the physician's professional liability insurance or under the physician's self-insurance maintained for professional liability purposes;

(3) Any other health care provider having the legal capacity to sue and be sued and who is not included in subdivisions (1) and (2) of this subsection, including employees of any health care providers who are insured under the health care provider's professional liability insurance policy or self-insurance maintained for professional liability purposes.

The term "health care provider" is defined in section 538.205(4) as:

> [A]ny physician, hospital, health maintenance organization, ambulatory surgical center, long-term care facility, dentist, registered or licensed practical nurse, optometrist, podiatrist, pharmacist, chiropractor, professional physical therapist, psychologist, physician-in-training, and any other person or entity that provides health care services under the authority of a license or certificate.

Appellants contend that the two physicians and the corporation constitute a single defendant because, under paragraph 3 of section 538.210.2, all physicians employed by a corporation that provides health care services through such physicians and that insures such physicians under its professional liability insurance policy are included with such corporation as a single defendant. The question, therefore, is whether physicians practicing their profession through another health care provider are included within the meaning of "employees" of a health care provider under section 538.210.2(3). The meaning of the term "employees" as used in that paragraph is not clear and unambiguous. Section 538.210.2 and specifically paragraph 3 of the statute could plausibly be interpreted as defining a health care provider and the physicians employed by it either as one defendant or as separate defendants. Thus, resort to the rules of construction of a statute is necessary. *Stotts,* 118 S.W.3d at 664.

[18] [19] [20] [21] [22] [23] One rule of statutory construction is that the provisions of a statute are not read in isolation but construed together, and if reasonably possible, the provisions are harmonized with each other. *Bachtel v. Miller County Nursing Home Dist.,* 110 S.W.3d 799, 801 (Mo. banc 2003). Paragraph 1 of section 538.210.2 includes as a defendant hospital its "employees and physician employees." Paragraph 3, however, includes as a defendant any other health care provider not included in paragraphs 1 and 2 and its ***892** "employees." Physicians are specifically included as a defined defendant in paragraph 2 of the statute and the word "physicians" is omitted in paragraph 3. Presumably, a word has the same meaning in every place used within a statute. *Weston Point Resort Condo. Owners' Ass'n, Inc. v. Floro,* 796 S.W.2d 928, 930 (Mo.App. S.D.1990)(quoting *A.M.G. v. Mo. Div. of Family Servs.,* 660 S.W.2d 370, 372 (Mo.App. E.D.1983)). When different terms are used in different subsections of a statute, presumably, the legislature intended the terms to have different meaning and effect. *Landman,* 107 S.W.3d at 251–52. Accordingly, if the legislature intended for a health care provider and its employed physicians to enjoy the same protection it provided to a hospital and its physician employees, [6] it could have expressly provided similar language. To construe the term "employees" in paragraph 3 to include physicians as suggested by Appellants would render as superfluous the use of the term "employees" in paragraph 1. The legislature's inclusion of paragraph 2 applicable to physicians, including nonphysician employees, [7] is further reflective of its intent that physicians employed by a health care provider that is not a hospital be defined as separate defendants. If the legislature had intended for a health care provider to include its employed physicians for the purposes of defining a "defendant" under the noneconomic damages cap statute, it could have omitted paragraph 2, without which, a physician would have fallen within paragraph 3 as a health care provider. Presumably, the legislature intends that every word, clause, sentence, and provision of a statute have effect. *Landman,* 107 S.W.3d at 252. Conversely, a presumption exists that the legislature does not insert idle verbiage or superfluous language in the statute. *Id.* Thus, the legislature did not intend the term "employees" in paragraph 3 of section 538.210.2 to include physicians. Thus, under paragraphs 2 and 3 of the statute, JSA, Dr. Newman, and Dr. Dandridge each constitute a separate defendant. The point is denied.

Applicable Cap Amount

[24] In their final point on appeal, Appellants claim that the trial court erred in applying the noneconomic damages cap in effect at the time of trial rather than the cap in effect at the time of the occurrences. They assert that application of the cap amount in effect at the time of trial in 2002, $547,000, rather than that in effect at the time of the negligent acts in 1998, $513,000, imposed or ascribed new or different legal effects to such acts in violation of the constitutional proscription against retrospective laws.

***893** As originally enacted in 1986, the noneconomic damages cap statute provided that no plaintiff in a medical malpractice action could recover more than $350,000 in noneconomic damages per occurrence from any one defendant. § 538.210, RSMo 1986. A related statute enacted at the same time provides that this limitation applies "only to causes of action arising on or after February 3, 1986." § 538.235, RSMo 1986. The cap statute further provides that the limitation amount is to be increased or decreased every year in accordance with a specified economic index:

> The limitation on awards for noneconomic damages provided for in this section shall be increased or decreased on an annual basis effective January first of each year in accordance with the Implicit Price Deflator for Personal Consumption Expenditures as published by the Bureau of Economic Analysis of the United States Department of Commerce. The current value of the limitation shall be calculated by the director of the department of insurance, who shall furnish that value to the secretary of state, who shall publish such value in the Missouri Register as soon after each January first as practicable, but it shall otherwise be exempt from the provisions of section 536.021, RSMo.

§ 538.210.4.

[25] "The general rule of law is expressed as a reluctance of retroactive application of newly enacted legislation." *State Bd. of Registration for the Healing Arts v. Warren,* 820 S.W.2d 564, 565 (Mo.App. W.D.1991)(citing *State ex rel. St. Louis–San Francisco Ry. Co. v. Buder,* 515 S.W.2d 409, 411 (Mo. banc 1974)). Article I, Section 13 of the Missouri Constitution provides that no ex post facto law, nor law impairing the obligations of contracts nor retrospective in its operation shall be enacted. *Buder,* 515 S.W.2d at 410.

> [T]he underlying repugnance to the retrospective application of laws is that an act or transaction, to which certain legal effects were ascribed at the time they transpired, should not, without cogent reasons, thereafter be subject to a different set of effects which alter the rights and liabilities of the parties thereto.

Id. at 411.

[26] **[27]** **[28]** **[29]** "Under the rules of statutory construction, statutory provisions that are substantive 'are generally presumed to operate prospectively unless the legislative intent that they be given retroactive operation clearly appears from the express language of the act or by necessary or unavoidable implication.' " *Callahan v. Cardinal Glennon Hosp.,* 863 S.W.2d 852, 872 (Mo. banc 1993)(quoting *Dep't. of Soc. Servs. v. Villa Capri Homes, Inc.,* 684 S.W.2d 327, 332 (Mo. banc 1985)). Conversely, statutory provisions that are remedial or procedural operate retrospectively unless the legislature expressly states otherwise. *Id.* Substantive law creates, defines and regulates rights; procedural law prescribes a method of enforcing rights or obtaining redress for their invasion. *Wilkes v. Mo. Highway & Transp. Comm'n,* 762 S.W.2d 27, 28 (Mo. banc 1988). The distinction between substantive law and procedural law is that substantive law relates to the rights and duties giving rise to the cause of action, while procedural law is the machinery used for carrying on the suit. *Id.* Merely to label certain consequences as substantive and others as procedural is not sufficient; notions of justice and fair play in a particular case are always germane. *Croffoot v. Max German, Inc.,* 857 S.W.2d 435, 436 (Mo.App. E.D.1993)(citing *Buder,* 515 S.W.2d at 411).

Appellants cite two cases, *State ex rel. St. Louis–San Francisco Railway Co. v.* ***894** *Buder,* 515 S.W.2d 409 (Mo. banc 1974), and *Stillwell v. Universal Construction Co.,* 922 S.W.2d 448 (Mo.App. W.D.1996), for the proposition that legislative change to a statutory ceiling on damages in a particular type of case is considered substantive and, therefore, cannot be applied retroactively. In *Buder,* the Missouri Supreme Court reviewed the application of a change in the statute that set a $50,000 recovery limitation in wrongful death actions. 515 S.W.2d at 409–10. After the decedent's death but before trial, the limit was removed by the legislature. *Id.* The Court held that the limit in effect at the time of the accident still applied because the statutory limit had served

to protect defendants from verdicts in excess of the limit. *Id.* at 411.

In *Stillwell,* the court reviewed an amended workers' compensation statute increasing the monetary limit of an employer's liability for burial expenses for work-related death. 922 S.W.2d at 455–56. The statutory maximum was increased by the legislature after the accident. *Id.* at 455. This court denied retrospective application of the statutory increase holding that the amendment of the statute affected the substantive rights of the employer because the employer possessed a vested right under the statute that its liability for burial expenses could not exceed a certain amount. *Id.* at 456.

This case is distinguishable from *Buder* and *Stillwell.* First, the noneconomic damages cap statute was not amended between the time of the negligent acts that cause the death of Ms. Cook and the time of trial. Section 538.210 was enacted in 1986 and has remained unchanged since. It provides a cap on noneconomic damages in a medical malpractice action and for a yearly increase or decrease in the cap amount in accordance with a specified economic index. The legislature unambiguously provided that the noneconomic damages cap statute only applied prospectively to causes of action arising on or after February 3, 1986. § 538.235. Respondents' cause of action arose in 1998 after the enactment of the cap statute. Thus, in the sense that the legislature did not *enact* a statute during the life of this cause of action, Article I, Section 13 of the Missouri Constitution is inapplicable in this case.

[30] Additionally, the noneconomic damages cap statute was enacted to maintain the integrity of health care for all Missourians by limiting the liability of health care providers for noneconomic damages caused by their acts of medical malpractice. *Adams By & Through Adams v. Children's Mercy Hosp.,* 832 S.W.2d 898, 904 (Mo. banc 1992), *cert. denied,* 506 U.S. 991, 113 S.Ct. 511, 121 L.Ed.2d 446 (1992); *Scott v. SSM Healthcare St. Louis,* 70 S.W.3d 560, 570 (Mo.App. E.D.2002). While pursuing that purpose, the legislature contemplated the effect of inflation on an award of noneconomic damages in subsection 4 of the statute. Section 538.210.4 unambiguously expresses the legislative intent that a plaintiff's noneconomic damages award be protected from inflation. The practical effect of the subsection is that compensation received from injury incurred is not diminished from the time of the act of negligence to the time of trial, which may occur years later, by the impact of inflation. In that regard, the annual adjustment for inflation merely affects procedure or remedy. It neither defines or regulates a plaintiff's right to compensation nor imposes or ascribes new or different legal effects to a defendant's conduct in violation of the constitutional proscription against retrospective laws. Thus, the applicable cap amount in this case is $547,000, the cap amount in effect at the time of trial. *See Adams,* 832 S.W.2d at 902 n. 4, 904; *Scott,* 70 S.W.3d at 570 n. 10; ***895** *Burns v. Elk River Ambulance, Inc.,* 55 S.W.3d 466, 485 (Mo.App. S.D.2001)(where courts applied cap amounts in effect at time of trial). The point is denied.

Conclusion

The trial court erred in applying twelve statutory caps for noneconomic damages in this case. Instead, four noneconomic damages caps each in the amount of $547,000 shall be awarded. For the occurrence of Dr. Newman's negligence, Respondents, as a single plaintiff, shall collect a statutory cap from Dr. Newman and a separate statutory cap from JSA. For the occurrence of Dr. Dandridge's negligence, Respondents, as a single plaintiff, shall collect a statutory cap from Dr. Dandridge and a separate statutory cap from JSA. The judgment is, therefore, reversed, and the case is remanded to the trial court for entry of a judgment consistent with this opinion.

All concur.

All Citations

142 S.W.3d 880

Footnotes

1 All statutory references are to RSMo 2000 unless otherwise indicated.

2 Respondents also sued Alan Buchele, M.D. and Alan Buchele, M.D., P.C. The jury rendered a verdict in favor of these defendants, and judgment was entered in their behalf; therefore, they are not parties to this appeal.

3 Appellants' points are not addressed in the order presented in their brief.

4 Appellants claim in another point on appeal that the trial court erred in failing to apportion the jury's award of damages among the three plaintiffs before reducing the jury's award in accordance with the cap statute. They contend that because the trial court allocated damages after it calculated the amount of noneconomic damages recoverable, the surviving children actually received a greater award, the amount of the statutory cap, than they were entitled to receive based on the court's allocation. Appellants' argument, however, is based on a finding that Ms. Cook's surviving husband and two children were each a plaintiff for purposes of section 538.210. As discussed in this point, however, such determination by the trial court is reversed; therefore, this point need not be addressed.

5 See verdict directors in Facts section above.

6 The term “physician employee” is defined in section 538.205, RSMo 2000, as “any person or entity who works for hospitals for a salary or under contract and who is covered by a policy of insurance or self-insurance by a hospital for acts performed at the direction or under control of the hospital.” Merely because the term “physician employee” is defined to include not only physicians but entities who work for a hospital under a salary or contract does not negate the fact that the legislature did not intend the term “employees” to include physicians in section 538.210.2(3).

7 Appellants also argue that because the legislature used the term “nonphysician employees” in paragraph 2, it did not intend to use the word “employees” in the other paragraphs of the statute to refer only to nonphysician employees. The legislature's use of the term “nonphysician employees” in paragraph 2, however, merely indicates its intent to exclude from a defendant physician other physicians who are employed by the defendant physician. The use of the term in paragraph 2 is not inconsistent with interpretation of the term “employees” as not including physicians in paragraph 3.

972 So.2d 555
Supreme Court of Mississippi.

The ESTATE OF Stacey Kay KLAUS by Alta KLAUS, Administratrix and Alta Klaus as Personal Representative of the Wrongful Death Beneficiaries of Stacey Kay Klaus.
v.
VICKSBURG HEALTHCARE, LLC d/b/a River Region Health Systems, River Region Medical Corporation, Triad Hospitals, Inc., Stephanie Vanderford, R.N., and Eugene Ferris, III, M.D.

No. 2006–IA–00675–SCT.
|
Nov. 29, 2007.
|
Rehearing Denied Jan. 31, 2008.

Synopsis

Background: Mother of patient who died following surgery, as administratrix of patient's estate and as personal representative of patient's wrongful-death beneficiaries, filed medical malpractice action against hospital, physician, and nurse. Subsequently, mother filed motion seeking declaration determining whether cap on non-economic damages limited each plaintiff's non-economic damages to $500,000 or the suit's total non-economic damages to $500,000. The Circuit Court, Warren County, Frank G. Vollor, J., entered "declaratory judgment" finding that cap applied to cause of action regardless of the number of beneficiaries. Mother petitioned for interlocutory appeal.

[Holding:] The Supreme Court, en banc, Randolph, J., held that cap applies to all plaintiffs who bring a wrongful-death action, rather than each plaintiff.

Affirmed and remanded.

Diaz, P.J., dissented and filed opinion in which Graves, J., joined.

West Headnotes (2)

[1] Appeal and Error
Death

Issue on appeal of whether statute limited non-economic damages to $500,000 for all wrongful death beneficiaries and the estate in an action for medical malpractice involved a question of law and interpretation of a statute, and thus standard of review was de novo. West's A.M.C. § 11–1–60(2)(a).

4 Cases that cite this headnote

[2] Death
Statutory limitations

The statutory cap on noneconomic damages in a medical malpractice action applies to all plaintiffs who bring a wrongful-death action, rather than each plaintiff. West's A.M.C. §§ 1–3–33, 11–1–60(2)(a), 11–7–13.

3 Cases that cite this headnote

Attorneys and Law Firms

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EN BANC.

Opinion

***556** RANDOLPH, Justice, for the Court.

¶ 1. In this interlocutory appeal, the Court is asked to address the legislatively-instituted cap on non-economic damages found in Mississippi Code Annotated Section 11–1–60(2)(a) (Supp.2007) and its effect, vel non, on the wrongful-death statute, i.e., Mississippi Code Annotated Section 11–7–13 (Rev.2004).

FACTS

¶ 2. Stacey Kay Klaus ("Stacey") died following surgery at River Region Hospital. On July 18, 2005, Stacey's mother, Alta, filed a medical malpractice complaint against the Appellees in the Circuit Court of Warren County, Mississippi, as Administratrix of Stacey's estate and "as personal representative of the wrongful-death beneficiaries of [Stacey]...." Stacey's wrongful-death beneficiaries ("Klauses") are Alta; her father, Sylvain; and her half-sister, Marian.

¶ 3. Subsequently, the Klauses filed a "Motion for Declaratory Judgment" in the trial court, stating:

> 2. Under Miss.Code Ann. § 11–1–60, non-economic damages are limited to $500,000.00 for "the plaintiff."
>
> 3. This wrongful death claim actually has three plaintiffs being the mother, father and half-sister. Although by statute each plaintiff must share equally in any award, each plaintiff has a separate claim for damages incurred for the death of [Stacey] because each plaintiff has a different relationship with [her].
>
> 4. The rights of each beneficiary plaintiff is affected by Miss.Code Ann. § 11–1–60. [The Klauses] pursuant to Rule 57 M.R.C.P. seeks a declaration from this Court, deciding *whether <u>each</u> plaintiff's non-economic damages are limited to $500,000.00 or the suit's total non-economic damages are limited to $500,000.00.*

(Emphasis added). Dr. Eugene Ferris filed his Response to that motion,[1] arguing that "the noneconomic damages of all of the wrongful death beneficiaries of [Stacey], in the aggregate, are capped at the statutory maximum of $500,000 under Miss.Code Ann. § 11–1–60." Following hearing, the circuit court entered a "Declaratory Judgment" finding that "the limitation on non-economic damages in 11–1–60(2)(a) to $500,000.00 applies to this cause of action regardless of the number of beneficiaries." This Court granted the Klauses' timely petition for interlocutory appeal. *See* M.R.A.P. 5.

ISSUE

¶ 4. This Court will consider:

> (1) Does Mississippi Code Annotated Section 11–1–60(2)(a) limit non-economic damages to $500,000 for all wrongful death beneficiaries and the estate in an action for medical malpractice?

ANALYSIS

[1] ¶ 5. As this interlocutory appeal involves "a question of law and interpretation of a statute[,] ... the standard of review is de novo." *Miss. Dep't of Transp. v. Allred,* 928 So.2d 152, 154 (Miss.2006) (citing *Cooper v. Crabb,* 587 So.2d 236, 239 (Miss.1991)). This Court has stated that:

> [i]n considering a statute passed by the legislature, ... the first question a court should decide is whether the statute is ambiguous. If it is not ambiguous, the court should simply apply the statute according to its plain meaning and should not use principles of statutory construction. Whether the statute is ambiguous or not, the ultimate goal of ***557** this Court is to discern and give effect to the legislative intent.

City of Natchez v. Sullivan, 612 So.2d 1087, 1089 (Miss.1992) (citations omitted).

¶ 6. Mississippi Code Annotated Section 11–1–60(2)(a) provides that:

> [i]n any cause of action filed on or after September 1, 2004, for injury based on malpractice or breach of standard of care against a provider of health care, including institutions for the aged or infirm, in the event the trier of fact finds the defendant liable, they shall not award *the plaintiff* more than Five Hundred Thousand Dollars ($500,000.00) for noneconomic damages.

Miss.Code Ann. § 11–1–60(2)(a) (Supp.2007) (emphasis added). In pertinent part, the wrongful-death statute authorizes that:

> [t]he action for such damages may be brought in the name of the personal representative of the deceased person ... for the benefit of all persons entitled under the law to recover, ... or by the parent for the death of a child, ... or by a sister for the death of a sister, ... or all parties interested may join in the suit, and *there shall be but one (1) suit for the same death which shall ensue for the benefit of all parties concerned, but the determination of such suit shall not bar another action unless it be decided on the merits.* Except as otherwise provided in Section 11–1–69, in such action the party or parties suing shall recover such damages allowable by law as the jury may determine to be just, taking into consideration all the damages of every kind to the decedent and all damages of every kind to any and all parties interested in the suit.

Miss.Code Ann. § 11–7–13 (Rev.2004) (emphasis added).

¶ 7. The Klauses argue that these two statutes, read together, create an ambiguity. Specifically, they maintain that the "shall not award the plaintiff more than Five Hundred Thousand ($500,000.00) for noneconomic damages" language of Mississippi Code Annotated Section 11–1–60(2)(a) is incongruent with the fact that, under the wrongful-death statute of Mississippi Code Annotated Section 11–7–13, multiple plaintiffs may have standing to file suit. The Appellees respond that "[w]rongful death actions are, inherently, derivative" and, therefore, "any defense which would have been available against the deceased, is available against the wrongful death beneficiaries." *See Lee v. Thompson,* 859 So.2d 981, 987 (Miss.2003). Therefore, the Appellees argue that "the plain language of § 11–1–60 establishes that the cap applies to the total amount of recoverable damages and that it is not multiplied by the number of parties involved." Furthermore, the Appellees assert that following this Court's decision in *Allred,* Mississippi Code Annotated Section 11–1–60, "when read *in pari materia* with §§ 1–3–1 and 1–3–33, applies regardless of the number of plaintiffs."

¶ 8. In *Allred,* this Court addressed the question of:

> when multiple governmental defendants have been sued in "single occurrence" jurisdictions, such as Mississippi, does the limitation of liability [in Mississippi Code Annotated Section 11–46–15(1)(a)[2] ***558**] provide for one maximum dollar amount of liability for a single tortious act, regardless of the number of governmental entities sued, or does the maximum dollar amount of liability apply separately to each governmental entity defendant?

Allred, 928 So.2d at 154. In response to Allred's argument that the $50,000 limit in Mississippi Code Annotated Section 11–46–15(1) is to be applied per person, *see id.* at 153, this Court found:

> Miss.Code Ann. Section 1–3–1, states, "this chapter is applicable to every statute unless its general object, or the context of the language construed, or other provisions of law indicate that a different meaning or application was intended from that required by this chapter." Specifically pertinent in this case is Miss.Code Ann. Section 1–3–33 which states, "*words used in the singular number only, either as descriptive of persons or things, shall extend to and embrace the plural number;* and words used in the plural number shall extend to and embrace the singular number, *except where a contrary intention is manifest.*"
>
> The common maxim is that statutes *in pari materia* are to be construed together. When a statute is *in pari materia* with a later one, it is simply part of its context to be considered by the Court in deciding whether the meaning of a provision in the later statute is plain. *See* Rupert Cross, *Statutory Interpretation* 128 (1976). Applying Miss.Code Ann. Section 1–3–33 to an analysis of the Mississippi Tort Claims Act, it is abundantly clear that the Act fails to manifestly express a contrary

> intention, as required by Miss.Code Ann. Section 1–3–33. *The Legislature had the opportunity to declare that the statute at issue was to be read only in the singular, but did not. Additionally, the Legislature did not manifestly express a contrary intention not to include plural language in its Declaration of Legislative Intent. Miss.Code Ann. § 11–46–3. The Legislature had the opportunity to manifest an intent that the statute should be read only in the singular; however, it is clear the Legislature did not do so. There being no ambiguity, the Court is bound to simply apply the statutes according to their plain meaning.*

Allred, 928 So.2d at 155–56 (emphasis added). Therefore, this Court concluded that Mississippi Code Annotated Section 11–46–15(1) "shall be interpreted by using singular *or* plural language." *Id.* at 156 (emphasis added).

¶ 9. The learned circuit judge did not have the benefit of *Allred* when he entered "Declaratory Judgment" in favor of the Appellees. Nonetheless, he correctly observed that the Klauses' "argument that the use of the singular form of 'plaintiff' in § 11–1–60 MCA would apply to each beneficiary, individually, is not persuasive...." Just as in *Allred,* "[t]he Legislature had the opportunity to declare that the statute at issue was to be read only in the singular, but did not. Additionally, the Legislature did not manifestly express a contrary intention not to include plural language in its Declaration of Legislative Intent." *Id.* Accordingly, the statute is to be applied according to its plain meaning and "the plaintiff" in Mississippi Code Annotated Section 11–1–60(2)(a) "shall be interpreted by using the singular or plural language" when considered *in pari materia* with Mississippi Code Annotated Section 1–3–33 (Rev.2005).

***559** ¶ 10. While acknowledging the rectitude of the majority view, stating it "is consistent with the legislative purpose behind Section 11–1–60" (Dissenting Opinion at ¶ 21), the dissent then mulls over the potential unintended consequences of the legislative act and concludes that these potential unjust results were "not fully taken into consideration by the Legislature." (Dissenting Opinion at ¶ 23). If perchance the Legislature should subscribe to these assumptions, it may amend Mississippi Code Annotated Section 11–1–60 and expressly manifest a contrary intention to the plain language of Mississippi Code Annotated Section 1–3–33. *See Miss. Ethics Comm'n v. Grisham,* 957 So.2d 997, 1003 (Miss.2007) ("[t]he power to change this result lies with the legislature to amend the statute."). However, the dissent's suggestion that this Court should redress the perceived legislative error by judicial fiat requires an act of judicial activism. To properly preserve the separation of powers mandated by the Mississippi Constitution, *see* Miss. Const. art. I, §§ 1–2, this Court should act with restraint. *See Grisham,* 957 So.2d at 1003 ("[t]he privilege to amend a statute, not constitutionally infirm, does not rest with this Court.").

CONCLUSION

[2] ¶ 11. By enacting Mississippi Code Annotated Section 11–1–60(2)(a), the Legislature expressly instituted a cap on noneconomic damages recoverable by "the plaintiff." Mississippi Code Annotated Section 1–3–33 provides that words written in the singular are to be read in the plural. In light of Mississippi Code Annotated Section 1–3–33 and this Court's decision in *Allred,* the cap on noneconomic damages applies to plaintiff or plaintiffs. Therefore, the cap on noneconomic damages in Mississippi Code Annotated Section 11–1–60(2)(a) applies to all plaintiffs who bring a wrongful-death action pursuant to Mississippi Code Annotated Section 11–7–13. Accordingly, the judgment of the Circuit Court of Warren County is affirmed, and this case is remanded to that court for further proceedings consistent with this opinion.

¶ 12. **AFFIRMED AND REMANDED.**

SMITH, C.J., WALLER, P.J., EASLEY, CARLSON, DICKINSON, AND LAMAR, JJ., CONCUR. DIAZ, P.J., DISSENTS WITH SEPARATE WRITTEN OPINION JOINED BY GRAVES, J.

DIAZ, Presiding Justice, Dissenting.

¶ 13. "In considering a statute passed by the legislature ... the first question a court should decide is whether the statute is ambiguous." *City of Natchez, Miss. v. Sullivan,* 612 So.2d 1087, 1089 (Miss.1992). Section 11–1–60(2)(a) provides in pertinent part: "In a cause of action filed on or after September 1, 2004, ... the trier of fact ... shall not award *the plaintiff* more than Five Hundred Thousand Dollars ($500,000) in noneconomic damages." Miss.Code Ann. § 11–1–60(2)(a) (Supp.2007) (emphasis added). When read alone, this provision is unambiguous: It caps the amount of noneconomic damages a plaintiff

can recover in a medical malpractice action at $500,000. However, Section 11–1–60(2)(a) becomes ambiguous when considered in the context of a wrongful death action, where one action is frequently filed by multiple plaintiffs. [3]

***560** ¶ 14. The majority finds the provision at issue unambiguous and contends that it "is to be applied according to its plain meaning [.]" According to the majority, the plain meaning of Section 11–1–60(2)(a) is that the noneconomic damages cap set forth in that provision applies to all wrongful death beneficiaries in the aggregate, rather than to each beneficiary individually. The majority reaches this conclusion by reading the term "plaintiff" in its plural form ("plaintiffs") in accordance with Mississippi Code Annotated Section 1–3–33 (Rev.2005).

¶ 15. I agree that the term "plaintiff" Section 11–1–60(2)(a) must be read in both its singular and plural form because the Legislature did not express an intent that the statute be read only in the singular. Miss.Code Ann. § 1–3–33 (Rev.2005). However, even if one reads the term "plaintiff" in its plural form, the plain meaning of Section 11–1–60(2)(a) is not that the noneconomic damages cap applies to all wrongful death beneficiaries in the aggregate. When "plaintiffs" is substituted for "plaintiff," the statute remains ambiguous: "the trier of fact ... shall not award the plaintiff[s] more than Five Hundred Thousand Dollars ($500,000) for noneconomic damages." Miss.Code Ann. § 11–1–60(2)(a) (Rev.2005). When read in that form, the statute can be interpreted to mean either that plaintiffs cannot recover more than a total of $500,000 in noneconomic damages in a wrongful death action or that each plaintiff in a wrongful death action cannot recover more than $500,000 in noneconomic damages.

¶ 16. "Where statutes are ambiguous or in conflict with one another, it is proper to resort to the rules of statutory construction." *Miss. Gaming Comm'n v. Imperial Palace of Miss., Inc.,* 751 So.2d 1025, 1028 (Miss.1999). "The primary rule of construction is to ascertain the intent of the legislature from the statute as a whole and from the language used therein." *Clark v. State ex rel. Miss. State Med. Ass'n,* 381 So.2d 1046, 1048 (Miss.1980).

¶ 17. The intent of the Legislature in enacting Section 11–1–60 is explicitly stated in the statute: "It is the intent of this section to limit all noneconomic damages to the above." Miss.Code Ann. § 11–1–60 (Supp.2007). Based on a plain reading of the statute, it is clear that the Legislature intended to cap the amount of noneconomic damages that could be recovered by a single plaintiff in a single medical malpractice cause of action. However, it is not apparent that the Legislature intended to cap the total amount of noneconomic damages that could be recovered by multiple plaintiffs in a wrongful death action premised on medical malpractice at $500,000.

¶ 18. When the Legislature has intended to place a cap on plaintiffs' damages in the aggregate in other contexts, it has done so explicitly. For example, in Mississippi Code Annotated Section 11–46–15(1) (Rev.2002), a provision of the Mississippi Tort Claims Act, the Legislature "establish[ed] a per occurrence cap on governmental liability." *Allred v. Yarborough,* 843 So.2d 727, 730 (Miss.2003). Section 11–46–15(1) provides in pertinent part: "In any claim or suit for damages against a governmental entity or its employee brought under the provisions of this chapter, the liability shall not exceed the following for *all claims* arising out of a single occurrence for all damages permitted under this chapter...." Miss.Code Ann. § 11–46–15(1) (Rev.2002) (emphasis added).

¶ 19. It is well-settled that "the omission of language from a similar provision ***561** on a similar subject indicates that the legislature had a different intent in enacting the provisions, which it manifested by the omission of the language." *City of Natchez,* 612 So.2d at 1089. The fact that Section 11–1–60(2)(a) does not contain language similar to that of Section 11–46–15(1), limiting damages for all claims arising out of a single occurrence or incident, indicates that the Legislature did not intend for the $500,000 noneconomic damages cap to apply to all claims arising out of a single act of medical malpractice.

¶ 20. "[I]n determining the legislative intent, [the Court] may look not only to the language used [in the statute] but also to [the statute's] historical background, its subject matter, and the purposes and objects to be accomplished." *Clark,* 381 So.2d at 1048. Section 11–1–60 was passed in the special session of the Mississippi Legislature on tort reform in 2002. E. Farish Percy, *Checking Up on the Medical Malpractice Liability Insurance Crisis in Mississippi: Are Additional Reforms the Cure?,* 73 Miss. L.J. 1001, 1002 (2004). The ultimate purpose of Section 11–1–60 was to alleviate the perceived medical malpractice

liability insurance crisis in Mississippi. *See id.* at 1001–1003, 1034–37. Specifically, Section 11–1–60 was designed to put an end to excessive damage awards in medical malpractice cases, [4] which, in turn, would help bring down the cost of medical malpractice insurance in the state. *See id.* at 1036 n. 126.

¶ 21. Although the majority's holding that Section 11–1–60(2)(a) limits noneconomic damages per medical malpractice incident in the aggregate is consistent with the legislative purpose behind Section 11–1–60, I believe the holding will have ramifications that the Legislature did not intend. [5] "Unthought of results must be avoided if possible, especially if injustice follows, and unwise purpose will not be imputed to the Legislature when a reasonable construction is possible." *McCullen v. State ex rel. Alexander,* 217 Miss. 256, 271, 63 So.2d 856, 861 (1953) (internal quotation marks and citation omitted). Many "unthought of [and unjust] results" will flow from today's holding. [6]

***562** ¶ 22. First, wrongful death beneficiaries who are members of smaller classes of beneficiaries will receive more damages for their claims for loss of society and companionship than beneficiaries who belong to larger classes. Second, in wrongful death cases where the jury determines that the decedent's pain and suffering between injury and death and the wrongful death beneficiaries' claims for loss of society and companionship warrant an award of damages in excess of $500,000, the beneficiaries will not be fully compensated for the decedent's pain and suffering or their loss of society and companionship. [7] Third, today's holding will affect medical malpractice cases not involving wrongful death. A married couple that brings a medical malpractice action consisting of a personal-injury claim and a claim for loss of consortium will not be fully compensated if the jury determines that the injured spouse's damages for pain and suffering and the other spouse's damages for loss of consortium exceed $500,000. [8]

¶ 23. I do not believe the Legislature intended for the noneconomic damages cap set forth in Section 11–1–60(2)(a) to produce such unjust results. This Court has noted that the Legislature did not contemplate the impact that the tort reform measures it enacted would have on the wrongful death statute: "The Legislature clearly made major reforms in various statutes during recent sessions which included passing Mississippi Code Ann. Section 11–11–3(3). However, it is equally clear that the wrongful death statute, Section 11–7–13, was not considered concerning events and multiple defendant doctors such as what we have before us now, when these changes in various statutes where made." *Rose v. Bologna,* 942 So.2d 1287, 1290(¶ 9) (Miss.2006). Clearly, the impact that Section 11–1–60 could potentially have on the wrongful death statute was not fully taken into consideration by the Legislature.

¶ 24. "The purposes of the wrongful death statute are to prevent the wrongful termination of life and provide the beneficiary with compensation for the loss of companionship and society of the deceased, the pain and suffering of the deceased between injury and death, and punitive damages." *66 Fed. Credit Union v. Tucker,* 853 So.2d 104, 109–10 (Miss.2003); *see also* Miss.Code Ann. § 11–7–13 (Rev.2004) ("the party or parties suing shall recover such damages allowable by law as the jury may determine to be just, taking into consideration *all the damages of every kind to the decedent and all damages of every kind to any and all parties interested in the suit* ") (emphasis added). To hold that the Legislature intended for the noneconomic damages cap on medical malpractice actions to apply to wrongful death beneficiaries in the aggregate, would mean that the Legislature enacted Section 11–1–60 in direct contravention of one of the purposes of the wrongful death statute: to fully compensate all beneficiaries for their loss of society and companionship and the pain and suffering of the decedent. This Court should not impute such an unwise purpose to the Legislature, especially when a reasonable ***563** construction of the statute that does not produce unjust results is possible. *McCullen,* 63 So.2d at 861.

¶ 25. Construing Section 11–1–60(2)(a) to apply to each wrongful death beneficiary separately, rather than in the aggregate, prevents that provision from abrogating an essential part of the wrongful death statute. Further, such a construction gives effect to the Legislature's intent in enacting Section 11–1–60–limiting the amount of noneconomic damages awarded in medical malpractice cases—because each beneficiary will not be allowed to recover more than $500,000 in noneconomic damages. This approach does not subvert the cap created by the Legislature. Rather, it balances the Legislature's goal of protecting the health care industry with the mandate of the wrongful death statute that all wrongful

death beneficiaries be fully compensated for their claims. Accordingly, I would hold that the noneconomic damages cap set forth in Section 11–1–60(2)(a) applies to each wrongful death beneficiary individually. [9]

¶ 26. The Supreme Court of Florida reached the same conclusion when faced with a very similar issue. *St. Mary's Hosp., Inc. v. Phillipe,* 769 So.2d 961, 967–71 (Fla.2000). In that case the court was presented with the question of whether the $250,000 noneconomic damages cap in the arbitration provisions of Florida's Malpractice Act applied to all wrongful death claimants in the aggregate or to each claimant individually. *Id.* at 967. The provision in question reads as follows:

> Noneconomic damages shall be limited to a maximum of $250,000 *per incident,* and shall be calculated on a percentage basis with respect to capacity to enjoy life, so that a finding that the *claimant's* injuries resulted in a 50–percent reduction in *his or her* capacity to enjoy life would warrant an award of not more than $125,000 noneconomic damages.

Fla. Stat. § 766.207(7)(b) (emphasis added).

¶ 27. The court acknowledged that the provision stated that "noneconomic damages shall be limited to a maximum of $ 250,000 *per incident,*" but concluded that the use of the singular "claimant" made the provision ambiguous. *Phillipe,* 769 So.2d at 968. Because the statute was ambiguous, the court proceeded to "look to the legislative intent for guidance." *Id.* It determined that the noneconomic damages cap provided "liability insurers with the ability to improve the predictability of the outcome of claims for the purpose of loss planning in risk assessment for premium purposes." *Id.* at 970.

¶ 28. After discerning the legislative intent, the court "conclude[d] that the cap on noneconomic damages applies to each claimant individually." *Id.* at 972. The court explained its reasoning as follows: "[I]n order for the assessment of a survivor's noneconomic damages to be equitable, each survivor's loss must be independently determined. Moreover, the loss of a survivor [should] not [be] diminished by the mere fact that there are multiple survivors." *Id.* at 971. The court also determined ***564** that its holding was consistent with the purpose of the arbitration provision:

> Such an interpretation would provide increased predictability in the outcome of the claims as the insurers would no longer be contending with the possibility of exorbitant noneconomic damage awards but would have a fixed dollar amount ($ 250,000), which each claimant's award could not exceed. Moreover, this interpretation does more to promote early resolution of medical negligence claims, as it provides an equitable result which will in turn further encourage claimants to seek resolution through arbitration.

Id. at 970. In addition, the court acknowledged that "were we to interpret the noneconomic damages cap to apply to all claimants in the aggregate, we conclude that such an interpretation would create equal protection concerns." *Id.* at 971.

¶ 29. I find the Supreme Court of Florida's analysis and reasoning to be very persuasive. I agree that each wrongful death beneficiary's noneconomic damages must be determined separately in order to be equitable and that the recovery of a beneficiary should not be reduced by the existence of other beneficiaries. Like the Florida Supreme Court, I conclude that applying the noneconomic damages cap per beneficiary is consistent with the legislative goal of limiting health care providers' exposure to liability. I also believe that the holding in today's case creates equal protection concerns. [10]

¶ 30. For these reasons, I would hold that the noneconomic damages cap of Section 11–1–60(2)(a) applies to each wrongful death beneficiary individually, reverse the judgment of the circuit court and remand this case for further proceedings consistent with that holding. Accordingly, I must respectfully dissent.

GRAVES, J., JOINS THIS OPINION.

All Citations

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Footnotes

1 Subsequently joined by the other Appellees.

2 Mississippi Code Annotated Section 11–46–15(1)(a) states, in pertinent part, that:

> (1) In any claim or suit for damages against *a governmental entity or its employee* brought under the provisions of this chapter, *the liability shall not exceed the following for all claims arising out of a single occurrence for all damages permitted under this chapter:*
>
> (a) For claims or causes of action arising from acts or omissions occurring on or after July 1, 1993, the sum of *Fifty Thousand Dollars ($50,000.00).*

Miss.Code Ann. § 11–46–15(1)(a) (Rev.2002) (emphasis added).

3 Under the wrongful death statute, only one wrongful death action may be brought on behalf of all the wrongful death beneficiaries: "[T]here shall be but one (1) suit ..." Miss.Code Ann. § 11–7–13 (Rev.2004). But a wrongful death action may be brought "by all interested parties," and "all parties interested may join the suit[.]" *Id.*

4 In fact, not many large medical malpractice verdicts were returned in the period preceding the movement for tort reform. One study found that the number of medical malpractice verdicts exceeding one million dollars averaged one per year from 1995 through mid–2002. Neil Vidmar and Leigh Anne Brown, *Tort Reform and the Medical Liability Insurance Crisis in Mississippi: Diagnosing the Disease and Prescribing a Remedy,* 22 Miss. C.L.Rev. 9, 15–20 (2002) (concluding that "there is no evidence that Mississippi juries are out of control in medical malpractice cases").

5 By stating that today's holding is consistent with the legislative purpose behind Section 11–1–60, I do not mean that the majority's application of Section 11–1–60(2)(a) is correct in any regard. I am not "validating" the majority's "analysis" at all. I am simply stating the obvious: Applying Section 11–1–60(2)(a) per medical malpractice incident in the aggregate, as the majority does, is consistent with the statute's legislative purpose of limiting the amount of noneconomic damages awarded in medical malpractice cases because it will limit the amount of noneconomic damages awarded in medical malpractice cases. Of course, the construction of the statute that I advocate is also consistent with the legislative purpose behind the statute. The ultimate question is not whether a particular application of Section 11–1–60(2)(a) is consistent with the general purpose of the statute, but whether it effectuates the intent of the Legislature. In my view, the majority's application of Section 11–1–60(2)(a) in this case does not effectuate the intent of the Legislature. Accordingly, I do not acknowledge the "rectitude" of the holding in this case.

6 As discussed infra, there is nothing "potential" about the unjust results of today's decision, contrary to the majority's assertion.

7 As a result of the holding in today's case, in wrongful death cases not premised on medical malpractice, the beneficiaries will not be fully compensated if a jury determines that the noneconomic damages exceed $1,000,000. Miss.Code Ann. § 11–1–60(2)(b) (Supp.2007).

8 This will be the effect because in a medical malpractice case involving a primary personal-injury claim and a loss-of-consortium claim, there is one cause of action and more than one plaintiff, as in a wrongful death action. *See Choctaw, Inc. v. Wichner,* 521 So.2d 878, 881 (Miss.1988) (holding that a claim for loss of consortium is a derivative claim, not an independent cause of action).

9 The majority claims that my proposed construction of Section 11–1–60(2)(a) is intended to "correct [a] perceived legislative error by judicial fiat," and would constitute an "act of judicial activism." The majority is mistaken. I am not attempting to correct a legislative error; rather, I am seeking to discover the intent of the Legislature in enacting Section 11–1–60(2)(a) and apply it accordingly. After construing the statute, unlike the majority, I find that the Legislature did not intend for Section 11–1–60(2)(a) to cap the total amount of noneconomic damages that can be recovered in a wrongful death action at $500,000. Accordingly, my conclusion is the opposite of judicial activism.

10 I not only have equal protection concerns about the application of the noneconomic damages cap on medical malpractice actions to wrongful death cases, but I also have equal protection concerns about the cap itself. Several courts have held that such a cap violates their state's equal protection clause. The Alabama Supreme Court held that placing a cap on noneconomic damages in medical malpractice cases "creates a favored class of tort-feasors, based solely upon their connection with health care [.]" *Moore v. Mobile Infirmary Ass'n,* 592 So.2d 156, 166–67 (Ala.1991); *see also Carson v. Maurer,* 120 N.H. 925, 940–41, 424 A.2d 825, 835–36 (1980), *overruled on other grounds by Cmty. Res. for Justice,*

Inc. v. City of Manchester, 154 N.H. 748, 917 A.2d 707, 721 (2007). Because this issue was not raised on appeal, I will not address it.

End of Document

SECTION 15-78-120. Limitation on liability; prohibition against recovery of punitive or exemplary damages or prejudgment interest; signature of attorney on pleadings, motions, or other papers.

(a) For any action or claim for damages brought under the provisions of this chapter, the liability shall not exceed the following limits:

(1) Except as provided in Section 15-78-120(a)(3), no person shall recover in any action or claim brought hereunder a sum exceeding three hundred thousand dollars because of loss arising from a single occurrence regardless of the number of agencies or political subdivisions involved.

(2) Except as provided in Section 15-78-120(a)(4), the total sum recovered hereunder arising out of a single occurrence shall not exceed six hundred thousand dollars regardless of the number of agencies or political subdivisions or claims or actions involved.

(3) No person may recover in any action or claim brought hereunder against any governmental entity and caused by the tort of any licensed physician or dentist, employed by a governmental entity and acting within the scope of his profession, a sum exceeding one million two hundred thousand dollars because of loss arising from a single occurrence regardless of the number of agencies or political subdivisions involved.

(4) The total sum recovered hereunder arising out of a single occurrence of liability of any governmental entity for any tort caused by any licensed physician or dentist, employed by a governmental entity and acting within the scope of his profession, may not exceed one million two hundred thousand dollars regardless of the number of agencies or political subdivisions or claims or actions involved.

(5) The provisions of Section 15-78-120(a)(3) and (a)(4) shall in no way limit or modify the liability of a licensed physician or dentist, acting within the scope of his profession, with respect to any action or claim brought hereunder which involved services for which the physician or dentist was paid, should have been paid, or expected to be paid at the time of the rendering of the services from any source other than the salary appropriated by the governmental entity or fees received from any practice plan authorized by the employer whether or not the practice plan is incorporated and registered with the Secretary of State.

(b) No award for damages under this chapter shall include punitive or exemplary damages or interest prior to judgment.

(c) In any claim, action, or proceeding to enforce a provision of this chapter, the signature of an attorney or party constitutes a certificate by him that he has read the pleading, motion, or other paper; that to the best of his knowledge, information, and belief formed after reasonable inquiry it is well-grounded in fact and is warranted by existing law or a good faith argument for the extension, modification, or reversal of existing law, and that it is not interposed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation. If a pleading, motion, or other paper is not signed, it shall be stricken unless it is signed promptly after the omission is called to the attention of the pleader or movant. If a pleading, motion, or other paper is signed in violation of this rule, the court, upon motion or upon its own initiative, shall impose upon the person who signed it, a represented party, or both, an appropriate sanction, which may include an order to pay the other party or parties the amount of the reasonable expenses incurred because of the filing of the pleading, motion, or other paper, including a reasonable attorney's fee.

SECTION 33-56-170. Definitions of "charitable organization" and "employee" for purposes of Section 33-56-180.

For purposes of Section 33-56-180:

(1) "Charitable organization" means any organization, institution, association, society, or corporation which is exempt from taxation pursuant to Section 501(c)(3) or 501(d) of Title 26 of the United States Code, as amended.

(2) "Employee" means an agent, servant, employee, or officer of a charitable organization.

HISTORY: 1994 Act No. 461, Section 1; 2000 Act No. 336, Section 1.

SECTION 33-56-180. Limitation of liability for injury or death caused by employee of charitable organization.

(A) A person sustaining an injury or dying by reason of the tortious act of commission or omission of an employee of a charitable organization, when the employee is acting within the scope of his employment, may recover in an action brought against the charitable organization only the actual damages he sustains in an amount not exceeding the limitations on liability imposed in the South Carolina Tort Claims Act in Chapter 78 of Title 15. An action against the charitable organization pursuant to this section constitutes a complete bar to any recovery by the claimant, by reason of the same subject matter, against the employee of the charitable organization whose act or omission gave rise to the claim unless it is alleged and proved in the action that the employee acted in a reckless, wilful, or grossly negligent manner, and the employee must be joined properly as a party defendant. A judgment against an employee of a charitable organization may not be returned unless a specific finding is made that the employee acted in a reckless, wilful, or grossly negligent manner. If the charitable organization for which the employee was acting cannot be determined at the time the action is instituted, the plaintiff may name as a party defendant the employee, and the entity for which the employee was acting must be added or substituted as party defendant when it reasonably can be determined.

(B) If the actual damages from the injury or death giving rise to the action arose from the use or operation of a motor vehicle and exceed two hundred fifty thousand dollars, this section does not prevent the injured person from recovering benefits pursuant to Section 38-77-160 but in an amount not to exceed the limits of the uninsured or underinsured coverage.

HISTORY: 1994 Act No. 461, Section 1; 2000 Act No. 336, Section 1.

329 S.W.3d 548
Court of Appeals of Texas,
Amarillo,
Panel E.

THI OF TEXAS AT LUBBOCK I, LLC, d/b/a Southwest Regional Specialty Hospital, Appellant,
v.
Mario PEREA, Individually and as Representative of the Estate of Jacob Perea, Deceased; Max Perea; Tony Perea; and George Perea, Appellees.

No. 07–08–0359–CV.
|
July 28, 2010.

Synopsis

Background: Family of deceased patient brought medical malpractice action against skilled nursing facility for prescribing a drug patient was allergic to. The 72th District Court of Lubbock County, Ruben Reyes, J., entered judgment on a jury verdict for plaintiffs, and nursing facility appealed.

Holdings: The Court of Appeals, Patrick A. Pirtle, J., held that:

[1] evidence was sufficient to establish that skilled nursing facility breached standard of care by hiring charging nurse who had been disciplined in another state for prescribing drug without physician permission;

[2] evidence was sufficient to establish that employment of nurse was the proximate cause of patient's death;

[3] evidence was sufficient to establish that administration of drug to which patient was allergic was the proximate cause of patient's death;

[4] evidence was sufficient to establish that facility's employment of nurse was grossly negligent, for purposes of a punitive damages award;

[5] patient's estate and four sons were one claimant, for purposes of statutory damages caps;

[6] statutes capping damages were not affirmative defenses that nursing facility was required to either plead or waive; and

[7] statute capping punitive damages in any case applied, though another statute also capped all damages in wrongful death and survival actions.

Reversed and remanded.

James T. Campbell, J., concurred in part and dissented in part, and filed opinion.

West Headnotes (48)

[1] Evidence
Certainty of testimony;probability, or possibility

"Perhaps" and "possibly" in a medical expert's testimony indicate conjecture, speculation, or mere possibility, rather than qualified opinions based on reasonable medical probability.

Cases that cite this headnote

[2] Appeal and Error
Instructions

A trial court's decision to submit or refuse a particular jury instruction is reviewed under an abuse of discretion standard.

Cases that cite this headnote

[3] Appeal and Error
Instructions

Although a trial court has great latitude and considerable discretion to determine necessary and proper jury instructions, the trial court abuses its discretion if the court acts arbitrarily, unreasonably or without reference

to guiding principles of law. Vernon's Ann.Texas Rules Civ.Proc., Rule 277.

1 Cases that cite this headnote

[4] Appeal and Error

Instructions

When a trial court refuses to submit a requested instruction on an issue raised by the pleadings and evidence, the question on appeal is whether the request was reasonably necessary to enable the jury to render a proper verdict.

2 Cases that cite this headnote

[5] Appeal and Error

Relation between error and final outcome or result in general

Omission of an instruction is harmful, or reversible error, only if the omission probably caused the rendition of an improper judgment, and is harmless when the findings of the jury in answer to other issues are sufficient to support the judgment.

1 Cases that cite this headnote

[6] Appeal and Error

Relation between error and final outcome or result in general

Trial

Construction and Effect of Charge as a Whole

Whether harm exists due to an omission of a requested jury instruction is viewed in the context of the whole charge.

1 Cases that cite this headnote

[7] Death

Nature of Act or Omission Causing Death

To establish a cause of action under either the Wrongful Death Act or the Survival Statute, a claimant must establish a death and the occurrence of a wrongful act. V.T.C.A., Civil Practice & Remedies Code §§ 71.002, 71.004, 71.021.

6 Cases that cite this headnote

[8] Death

Nature of Act or Omission Causing Death

If negligence is alleged as the wrongful act, in a wrongful death/survival action, a claimant must show that the defendant's negligent act or omission was a substantial factor in bringing about the decedent's death, and without it, the decedent's death would not have occurred. V.T.C.A., Civil Practice & Remedies Code §§ 71.002, 71.004, 71.021.

6 Cases that cite this headnote

[9] Death

Nature and form of remedy

Death

Survival of right of action of person injured

The difference between the Survival Statute and the Wrongful Death Act is the nature of the damages that may be recovered and who may collect them; the purpose of the Survival Statute is to continue a decedent's cause of action beyond death to redress decedent's estate for decedent's injuries that occurred before he died, while the purpose of the Wrongful Death Act is to permit a surviving husband, wife, child, and parents of the decedent to bring a cause of action to redress their injuries resulting from the decedent's death. V.T.C.A., Civil Practice & Remedies Code §§ 71.002, 71.004, 71.021.

7 Cases that cite this headnote

[10] Negligence

Elements in general

A cause of action for negligence requires three elements: (1) a legal duty owed by one person to another; (2) breach of that duty; and (3) damages proximately caused by the breach.

1 Cases that cite this headnote

[11] Death

Cause of death and negligence

Jury instructions in wrongful death/survival medical malpractice action that family of deceased patient brought against skilled nursing facility properly informed the jury that family could recover only if they established that the facility's wrongful administration of a drug caused patient's death, though trial court used broad-form negligence and proximate cause instructions that used the term "injury" rather than "death," as the vast majority of the evidence related to patient's manner of death and whether the drug caused patient's death, and damage instructions reminded the jury that they were limited to damages resulting from patient's death. V.T.C.A., Civil Practice & Remedies Code §§ 71.002, 71.004, 71.021.

Cases that cite this headnote

[12] Trial

Multifariousness or Duplicity

While trial courts should obtain fact findings on all theories pleaded and supported by the evidence, a trial court is not required to, and should not, confuse the jury by submitting differently worded questions that call for the same factual finding.

Cases that cite this headnote

[13] Pleading

During trial in general

A trial court may not refuse a trial amendment to a petition unless: (1) the opposing party presents evidence of surprise or prejudice, or (2) the amendment asserts a new cause of action or defense and thus is prejudicial on its face and the opposing party objects to the amendment. Vernon's Ann.Texas Rules Civ.Proc., Rule 66.

Cases that cite this headnote

[14] Appeal and Error

Objections to pleadings

Pleading

Affidavits and other proofs

The opponent of the trial amendment to a petition has the burden of showing surprise or prejudice, and a motion for continuance based upon the ground of surprise or prejudice is essential before the filing of a trial amendment will constitute reversible error. Vernon's Ann.Texas Rules Civ.Proc., Rule 66.

Cases that cite this headnote

[15] Appeal and Error

Sufficiency and scope of motion

Skilled nursing facility did not preserve for appeal assertion that trial court erred in wrongful death/survival medical malpractice action by granting trial amendment to patient's family petition to assert a negligent credentialing/hiring claim in regard to facility's charge nurse, where facility did not object to the amendment because of surprise or prejudice nor sought a continuance, and facility instead asserted that the claim was legally deficient and that the underlying evidence in support of the claim was irrelevant. Rules App.Proc., Rule 33.1(a).

Cases that cite this headnote

[16] Health

Particular procedures

Negligent credentialing and hiring claims against health care providers are health care liability claims as well as negligence causes of action, and require expert testimony to establish the elements of a claim. V.T.C.A., Civil Practice & Remedies Code § 74.001 et seq.

Cases that cite this headnote

[17] Labor and Employment

Negligent Hiring

Labor and Employment

Negligent retention

Labor and Employment

Negligent training and supervision

To establish a claim for negligent hiring, supervision and retention, a plaintiff must prove the following elements: (1) a duty to hire, supervise, and retain competent employees; (2) an employer's breach of the duty; and (3) the employer's breach of the duty proximately caused the damages sued for.

2 Cases that cite this headnote

[18] **Labor and Employment**

Negligent Hiring

Labor and Employment

Negligent retention

Labor and Employment

Negligent training and supervision

An employer is liable for negligent hiring, supervision, or retention when proof is presented that the employer hired an incompetent or unfit employee whom it knew or, by the exercise of reasonable care, should have known was incompetent or unfit, thereby creating an unreasonable risk of harm to others.

2 Cases that cite this headnote

[19] **Evidence**

Due care and proper conduct

Health

Pharmacological services

Evidence was sufficient to establish that skilled nursing facility breached its standard of care by hiring charging nurse who subsequently ordered that patient be sedated by a drug to which patient was allergic, in trial of negligent credentialing and hiring claim that patient's family asserted against facility in wrongful death/survival action; family's expert physician testified that director of nurses and hospital administrators should have some involvement in assuring that nurses do not write prescription orders without a doctor's permission and that directors and administrators had a duty to research the background of people they hired, charging nurse testified that he was hired despite telling the person who recruited him that he was on probation in another state for administrating the same drug without a physician's order, and there was evidence that charging nurse without prior approval ordered that the drug be administered to patient.

Cases that cite this headnote

[20] **Labor and Employment**

Negligent Hiring

An employer owes a duty to its other employees and to the general public to ascertain the qualifications and competence of the employees it hires, especially when the employees are engaged in occupations that require skill or experience and that could be hazardous to the safety of others.

Cases that cite this headnote

[21] **Health**

Pharmacological services

Evidence was sufficient to establish that skilled nursing facility's employment of charging nurse, who was on probation in another state for ordering the administration of a drug without permission from a physician, proximately caused the death of patient who was allergic to the same drug, in trial of negligent credentialing and hiring claim that patient's family asserted against facility in wrongful death/survival action; there was evidence that person who recruited charging nurse was aware that the nurse was on probation in another state, that such person did not report the fact to Texas nursing authorities, and that such person did not only not take precautions to prevent a similar incident but promoted nurse to a position of authority where it was relatively easy for the nurse to engage in the same behavior.

Cases that cite this headnote

[22] Health

Proximate cause

While proximate cause in a medical malpractice case must be based upon reasonable medical probability, the quantum of proof required is simply that it is more likely than not that the ultimate harm or condition resulted from such negligence.

Cases that cite this headnote

[23] Health

Proximate Cause

A plaintiff in a medical malpractice action is not required to exclude every other reasonable hypothesis, and more than one proximate cause may exist.

Cases that cite this headnote

[24] Health

Proximate cause

Whether a particular act of negligence is a cause-in-fact of an injury is a particularly apt question for jury determination in a medical malpractice action.

Cases that cite this headnote

[25] Appeal and Error

Necessity of timely objection

To preserve a complaint that scientific evidence is unreliable and thus, no evidence, a party must object to the evidence before trial or when the evidence is offered.

Cases that cite this headnote

[26] Evidence

Testimony of Experts

Whether an expert's testimony is credible or not is best left to the jury.

Cases that cite this headnote

[27] Evidence

Cause and effect

Health

Pharmacological services

Evidence was sufficient to establish that skilled nursing facility's negligence in administering drug to elderly patient, when the medical records indicated patient was allergic or reacted badly to the drug, proximately caused patient's death, in wrongful death/survival action brought by patient's family; family's expert physician, who treated patients over the age of 65 and had cared for patients taking the same class of drugs, testified that the common side effects of the drug included respiratory depression, that an overdose of the drug could cause respiratory depression to the extent that a person's heart stopped, that patient's medical records indicated he had reacted badly to the drug on prior occasions, and that second dose of the drug caused patient's breathing to become more shallow until there was insufficient oxygen to support heart functions, causing heart to go into arrhythmia.

1 Cases that cite this headnote

[28] Health

Proximate cause

A jury in a medical malpractice action has broad latitude to infer proximate cause from the evidence and the circumstances surrounding the injury-producing act, especially when it is not possible to produce direct proof of proximate cause or lack of proximate cause.

1 Cases that cite this headnote

[29] Damages

Grounds for Exemplary Damages

Two elements comprise gross negligence, for purposes of an exemplary damages award: (1) viewed objectively from the actor's standpoint, the act or omission complained of must depart from the ordinary standard of care to such an extent that it creates an extreme degree of risk of harming others,

and (2) the actor must have actual, subjective awareness of the risk involved and choose to proceed in conscious indifference to the rights, safety, or welfare of others. V.T.C.A., Civil Practice & Remedies Code §§ 41.001(11), 41.003(a)(3), (b).

Cases that cite this headnote

[30] Damages

Grounds for Exemplary Damages

The subjective component that separates ordinary negligence from gross negligence, for purposes of exemplary damages, is the defendant's state of mind; in other words, the plaintiff must show the defendant knew about the peril, but his acts or omissions demonstrate he or she did not care. V.T.C.A., Civil Practice & Remedies Code §§ 41.001(11), 41.003(a)(3), (b).

Cases that cite this headnote

[31] Damages

Grounds for Exemplary Damages

It is the mental attitude of reckless indifference that permits a jury to find that the defendant had decided to ignore the rights of others even in light of probable and threatened injury to them, for purposes of exemplary damages. V.T.C.A., Civil Practice & Remedies Code §§ 41.001(11), 41.003(a)(3), (b).

Cases that cite this headnote

[32] Death

Damages

Evidence was sufficient to establish that charging nurse employed at skilled nursing facility had actual awareness of the extreme risk involved in prescribing drug to which patient was allergic or sensitive without physician approval, as required to establish gross negligence for an exemplary damages award, in wrongful death/survival medical malpractice action that family of patient brought against skilled nursing facility; there was evidence that a myriad of precautions were supposed to be in place to assure that patients did not receive drugs to which they were allergic, that patient's medical records stated patient was allergic or sensitive to the drug, and that charging nurse had been disciplined in another state for giving the same drug to a patient without a doctor's order. V.T.C.A., Civil Practice & Remedies Code §§ 41.001(11), 41.003(a)(3), (b).

Cases that cite this headnote

[33] Corporations and Business Organizations

Exemplary damages

A corporation may be liable in punitive damages for gross negligence only if the corporation itself commits gross negligence. V.T.C.A., Civil Practice & Remedies Code §§ 41.001(11), 41.003(a)(3), (b).

Cases that cite this headnote

[34] Corporations and Business Organizations

Ratification and Repudiation

Corporations and Business Organizations

Exemplary damages

A corporation is grossly negligent, for purposes of a punitive damages award, if it authorizes or ratifies an agent's gross negligence, or if it is directly negligent in hiring an unfit agent. V.T.C.A., Civil Practice & Remedies Code §§ 41.001(11), 41.003(a)(3), (b).

1 Cases that cite this headnote

[35] Corporations and Business Organizations

Wrongful Acts or Omissions

Corporations and Business Organizations

Exemplary damages

A corporation may be grossly negligent, for purposes of a punitive damages award, through the acts or inactions of a vice-principal. V.T.C.A., Civil Practice & Remedies Code §§ 41.001(11), 41.003(a)(3), (b).

Cases that cite this headnote

[36] **Corporations and Business Organizations**
Vice principals in general

Corporations and Business Organizations
Imputed liability in general

Vice-principals, whose grossly negligent acts may be attributable to a corporation for purposes of a punitive damages award, include corporate officers, those who have authority to employ, direct, and discharge other employees, those engaged in performing the corporation's nondelegable or absolute duties, and those responsible for the management of the whole or a department or a division of the business.

Cases that cite this headnote

[37] **Appeal and Error**
On review of verdict, findings, and sufficiency of evidence

In determining whether acts are directly attributable to the corporate employer for purposes of punitive damages, a reviewing court does not restrict its review to individual elements or facts but instead considers all the surrounding facts and circumstances to determine whether the corporation itself is grossly negligent. V.T.C.A., Civil Practice & Remedies Code §§ 41.001(11), 41.003(a)(3), (b).

Cases that cite this headnote

[38] **Appeal and Error**
On Review of Damages or Other Monetary Relief

The facts and circumstances, reviewed by an appellate court when determining whether acts are attributable to a corporate employer for purposes of punitive damages, include reasonable inferences the fact finder can draw from what the corporation did or failed to do and the facts existing at relevant times that contributed to a plaintiff's alleged damages. V.T.C.A., Civil Practice & Remedies Code §§ 41.001(11), 41.003(a)(3), (b).

Cases that cite this headnote

[39] **Death**
Damages

Evidence was sufficient to establish that skilled nursing facility was grossly negligent in hiring and retaining an unfit charging nurse that gave patient a drug to which patient was allergic, as required in order to support an exemplary damages award for patient's family, in family's wrongful death/survival medical malpractice action against facility; there was evidence that supervisor who recruited charging nurse to work at facility was aware that nurse had been disciplined in another state for prescribing the same drug to another patient without physician permission, that despite such knowledge supervisor placed nurse in a position where he initiated orders for prescribed medications, that after patient's death supervisor continued to allow nurse to work at facility after he told her he was a drug addict, and that nurse's addition was permitted to progress until he was reported falling asleep at patient's bed sides and misappropriated morphine. V.T.C.A., Civil Practice & Remedies Code §§ 41.001(11), 41.003(a)(3), (b).

Cases that cite this headnote

[40] **Appeal and Error**
On review of verdict, findings, and sufficiency of evidence

Appeal and Error
Review for Factual or Legal Sufficiency; "No Evidence" Review

When the burden of proof is clear and convincing evidence, the distinction between legal and factual sufficiency is very fine, and in such a factual sufficiency review an appellate court must consider all the evidence the fact finder could reasonably have found to be clear and convincing, and then determine whether any fact finder could reasonably have formed

a firm belief or conviction of the truth of the allegations.

4 Cases that cite this headnote

[41] Death

Statutory limitations

Patient's estate and four sons were a single claimant in wrongful death/survival action brought against skilled nursing facility, for purposes of statute limiting the amount of damages, including exemplary damages but excluding the costs for necessary medical care, that could be awarded to a claimant on a health care liability claim in a wrongful death or survival action. V.T.C.A., Civil Practice & Remedies Code §§ 74.001(a)(2), 74.303.

Cases that cite this headnote

[42] Statutes

Superfluousness

A court must not interpret a statute in a manner that renders any part of the statute meaningless or superfluous.

1 Cases that cite this headnote

[43] Health

Wrongful death

Statute, limiting the amount of noneconomic damages that could be awarded on a health care liability claim against a single health care institution to $250,000, applied, in family's wrongful death/survival medical malpractice action against skilled nursing facility, though another statute limited the amount of damages including exemplary damages that could be awarded on a health care liability claim in a wrongful death or survival action, as the two statute did not conflict on their face. V.T.C.A., Civil Practice & Remedies Code §§ 74.301(b), 74.303.

Cases that cite this headnote

[44] Health

Wrongful death

Patient's estate and four sons were a single claimant in wrongful death/survival medical malpractice action brought against skilled nursing facility, for purposes of statute limiting the amount of noneconomic damages that could be awarded on a health care liability claim against a single health care institution to $250,000. V.T.C.A., Civil Practice & Remedies Code § 74.301(b).

1 Cases that cite this headnote

[45] Health

Pleading

Statute limiting the amount of noneconomic damages that could be awarded on a health care liability claim against a single health care institution to $250,000 was not an affirmative defense, and thus skilled nursing facility did not waive the application of the statute by not pleading it as an affirmative defense, in wrongful death/survival medical malpractice action brought against facility by patient's family. V.T.C.A., Civil Practice & Remedies Code § 74.301(b).

Cases that cite this headnote

[46] Health

Pleading

Statute limiting the amount of exemplary damages that could be awarded against a defendant was not an affirmative defense, and thus skilled nursing facility did not waive the application of the statute by not pleading it as an affirmative defense, in wrongful death/survival medical malpractice action brought against facility by patient's family. V.T.C.A., Civil Practice & Remedies Code § 41.008(b).

2 Cases that cite this headnote

[47] Health

Wrongful death

Statute, limiting the amount of exemplary damages that could be awarded in any suit, applied to wrongful death/survival medical malpractice action that patient's

family brought against skilled nursing facility, though another statute capped all damages that could be awarded in wrongful death and survival actions, as the two statute did not conflict on their face, and the statutes could be harmonized by applying the exemplary damages cap first, and then by applying the overall damages cap. V.T.C.A., Civil Practice & Remedies Code §§ 41.008(b), 74.301(b), 74.303.

2 Cases that cite this headnote

[48] Interest

Torts;wrongful death

Prejudgment interest is an element of recoverable actual damages, and thus subject to overall damages limit imposed by statute on health care liability claims in wrongful death and survival actions. V.T.C.A., Finance Code § 304.102; V.T.C.A., Civil Practice & Remedies Code § 74.303.

1 Cases that cite this headnote

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Before CAMPBELL, PIRTLE, JJ. and BOYD, S.J. [1]

OPINION

PATRICK A. PIRTLE, Justice.

Appellant, THI of Texas at Lubbock I, LLC, (THI), d/b/a Southwest Regional Specialty Hospital (Southwest Hospital) appeals from a judgment entered following a jury trial in a medical malpractice action seeking wrongful death and survival damages in favor of Appellees, Max Perea, Mario Perea, Tony Perea, and George Perea (collectively Perea), and the estate of their deceased father, Jacob Perea (Jacob). In support, THI asserts: (1) the trial court erred by denying THI's proposed jury instruction on negligence; (2) the trial court erred by permitting Appellees to amend their petition during trial to assert an action for negligent credentialing/hiring; (3) the trial court erred by granting judgment on Appellees' negligence theories; (4) Appellees' evidence of gross negligence was legally and (5) factually insufficient; (6) the trial court erroneously excluded THI's testimony regarding an in-house investigation into the circumstances of Jacob's death; and (7) the trial court failed to apply certain statutory liability caps to the damage awarded in Appellees' favor. [2] We reverse the trial court's judgment and remand the case for further proceedings.

Background

In December 2005, Appellees filed a medical malpractice action against THI, Pharmasource Healthcare, Inc. and Omnicare Inc., d/b/a Pharmasource Healthcare, Inc. (collectively Pharmasource), seeking wrongful death and survival damages. [3] Appellees' amended petition alleged that Southwest Hospital's nurses were negligent and grossly negligent in administering two fatal doses of Ativan to Jacob despite information known to Southwest Hospital's staff and located in his medical records indicating he had an allergy to Ativan. [4] Appellees asserted THI and Pharmasource acted with negligence, gross negligence, and malice.

I. Trial Amendment

During their case-in-chief, Appellees elicited testimony from Leonard Espinoza, a former charge nurse at Southwest Hospital who allegedly wrote an unauthorized order prescribing Ativan for Jacob, that he ***556** had, prior to being employed by THI at Southwest Hospital, similarly administered Ativan to a patient without a physician's authorization and was disciplined by the Colorado Board of Nurse Examiners. Afterwards, Appellees sought to amend their original petition to allege THI was negligent for credentialing or hiring Espinoza because "it knew or should have known [Espinoza] was

incapable of providing safe and competent care to" Jacob. The trial court permitted the amendment.

II. Evidence at Trial–Medical Malpractice Claim

In 2004, Jacob was a seventy-eight year old widower with four sons—Tony, George, Max, and Mario. He had a history of heart disease complicated by respiratory issues and diabetes. Nevertheless, until he experienced a fall in November 2004, Jacob spent his time maintaining seventeen acres of land owned by his sons. During the summer, he arose at 5:00 a.m. to mow and shred the land, quit at 10:00 a.m. due to the heat and then resumed at 6:00 p.m. He cleaned his own home and did not regularly use a walker or cane. He performed these tasks despite intervening gallbladder and heart surgeries.

In April 2004, Jacob was admitted to Covenant Medical Center in Lubbock, Texas, to have his gallbladder removed. While at Covenant, Jacob experienced confusion and was sedated with morphine and Ativan. Two days later, his cardiologist noted Jacob's "confusion [was] worse" and that "he may be over-sedated." Later, the same day, his cardiologist noted Jacob "was still confused, too sedated," and suspended the use of Ativan. The following day Jacob's neurologist noted Jacob was sitting in a chair, quite alert and attentive but still confused. His neurologist also noted that "holding ... other potentially sedating meds is also working." Two days after the medication change, Jacob was discharged. [5] Several days after returning home, Mario observed that his father's "mind was straight."

In May, Jacob was again seen at Covenant complaining of abdominal pain. On admission, his physical exam showed he was awake, alert, and able to answer questions reasonably well. His final diagnosis prior to discharge was acute renal failure. The discharge also stated Jacob was "not in clinic for congestive heart failure, medications adjusted, no episode of chest pain or shortness of breath, had baseline chronic renal insufficiency."

In June, Jacob returned to Covenant complaining of confusion and chest pain. During a consultation, his doctor noted Jacob had received Ativan the night before for agitation and appeared alert. His doctor opined that Jacob "likely has baseline dementia [with] secondary decompensation due to medical problems, change in environment, etc." His doctor subsequently issued an order to avoid Ativan. Jacob was later discharged home with continuation of home medications. His discharge summary indicated "[n]o acute interaction planned ... cardiac status-wise."

In July, Jacob underwent a successful coronary bypass surgery. Within weeks after the surgery, Jacob was driving and attending to his normal schedule. His doctors told Mario that morphine, prescribed for Jacob in the hospital, was causing him to be disoriented at home and Ativan was a major problem for Jacob. His discharge summary indicated there ***557** were no "operative complications, able to discharge home—stable condition."

In September, Jacob was admitted to Covenant suffering from shortness of breath. His doctor recommended Jacob continue his current heart medications while considering dialysis for chronic renal failure. Jacob was discharged three days later. His discharge summary stated "nothing acute, medications, home with family." In October, Jacob was admitted with complaints of shortness of breath. He was treated and "discharged in good condition."

In early November, Jacob was admitted to Covenant complaining of abdominal pain. He had missed his regularly scheduled dialysis and was feeling poorly with fluid overload. After a consultation, his doctor diagnosed Jacob as suffering from "congestive heart failure secondary to fluid overload." He recommended Jacob be discharged after dialysis and continue his current heart medications.

In late November, Jacob returned to Covenant complaining of a fall. His vital signs were stable. A CT scan showed a slight cervical spine fracture and he was placed in a collar. On examination, his doctor noted he was a "well-developed and well-nourished male who [was] sedated but arousable and follow[ed] commands." His doctor recommended Jacob undergo an MRI but recommended the test be delayed until the next day because Jacob was "too sedated [and] his myonclonus is too jerky for his MRI; at this time." His overall treatment plan was to admit Jacob, perform dialysis, resume his medication, and closely monitor.

During a discussion on December 1, Jacob's family informed Covenant's medical staff that Jacob became confused on Ativan. The staff then listed Ativan as an allergy for Jacob and notified the pharmacy. On

December 2, Dr. C.J. Wheeler wrote an order indicating Jacob was sensitive to "Ativan/Benzodiazepines." For the MRI, he ordered that Jacob be sedated with Demerol and Versed [6] with an antidote available in case of over sedation.

Prior to the MRI, Jacob was given Versed to sedate him while the MRI was being performed. Four hours later, Jacob went into cardiac arrest. He was intubated and placed on a breathing machine or ventilator. Naidu Chekuru, M.D., performed a consultation and noted that "[a]n MRI was planned; as [Jacob] was too restless I believe they gave him Ativan which led to cardiopulmonary arrest" and "[h]e was required to be intubated and ventilator support." A Covenant charge nurse's report showed Jacob was allergic to morphine and Ativan. The allergies were also listed in his Restraint Assessment, Physician Order and Documentation Protocol: "Allergies: Morphine/Ativan."

On December 12, Jacob was discharged from Covenant and transferred to Southwest Hospital, a skilled nursing facility, under the care of Kenneth Michael Rice, M.D. The narrative summary indicated Jacob, on admission, was "neurologically intact, stable cardiac evaluation." Recommendations included a neck brace to immobilize Jacob's neck and continuation of antibiotics. The discharge summary noted that Jacob was "released in stable condition" and he was "ALLERGIC TO LORAZEPAM [7] AND MORPHINE."

***558** On December 15, Nurse Jahomo admitted Jacob to Southwest Hospital at approximately 4:40–4:45 p.m. Jacob's original chart from Covenant indicated he had allergies to morphine and Ativan. In addition, Covenant's patient transfer form listed Ativan in the area related to drug sensitivity. Nurse Jahomo filled out a nursing assessment form indicating Jacob was allergic to Ativan, placed an allergy sticker on his chart and an allergy bracelet on his wrist. [8] On Dr. Rice's admitting orders, Nurse Jahomo wrote that Jacob had allergies to morphine and Ativan. [9] She testified that, from the information she initially put in the medical records, every nurse who later cared for Jacob on every shift should have known he was allergic to morphine and Ativan.

That evening, Dr. Rice received a call from Mario who was requesting to take his father home. Dr. Rice spoke to Mario and explained that his father had suffered a serious fracture and might be paralyzed if not properly taken care of. Mario relented but informed Dr. Rice that his father had allergies or side effects to morphine and Ativan. Dr. Rice assured Mario that Southwest Hospital had procedures to "guard against such a thing happening." [10]

On December 16, Dr. Rice noted in Jacob's "History and Physical: Allergies: ***559** Morphine and Ativan." [11] In an early morning Nursing Documentation Report ("NDR"), [12] the nurse acknowledged: "Allergies; MSO4 [morphine], Ativan." This acknowledgement was carried over to the NDR for the next shift beginning at 7:00 p.m. which also listed morphine and Ativan as allergies for Jacob. The NDR and Dr. Rice's progress note dated December 17 both indicated Zyprexia was effective for treating Jacob.

A physical examination showed "cardiovascular, regular rate and rhythm, chest—bilateral breath sounds are diminished throughout." The NDR for the shift ending at 7:00 a.m. on December 17 indicated the nurse had received the prior report and assumed care. Jacob received Zyprexia which he tolerated well and was resting. The Report also listed morphine, Ativan, and Demerol as allergies for Jacob. A second NDR for the 7:00 p.m. shift also listed Jacob's allergies as Ativan and Demerol.

On December 18, Kimberly Graham, Dr. Rice's Nurse Practitioner, [13] examined Jacob. She observed Jacob was a little sedated, but calm. She checked his breathing status, vital signs, noted his oxygen saturations, respiratory rate, and "didn't see anything abnormal." [14] She testified she had no discussions with Espinoza, the charge nurse then responsible for Jacob's care, while she was at the hospital. She also testified that she did not write an order permitting Espinoza to administer Ativan to Jacob. She testified that, if she had changed the prescription to Ativan, she would have had a prior discussion with Dr. Rice, and, if approved, written or phoned in an order prescribing a much lower dose than 2 mg. and discontinued Zyprexia—none of which occurred.

Nurse Frances Rosales was assigned to Jacob from 7:00 a.m. to 7:00 p.m. on December 18. She testified that to familiarize herself with Jacob, she reviewed his MAR and physician's orders for her shift—neither of which alerted her to Jacob's allergies. [15] She also could not

recall whether Jacob was wearing an allergy bracelet. At 1:00 p.m., she testified Jacob became upset, tried to get out of bed, and was agitated. At 2:00 p.m., she medicated him with Zyprexia to calm him. At 6:00 p.m., she testified Jacob was attempting to climb out of bed and she notified her supervisor, charge nurse Espinoza. She testified Espinoza told her to administer ***560** Ativan to Jacob. She gave Jacob two milligrams. For the remainder of her shift, she testified Jacob rested with his eyes closed.

Espinoza testified that, as charge nurse, he managed the staff of floor nurses and any communications to a physician came through him. Espinoza testified he "believe[d]" he contacted Kimberly Graham by telephone and she gave him the order for Ativan. [16] Although, on examination, he first denied ever giving Ativan to a patient without a doctor's authorization, he later conceded on cross-examination that he administered Ativan without a doctor's order when he was a nurse in Colorado and was disciplined for that conduct. He agreed it was extremely dangerous to give Ativan without a doctor's order and, after the Colorado incident, he realized he had put the patient in Colorado in extreme risk. He testified further that "[i]n December 18, 2004, he knew what extreme risk of harm he could put [Jacob] in by giving him Ativan without a doctor's orders." He also agreed that, "if he wrote the order, he would be consciously disregarding [Jacob's] health, safety and welfare."

Nurse Rosales reported Jacob's condition to Nurse Rick Joiner who was assigned to care for Jacob for the 7:00 p.m. to 7:00 a.m. shift. Nurse Joiner looked at Nurse Rosales's NDR, Jacob's MAR, and his CARDEX [17] — neither of which he testified indicated Jacob had an allergy to Ativan. [18] He noticed that, on Nurse Rosales's NDR, Jacob had received a two milligram dose of Ativan earlier. At 1:30 a.m., when Jacob was again acting agitated, Nurse Joiner administered a second two milligram dose of Ativan to Jacob. Before administering the drug, he noticed a pink band on Jacob's wrist but, because it was not one of theirs, he did not attend to it. [19] Nurse Joiner checked on Jacob at 3:30 a.m. and noted Jacob's "respiration [was] even, unlabored." At 5:40 a.m., he noted that Jacob was "sleeping quietly in bed." Nurse Joiner did not check Jacob's vital signs and testified each of these visits lasted a maximum of thirty-five seconds. When his shift ended at 7:00 a.m. on December 19, Nurse Joiner left the hospital. Fifteen minutes later, at 7:15 a.m., Joiner's replacement discovered Jacob had no vital signs and was unresponsive. CPR was started at 7:18 a.m., Jacob was intubated at 7:27 a.m., EMS obtained a good pulse and Jacob was transported to Covenant where he was admitted for respiratory failure. Southwest Hospital's discharge summary did not list Ativan as a medication received by Jacob. [20]

***561** After arriving at Covenant, Jacob was again intubated and placed on ventilation support. Dr. Wheeler examined Jacob and noted he was "currently obtunded, probably secondary to Ativan injection." [21] Dr. Wheeler noted that "allergies noted on [Southwest Hospital's] history show morphine and Ativan." Under medications, Dr. Wheeler stated: "[Jacob] was recently given Ativan 2 mg IV push q. 4 hours p.r.n., he has received two doses of this over the last 24 hour period." Dr. Wheeler's problem list was, in pertinent part, as follows: "1. decreased mental status, previous agitation; 2. respiratory failure now on ventilator and intubated ... 7. congestive heart failure with elevated BNP." He noted Jacob's "heart had a regular rate and rhythm," and, under allergies, he wrote: "MSO4 AND ATIVAN."

The admission report of consulting physician Srinivas Kadiyala noted Jacob was found at Southwest Hospital "unresponsive and in cardiorespiratory arrest." She also stated:

> As per the nursing staff on the floor, the patient apparently had a respiratory arrest when he was in this hospital a few weeks ago. It was felt he was sensitive to Ativan at the time of the CT scan study.

There was little, or no, change in Jacob's condition during the following week and, after a long discussion, Jacob's family decided to place him as do-not-resuscitate. Jacob expired shortly after he was removed from the ventilator.

III. Expert Testimony

Expert testimony at trial centered around whether Jacob's death was caused by the administration of the two doses of Ativan by Southwest Hospital's nurses on December 18 and 19.

A. Appellees' Expert—Joe Haines, M.D.

Joe Haines, M.D., testified that, in his opinion, Southwest Hospital's nurses were negligent in Jacob's care and treatment. He testified Southwest Hospital's nurses administered the Ativan despite extensive documentation of his allergy.

He also testified their negligence caused Jacob's death. Based on his experience, he testified common side effects from Ativan range from sedation and respiratory depression (not taking enough breaths or not breathing deeply enough) to agitation and confusion.[22] He also testified Ativan's manufacturer listed respiratory depression as the top adverse reaction to the drug and an overdose of Ativan can cause respiratory depression to the extent the person's heart stops. Based upon Jacob's past medical history that indicated Jacob had experienced serious problems with Ativan, in particular his cardiac arrest subsequent to being sedated for an MRI at Covenant, he opined the dosage was too high for Jacob considering his age, his sensitivity to ***562** the drug, the drug's side effects, and Jacob's multiple health problems.

Dr. Haines opined that, after Jacob received the second two milligram dose of Ativan at 1:30 a.m. on the morning of December 19, he was overdosed and over-sedated causing his breathing to become increasingly more shallow until there was insufficient oxygen to support the functions of the heart or brain causing his heart to go into arrhythmia until Jacob suffered a cardiac arrest and finally quit breathing altogether due to respiratory depression. Dr. Haines testified that prior to the multiple doses of Ativan, the medical records did not show Jacob was experiencing irregular heart rhythms that were dangerous or any symptoms indicating a heart attack, i.e., chest pains, nausea, shortness of breath.

He also testified that, although Jacob did not undergo a medical test to determine whether he had an actual "allergy" to Ativan, there was sufficient evidence in his medical records to show he reacted badly to the drug, i.e., Jacob quit breathing four hours after receiving Versed (a faster acting drug of the same class as Ativan–Benzodiazepine) prior to the MRI at Covenant. Dr. Haines testified that the documentary evidence showed his physicians had seen enough evidence and been sufficiently warned by Jacob's family to show "the doctor's [sic] [were] obviously concerned, and they are concerned enough to enter it on the chart, so that everybody that looks at the chart that day will see that.... So it's basically putting everybody on alert. Don't use this drug on this patient." Although he recognized that Jacob's reaction to Ativan might be characterized in his medical records as an "allergy," "sensitivity," "adverse reaction" or "paradoxical reaction," he testified "[w]hat is important is that they didn't want him to have [Ativan], because it was bad for him to have [Ativan], and they should have known that and not given it to him."

Dr. Haines opined that the administration of the two doses of Ativan to Jacob by Southwest Hospital's nurses involved an extreme degree of risk considering the probability and magnitude of potential harm to Jacob. Further, Dr. Haines opined that Espinoza had actual awareness of the risk involved but proceeded with conscious indifference to the rights, safety, and welfare of Jacob. In sum, Dr. Haines opined that Southwest Hospital and its nurses were grossly negligent.

B. THI's Experts—Stacey Hail, M.D. and Kenneth Rice, M.D.

Stacey Hail, M.D., opined that the two doses of Ativan did not proximately cause Jacob's death. Rather, she testified he died of a heart attack. She testified Jacob's medical records indicated he had a long history of coronary artery disease that resulted in scar tissue on his heart from past heart attacks. The scar tissue was irritable and had a tendency to cause arrhythmias, i.e., an accelerated heart rate. In her opinion, an arrhythmia caused Jacob's heart attack and he died from a fatal ventricular tachyarrhythmia.

[1] In support, she relied on approximately fifteen pages of telemetry strips obtained from heart monitors attached to Jacob on December 1, 3, 5, 6, 10, 14, and 15 while he was at Covenant.[23] She also ***563** relied on the results of a blood test taken on December 19 at 8:00 a.m., an hour after Jacob had been found unresponsive at Southwest Hospital and been admitted to Covenant. The blood test showed positive troponins measuring .26 indicating to her that Jacob had suffered a heart attack.[24] Later, at midnight (sixteen hours after Jacob had coded at Southwest Hospital), Jacob's troponin level measured 1.23. In addition, she testified his Basic Metabolism Panel

(BMP) was greater than 5,000 indicating the "possibility" of congestive heart failure. [25]

She further testified Ativan did not cause Jacob's death because he did not have an allergy to the drug and Ativan does not affect the cardiac muscle. She testified Ativan works on the same brain receptor that alcohol does and the drug makes you sleep—the higher the dose the longer you sleep.

She testified Ativan does not cause respiratory depression based upon her experience with suicidal patients she had seen in the emergency room. She opined that "two milligrams of Ativan is, by no means, an overdose," based on her experience in the emergency room where she has prescribed "a dose of eight milligrams at one time." [26]

Dr. Rice opined that Jacob died from his underlying medical conditions. After his first visit with Jacob, he noted his multiple medical problems [27] and concluded Jacob was "at a very high risk for respiratory failure, SCD [sudden cardiac death], and fluid overload." In support, he also relied on Jacob's troponin levels and an elevated BMP of 5,000, both measured after Jacob was transferred from Southwest Hospital to Covenant. [28] In his opinion, Covenant's laboratory results "proved conclusively that [Jacob] suffered an acute myocardial infarction and, most likely, based on his history and underlying medical problems, was the cause of his death."

Dr. Rice testified Jacob's death was not consistent with an overdose of Ativan because: (1) there is no scientific evidence that Ativan causes respiratory depression or distress; (2) heart attacks or sudden cardiac death usually occur within a very short period of time; and (3) he would have expected to see an adverse reaction from the Ativan within several minutes or hours.

On cross-examination, however, Dr. Rice agreed that respiratory failure is a side effect of Ativan reported by its manufacturer and decreased oxygen from decreased respirations can cause brain injury. Although he testified there was no scientific proof Ativan causes respiratory ***564** depression or failure, he conceded the side effect was listed by the manufacturer as a possible side effect. He also agreed that complications from taking a drug of the benzodiazepine class include obtundation—a level of consciousness before a coma.

He testified that he did not want Jacob to take Ativan because: (1) it is well known in literature that Ativan, in geriatric patients or in a severely ill patient, can cause a paradoxical result; (2) becoming more agitated was the type of reaction to Ativan described by Jacob's son; (3) he did not want Jacob to become significantly agitated because he had a bad heart, underlying disorders, and a C2 fracture; and (4) he did not want Jacob to raise his heart rate, nor put him on any type of stimulus that might cause him to have a heart attack or complicate his actions.

IV. Evidence at Trial—Negligent Credentialing/Hiring

In Appellees' case-in-chief, Dr. Haines was asked whether a director of nurses or administrator of a facility should have some involvement in ensuring the employment of competent nurses. Dr. Haines responded that a person in that position should research the references of people that they hire, i.e., they should determine the nature and extent of their training and their past employment record. They should also learn whether there were problems at previous hospitals, and they should investigate any previous firings or allegations of inappropriate conduct.

Espinoza testified that, in September 1997, he agreed to a stipulated order from the State Board of Nursing in Colorado placing him on probation for administering Ativan to a patient without a physician's order and failing to document the drug's administration while working at a care center in Colorado Springs, Colorado. The conditions of his year-long probation were: (1) service while employed as a nurse for at least an average of thirty-two hours a week under adequate supervision by a licensed nurse with an unrestricted license; (2) board notification of the commencement or termination of such nursing employment; (3) submission of a written plan of nursing supervision for the Board's review and approval within six months of obtaining nursing employment; (4) completion of Board-approved education courses (twelve to fifteen hours of legal/ethical course(s); one credit pharmacology course); (5) provision of a copy of the stipulated order to the immediate nursing supervisor at his place of employment; (6) submission of a written report to the Board acknowledging, among other things, that the stipulated order was read and that the role of nursing supervisor was understood by that supervisor; and (7) in the event of relocation to another state, Espinoza would notify the Board of his change of address and give consent to the Board that it may notify the Board of Nursing of

the state to which Espinoza relocated of the existence of the terms of and Espinoza's compliance with the stipulated order.

Espinoza testified that, after the complaint in Colorado was filed, he relocated to Texas and immediately started to practice as a nurse without disclosing the complaint or the Colorado Board proceedings. When the stipulated order was entered, he did not disclose that fact to his employer, Methodist Hospital in Lubbock, Texas, and he did not comply with any of the obligations required by that order.

From June 1996 to April 1997, Espinoza worked at Methodist Hospital. From May 1997 to September 2001, he worked at Highland Medical Center under the supervision of Connie Long. During the hiring process, although he did disclose his previous employment in Colorado, the Colorado Board disciplinary proceedings never came ***565** up. Sometime in 1997, more than six years prior to the incident giving rise to this litigation, Espinoza did speak to Long about his probation in Colorado.

Espinoza testified that in 2002 Long recruited him to work at Southwest Hospital. He testified that, at the time, even though she was aware of his stipulated order with the Colorado Board of Nursing, she did not have a problem putting him on the floor and permitting him to dispense medications to patients.

Espinoza further testified that in early 2005 he informed Long that he had a drug addiction.[29] Notwithstanding this admission, Long continued to permit him to work at Southwest Hospital. On December 22, 2005, just over a year after Jacob's death, Espinoza was discharged by Long and Southwest Hospital Administrator Deanna Graves. In May 2007, Espinoza surrendered his license to the Texas Board of Nurse Examiners pursuant to an agreed order. The agreed order indicated that from approximately July 28, 2005, through August 8, 2005, Espinoza misappropriated morphine and Demerol from Southwest Hospital's computerized medicine dispensing system and took the medicine himself without proper authorization. The order further indicated that he had used the drugs for his own use and not the patients, and that at times he was impaired on duty—sleepy, sleep-walking, running into walls, falling asleep at patients' bedsides. In addition, it was determined that he had inserted an external jugular venous catheter into a patient without authorization.

During trial, Dr. Rice was asked whether a nurse whose license was suspended in 1997 for giving a medication to a patient without having obtained a doctor's order was unfit for employment as a nurse in 2004, and he responded "no." He further testified that it was okay to hire such a nurse if he or she had done everything they were supposed to do as required by the board of nurse examiners to rectify the mistake. He opined that nurses that go through rehabilitation deserve a second chance because they have complied with the board's orders related to probation or suspension. If not, he testified, they would not have a license and could not work. He further testified that a nurse "out there writing orders without permission puts a patient in an extreme risk, if put in extreme risk, could suffer injury to the patient's life."

V. Jury Instructions

Following the presentation of all the evidence, the trial court issued its jury charge stating, in pertinent part, as follows:

> QUESTION 1
>
> Did the negligence, if any, of those named below proximately cause the injury in question?
>
> Answer "Yes" or "No" for each of the following:
>
> Southwest Regional Specialty Hospital _____
>
> Pharmasource Healthcare _____

STATE BAR OF TEX., TEXAS PATTERN JURY CHARGES—GENERAL NEGLIGENCE; INTENTIONAL PERSONAL TORTS, PJC 4.1 (2008).[30]

> ***566** QUESTION 3
>
> What sum of money would have fairly compensated Jacob Perea for—
>
> a. Pain and mental anguish ... means the conscious physical pain and emotional pain ... experienced by Jacob Perea before his death as a result of the occurrence in question....

STATE BAR OF TEX., TEXAS PATTERN JURY CHARGES—SURVIVAL DAMAGES, PJC 10.2 (2008).

QUESTIONS 4–7

What sum of money, if paid now in cash, would fairly and reasonably compensate [Mario, Max, Tony, George] for [their] damages, if any, resulting from the death of Jacob Perea?

STATE BAR OF TEX., TEXAS PATTERN JURY CHARGES—WRONGFUL DEATH DAMAGES, PJC 9.3 (2008).

THI sought to replace Question 1 with the following language: "[d]id the negligence, if any, of the ones named below proximately *cause the death* of Jacob Perea?" (Emphasis added). Appellant also made the following objection, in pertinent part, to the charge:

> [T]he question should be a question about whether the negligence of either of the two Defendant parties proximately caused the death of Mr. Perea.... And I say this because only in the event that the negligence of the Defendants caused the death of Mr. Perea are wrongful death beneficiaries entitled to recover. If the jury were to believe that some act or omission by the employees of Southwest .... or Pharmasource ... caused an injury to Mr. Perea, but not his death, then the wrongful death beneficiaries would not be entitled to recover.... *The only evidence of injury in this case is death.* So the Court's Charge should reflect that, and the jury's answer should also reflect that they are actually answering the question that would permit recovery of wrongful death beneficiaries.

[Emphasis added].

VI. Judgment

Thereafter, the jury found THI and Pharmasource proximately caused the injury in question [31] and awarded Jacob's estate $159,718.40 in damages for pain and mental anguish, medical expenses, and funeral and burial expenses. [32] Jacob's sons were each awarded $100,000 for past loss of companionship and society, future loss of companionship and society, past mental ***567** anguish, and future mental anguish for a total of $400,000. The jury also found that Southwest was grossly negligent and awarded exemplary damages of $1,250,000. Based upon these jury findings, the trial court entered a judgment decreeing that Appellees recover from THI the sum of $1,696,895.50. [33]

In its judgment, the trial court apportioned Appellees recovery as follows:

Mario Perea, as representative of Jacob's estate	$ 307,760.22
Mario Perea, individually	$ 347,283.82
Max Perea	$ 347,283.82
Tony Perea	$ 347,283.82
George Perea	$ 347,283.82
Total Judgment—Southwest Regional Specialty Hospital	$1,696,895.50

Thereafter, THI filed a motion for judgment notwithstanding the verdict, remittitur, and to modify, correct, or reform the judgment. The trial court denied

THI's motion and its motion for reconsideration. This appeal followed.

Discussion

THI asserts: (1) the trial court abused its discretion by using a broad-form jury instruction on negligence and proximate cause when Appellees sought survival and wrongful death damages; (2) the trial court abused its discretion by granting Appellees a trial amendment to assert an action for negligent credentialing/hiring because the amendment was prejudicial to the presentation of THI's defense; (3) Appellees' evidence was legally and factually insufficient to support a judgment on their claims of negligent credentialing/hiring and factually insufficient to support Appellees' claim of negligence, i.e., that THI's conduct proximately caused Jacob's death or the nurses at Southwest Hospital were negligent in the performance of their duties; (4) Appellees' evidence that THI was grossly negligent is legally and (5) factually insufficient; (6) the trial court abused its discretion by excluding evidence of the fact that THI had conducted an investigation related to Jacob's death; and (7) the trial court abused its discretion as a matter of law by failing to apply statutory damage caps in sections 41.008(b) and 74.301(b) of the Texas Civil Practice and Remedies Code.

I. Jury Instruction

A. Standard of Review

[2] **[3]** We review a trial court's decision to submit or refuse a particular jury instruction under an abuse of discretion standard. *Shupe v. Lingafelter,* 192 S.W.3d 577, 579 (Tex.2006). *See In the Interest of V.L.K.,* 24 S.W.3d 338, 341 (Tex.2000). Although a trial court has great latitude and considerable discretion to determine necessary and proper jury instructions; *see* Tex.R. Civ. P. 277; *H.E. Butt Grocery Company v. Bilotto,* 985 S.W.2d 22, 23 (Tex.1998), the trial court abuses its discretion if "the court acts arbitrarily, unreasonably or without reference to guiding principles of law." *McWilliams v. Masterson,* 112 S.W.3d 314, 317 (Tex.App.-Amarillo 2003, pet. denied).

[4] **[5]** **[6]** When a trial court refuses to submit a requested instruction on an issue raised by the pleadings and evidence, the question on appeal is whether the request was reasonably necessary to enable the jury to render a proper verdict. *Shupe,* 192 S.W.3d at 579 (citing *Tex. Workers Comp. Ins. Fund v. Mandlbauer,* 34 S.W.3d 909, 912 (Tex.2000)). Further, omission of an instruction is harmful, or reversible error, only if the omission probably caused the rendition of an improper ***568** judgment; Tex.R.App.P. 44.1(a), 61.1(a); *see Wal–Mart Stores, Inc. v. Johnson,* 106 S.W.3d 718, 723 (Tex.2003); and is harmless "when the findings of the jury in answer to other issues are sufficient to support the judgment." *Boatland of Houston, Inc. v. Bailey,* 609 S.W.2d 743, 750 (Tex.1980). *See City of Brownsville v. Alvarado,* 897 S.W.2d 750, 752 (Tex.1995) (a jury question may be immaterial, or harmless, "when its answer can be found elsewhere in the verdict or when its answer cannot alter the effect of the verdict"). Whether harm exists is viewed in the context of the whole charge. *Boatland,* 609 S.W.2d at 749–50.

B. Wrongful Death and Survival Actions

The Texas Survival Statute permits a decedent's heirs, legal representatives, and estates to bring actions for personal injuries the decedent suffered before his death; *see* Tex. Civ. Prac. & Rem. Code Ann. § 71.021 (Vernon 2008), while the Texas Wrongful Death Act confers a cause of action upon the surviving spouse, children, and parents of a decedent for their damages resulting from the decedent's death. *See* Tex. Civ. Prac. & Rem. Code Ann. §§ 71.002, 71.004 (Vernon 2008).

[7] **[8]** To establish a cause of action under either statute, the claimant must establish a death and the occurrence of a wrongful act. *Mayer v. Willowbrook Plaza Ltd. Partnership,* 278 S.W.3d 901, 909 (Tex.App.-Houston [14th Dist.] 2009, no pet.). If negligence is alleged as the wrongful act, the claimant must show that the defendant's negligent act or omission was a substantial factor in bringing about the decedent's death, and without it, the decedent's death would not have occurred. *See Columbia Medical Ctr. of Las Colinas, Inc. v. Hogue,* 271 S.W.3d 238, 246 (Tex.2008) (citing *IHS Cedars Treatment Ctr., Inc. v. Mason,* 143 S.W.3d 794, 798 (Tex.2004)).

[9] The difference between the two statutes is the nature of the damages that may be recovered and who may collect them. The purpose of the Texas Survival Statute

is "to continue a decedent's cause of action beyond death to redress decedent's estate for decedent's injuries that occurred before he died." *Borth v. Charley's Concrete Co.,* 139 S.W.3d 391, 395 (Tex.App.-Fort Worth 2004, pet. denied). *See* Tex. Civ. Prac. & Rem. Code Ann. § 71.021 (Vernon 2008). On the other hand, the purpose of the Wrongful Death Act is to permit a surviving husband, wife, child, and parents of the decedent to bring a cause of action to redress their injuries resulting from the decedent's death. *See* Tex. Civ. Prac. & Rem. Code Ann. §§ 71.002, 71.004, 71.010 (Vernon 2008).

[10] Here, the gist of Appellees' action is that Southwest Hospital's nurses wrongfully administered two doses of Ativan to Jacob proximately causing his death. Jacob's estate sought to recover Jacob's damages for injuries he suffered prior to his death [34] and Jacob's sons sought to recover damages they suffered because of his death. [35] Thus, in order to recover, Appellees were required to prove THI breached a duty owed to Jacob and the breach proximately caused the damages ***569** sought by Jacob's estate and sons. *Hogue,* 271 S.W.3d at 246. [36]

To determine whether Southwest Hospital was negligent, the trial court chose to charge the jury with the Texas Pattern Jury Charge or Broad Form Charge for Joint Submission of Negligence and Proximate Cause. *See* STATE BAR OF TEX., TEXAS PATTERN JURY CHARGES–GENERAL NEGLIGENCE; INTENTIONAL PERSONAL TORTS, PJC 4.1 (2008). Although the Texas Pattern Jury Charges are not "law," they are heavily relied upon by bench and bar and based on what the State Bar Committee perceives the present law to be. *H.E. Butt Co. v. Bilotto,* 928 S.W.2d 197, 199 (Tex.App.-San Antonio 1996), *aff'd,* 985 S.W.2d 22 (Tex.1998). *See Borden, Inc. v. Price,* 939 S.W.2d 247, 254 (Tex.App.-Amarillo 1997, writ denied). [37]

[11] The trial court's charge instructed the jury that, absent a proper legal definition for a term, the jury should attribute the "meaning commonly understood" to the words in the charge. Given the facts of this case and the similarity in the meanings of the terms "injury" and "death," as a precipitant to damages, we cannot say that, as a matter of law, a reasonable juror would have been misguided by the trial court's instruction. This is particularly so when the vast majority of the evidence at trial, both testimonial and documentary, was related to Jacob's manner of death and whether the Ativan dosage caused his death. In fact, during the trial court's hearing on the jury instructions, THI's counsel affirmatively stated that "[t]he only evidence of injury is death."

Further, while a Comment to PJC 4.1 addressing use of the terms "occurrence" or "injury" suggests that "[i]n a case involving death, the word 'death' *may* be used instead of 'injury' "; (emphasis added), this Comment addresses circumstances where there may be evidence of a plaintiff's negligence that is "injury-causing" or "injury-enhancing" but not "occurrence-causing." This Comment is inapplicable insofar as THI points to no evidence of record establishing that any negligence by Jacob, or by any other third party, may have either caused or enhanced his injury or death. Furthermore, THI did not request an issue attributing any negligence to Jacob.

[12] Neither did the trial court abuse its discretion by failing to issue two instructions, i.e., one using the word "injury" and one using the word "death." While trial courts should obtain fact findings on all theories pleaded and supported by the evidence, a trial court is not required to, and should not, confuse the jury by submitting differently worded questions that call for the same factual finding. *See Star Enterprise v. Marze,* 61 S.W.3d 449, 459 (Tex.App.-San Antonio 2001, pet. denied). Questions are duplicitous if they embrace the same fact question, whether identical in language or merely similar in form. *Miller v. Wal–Mart Stores,* 918 S.W.2d 658, 664 (Tex.App.-Amarillo 1996, writ denied) (citing *Holmes v. J.C. Penney Company,* ***570** 382 S.W.2d 472, 473 (Tex.1964)). Here, either "injury" or "death" would have been appropriate terms for the negligence instruction. Given the trial court's broad discretion in submitting jury questions, we cannot say the trial court abused its discretion by choosing the term "injury" over "death."

Finally, even if use of the term "injury" rather than "death" was error, the answers sought by Southwest Hospital can be found in Questions 3(c) and 4 through 7. While Question 1 sought to establish whether THI's conduct negligently caused Jacob's injury, Questions 3(c), and 4 through 7, sought to establish damages resulting from his death. [38] Moreover, THI fails to offer any evidence establishing that use of the term "injury" rather than "death" caused rendition of an improper judgment. Accordingly, THI's first issue is overruled.

II. Trial Amendment

During their case-in-chief, Appellees confronted Espinoza with the Colorado Board of Nursing's stipulated order and examined him without objection.[39] Thereafter, when Appellees sought to amend their petition to assert a negligent credentialing/hiring claim against THI, THI objected that (1) Appellees were pleading a cause of action for which there was no recovery because there were no damages; (2) the evidence was irrelevant because Espinoza worked as a Licensed Practical or Vocational Nurse in Colorado, not as a Registered Nurse; and (3) evidence of Espinoza's disciplinary proceeding six years earlier was irrelevant. THI did not seek a continuance.

[13] **[14]** Under Rule 66 of the Texas Rules of Civil Procedure, a trial court may not refuse a trial amendment unless (1) the opposing party presents evidence of surprise or prejudice, or (2) the amendment asserts a new cause of action or defense and thus is prejudicial on its face and the opposing party objects to the amendment. *Hart v. Moore,* 952 S.W.2d 90, 95 (Tex.App.-Amarillo 1997, writ denied) (citing *Greenhalgh v. Service Lloyds Insurance Co.,* 787 S.W.2d 938, 939 (Tex.1990)). *See The State Bar v. Kilpatrick,* 874 S.W.2d 656, 658 (Tex.) (*per curiam*) (decision to permit or deny trial amendment rests in sound discretion of trial judge if amendment asserts new cause of action or defense and thus prejudicial on its face), *cert. denied,* 512 U.S. 1236, 114 S.Ct. 2740, 129 L.Ed.2d 860 (1994).[40] The opponent of the ***571** trial amendment has the burden of showing surprise or prejudice, and "[a] motion for continuance based upon the ground of surprise or prejudice is essential before the filing of a trial amendment will constitute reversible error." *Resolution Trust Corp. v. Cook,* 840 S.W.2d 42, 46 (Tex.App.-Amarillo 1992, writ denied). *See Jones v. Blackmon,* 419 S.W.2d 434, 440 (Tex.Civ.App.-Houston [14th Dist.] 1967, writ ref'd n.r.e.) (trial court does not ordinarily abuse its discretion when party opposing an amendment does not ask for a postponement).

[15] Appellees' trial amendment was made during their case-in-chief. THI had yet to put on its defense. THI did not object to the amendment because of surprise or prejudice, nor did it seek a continuance. Rather, THI asserted that the proposed action was legally deficient and/or the underlying evidence in support of the action was irrelevant. Having failed to object to the amendment based upon surprise or prejudice, THI may not now assert these grounds on appeal.[41]

To preserve error on appeal, a party must make a timely, specific objection or motion to the trial court that states the grounds for the ruling sought with sufficient specificity and complies with the rules of evidence and procedure. *See* Tex.R.App.P. 33.1(a). Because THI presents this argument for the first time on appeal, it is waived. *Id. See Marine Transp. Corp. v. Methodist Hosp.,* 221 S.W.3d 138, 147 n. 3 (Tex.App.-Houston [1st Dist.] 2006, no pet.). THI's second issue is overruled.

III. Recovery Under Appellees' Negligence Theories

THI asserts Appellees' evidence at trial in support of their negligent credentialing/hiring claim is both legally and factually insufficient, i.e., Appellees failed to establish Southwest Hospital's conduct breached any standard of care in hiring Espinoza or that any negligence in hiring Espinoza caused Jacob's death. THI also asserts Appellees' evidence at trial in support of their negligence claim against Southwest Hospital is factually insufficient, i.e., Appellees' expert evidence that Southwest Hospital's negligence caused Jacob's death, when compared to THI's expert evidence, is so weak that it is clearly wrong and manifestly unjust.

A. Standard of Review

In conducting a legal sufficiency review,[42] we must consider the evidence in the light most favorable to the challenged finding, indulge every reasonable inference ***572** to support it; *City of Keller v. Wilson,* 168 S.W.3d 802, 822 (Tex.2005),[43] and credit favorable evidence if reasonable jurors could and disregard contrary evidence unless reasonable jurors could not. *Id.* at 827. A challenge to legal sufficiency will be sustained when, among other things, the evidence offered to establish a vital fact does not exceed a scintilla.[44] *Kroger Tex. Ltd. P'ship v. Suberu,* 216 S.W.3d 788, 793 (Tex.2006). Furthermore, so long as the evidence falls within the zone of reasonable disagreement, we may not invade the factfinding role of the jurors, who alone determine the credibility of witnesses, the weight to be given their testimony, and whether to accept or reject all or part of their testimony. *Wilson,* 168 S.W.3d at 822.

In reviewing a factual sufficiency challenge, we consider all the evidence and set aside a finding only if it is so against the great weight and preponderance of the evidence as to be clearly wrong and unjust. *Ortiz v. Jones,* 917 S.W.2d 770, 772 (Tex.1996). If, as here, the appellant is challenging the factual sufficiency of the evidence to support a finding on an issue on which the other party had the burden of proof, we must overrule the complaint unless, considering all the evidence, the finding is clearly wrong and manifestly unjust. *See Santa Fe Petroleum, L.L.C. v. Star Canyon Corp.,* 156 S.W.3d 630, 637 (Tex.App.-Tyler 2004, no pet.) (citing *Garza v. Alviar,* 395 S.W.2d 821, 823 (Tex.1965)). Inferences may support a judgment only if they are reasonable in light of all the evidence; *id.,* and, again, the trier of fact is the sole judge of the credibility of the witnesses and the weight to be given their testimony. *GTE Mobilnet of S. Tex. Ltd. P'ship v. Pascouet,* 61 S.W.3d 599, 615–16 (Tex.App.-Houston [14th Dist.] 2001, pet. denied). In addition, the mere fact that we might have reached a different conclusion on the facts does not authorize us to substitute our judgment for that of the jury. *Maritime Overseas Corp. v. Ellis,* 971 S.W.2d 402, 407 (Tex.1998). *See Richmond Condominiums v. Skipworth Commercial Plumbing, Inc.,* 245 S.W.3d 646, 658 (Tex.App.-Fort Worth 2008, no pet.).

B. Analysis

1. Negligent Credentialing/Hiring

Here, although Appellees' claim is that Southwest Hospital was negligent in credentialing or hiring Espinoza, the thrust of the claim is that the health care facility failed to protect its patient—a claim that "necessarily implicate[s] the acceptable standards of safety pursuant to the definition of health care liability claim." [45] *Diversicare Gen. Partner, Inc. v. Rubio,* 185 S.W.3d 842, 855 (Tex.2005). [46]

***573** **[16]** **[17]** Negligent hiring claims are both health care liability claims, *see In Re McAllen Medical Center Inc.,* 275 S.W.3d 458, 462 (Tex.2008), and "simple negligence causes of action." *Morris v. JTM Materials, Inc.,* 78 S.W.3d 28, 49 (Tex.App.-Fort Worth 2002, no pet.). To establish a claim for negligent hiring, supervision and retention, a plaintiff must prove the following elements: (1) a duty to hire, supervise, and retain competent employees; (2) an employer's breach of the duty; and (3) the employer's breach of the duty proximately caused the damages sued for. *See LaBella v. Charlie Thomas, Inc.,* 942 S.W.2d 127, 137 (Tex.App.-Amarillo 1997, writ denied).

[18] An employer is liable for negligent hiring, supervision, or retention when proof is presented that the employer hired an incompetent or unfit employee whom it knew or, by the exercise of reasonable care, should have known was incompetent or unfit, thereby creating an unreasonable risk of harm to others. *See Dangerfield v. Ormsby,* 264 S.W.3d 904, 912 (Tex.App.-Fort Worth 2008, no pet.). Because Appellees' claim of negligent credentialing and hiring is cognizable under chapter 74 of the Texas Civil Practice and Remedies Code; *Garland Community Hosp. v. Rose,* 156 S.W.3d 541, 544, 545–46 (Tex.2003), expert testimony is necessary to establish the elements of the claim. *Holguin,* 256 S.W.3d at 356.

[19] **[20]** THI asserts Appellees failed to produce more than a scintilla of probative evidence that THI breached its standard of care by hiring Espinoza and, if so, any breach by THI proximately caused Jacob's injuries. [47] Appellees' expert, Dr. Haines, testified on direct examination, without objection, that a director of nurses and hospital administrators should have some involvement in assuring that nurses on their staff will not write orders without a doctor's permission. He testified that, when hiring nurses, nursing directors, and administrators they should look at a nurse's past employment record and determine whether they had problems or troubles at prior nursing facilities. He further opined that nursing directors and hospital administrators had a duty to research the background of people they hired. [48]

Dr. Haines also testified that, if a nurse went "rogue" and administered prescription ***574** drugs without the authority to do so, the nurse should lose their license. Nurse Jahomo testified that, if she wrote an order for a patient's medication without a doctor's permission, she would be in violation of her nursing license. She also testified that, administering medication without the proper approval would be extremely dangerous for the patient and could cause the patient's death if there was an adverse effect. Nurse Graham testified that, in December 2004, Espinoza had a reputation for being a "rogue" nurse and agreed with Nurse Jahomo that a nurse who

administered prescription drugs without proper authority should lose their license.

Espinoza testified that, prior to being employed at Southwest Hospital, he had been disciplined by the Colorado Board of Nursing for administering Ativan to a patient without a physician's prior approval. The Colorado Board of Nursing placed Espinoza on probation with specific tasks to be completed prior to reinstatement of his nursing license. He testified he relocated to Texas, [49] began practicing as a nurse, and failed to comply with *any* conditions of his Colorado probation.

Espinoza further testified that in 1997 he was hired at Highland Medical Center where his supervising nurse was Connie Long. He testified that he spoke to Long about his probation in Colorado and she hired him despite knowing that he had his license suspended in Colorado for administering Ativan without a doctor's approval. [50] After Long moved to Southwest Hospital to take a position as Director of Nursing, she recruited Espinoza to join her and, in 2002, Espinoza began working at Southwest Hospital. Espinoza testified that, although Long was by then aware of his stipulated probation order with the Colorado Board of Nursing, she had no problem putting him on the floor and permitting him to dispense medications to patients. While he was employed at Southwest Hospital, he testified his evaluations were always above average.

Although Espinoza testified he wrote the order to administer Ativan to Jacob after receiving approval from Nurse Graham by telephone, the jury could reasonably infer from Dr. Rice's and Nurse Graham's testimony that Espinoza wrote the order himself without prior approval. Nurse Graham testified that she did not receive any calls from Espinoza that day and had no doubt that she did not approve the order to administer Ativan to Jacob.

Although the testimony regarding who approved the administration of Ativan to Jacob was conflicting, the jury's verdict indicates they credited and gave weight to Nurse Graham's testimony. *See Wilson,* 168 S.W.3d at 819 ("Jurors are the sole judges of the credibility of witnesses and the weight to give their testimony. They may choose to believe one witness and disbelieve another" and "[r]eviewing courts cannot impose their own opinions to the contrary."). *See also Texas Drydock, Inc. v. Davis,* 4 S.W.3d 919, 924 (Tex.App.-Beaumont 1999, no pet.). Moreover, ***575** "[c]ontroverted trial issues are properly within the province of the jury if reasonable minds could differ as to the truth of the controlling facts." *Collora v. Navarro,* 574 S.W.2d 65, 68 (Tex.1978).

Given this evidence, we conclude there was more than a scintilla of evidence establishing that THI breached its duty to hire nurses that were competent or fit for employment. The jury could reasonably infer from the evidence that THI, through Long, hired Espinoza knowing he was on probation due to disciplinary proceedings in another state, for conduct that reasonably endangered the health and safety of patients entrusted to his care. The evidence also reflects Long did so without taking any precautions to assure that Espinoza would not commit the same violations again. Further, Espinoza was permitted to medicate patients and then ultimately was placed in a managing position with responsibilities that included supervising authority over nurses, advising physicians or their assistants on medications, writing telephone orders for the administration of drugs to patients, and instructing nurses on which drugs to administer.

THI points to Dr. Rice's answer to a hypothetical question as evidence that Southwest Hospital was not negligent in hiring Espinoza. Dr. Rice testified he would not consider a previously disciplined nurse unfit if that nurse had complied with the rehabilitative conditions established by the board of nursing and had worked for six years at two different hospitals without further incident. Notwithstanding this statement, the jury was free to conclude that Espinoza never complied with the rehabilitative conditions of the Colorado order.

THI also asserts that the passage of six years time between the act that caused the Colorado Board of Nursing to place Espinoza on probation and Jacob's injury rendered the Colorado Board of Nursing Order irrelevant. This assertion overlooks the principle that, "[w]hen a plaintiff's credentialing [or hiring] complaint centers on the quality of the [patient's] treatment ... the hospital's acts or omissions in credentialing [or hiring] are inextricably intertwined with the patient's medical treatment and the hospital's provision of health care." *Rose,* 156 S.W.3d at 546. The *Rose* court stated, in pertinent part, as follows:

> Rose's is a case in point. She complains of acts and omissions that occurred, in significant part, during

> her treatment. Rose alleges that the Hospital acted negligently and maliciously in allowing Dr. Fowler to perform Rose's surgeries.... These decisions necessarily occurred during Rose's treatment. It is not necessary, however, to dissect Rose's claims in to pre-treatment and post-treatment components. *Regardless of when the acts occurred, the allegations all revolve around the same basic premise: that the Hospital put Rose at risk by allowing Dr. Fowler to treat her.* It makes no sense to conclude that some credentialing [or hiring] claims are subject to the MLIIA and others are not, depending on what point in time the credentialing decision occurred.

156 S.W.3d at 545. (Emphasis added). Accordingly, we cannot say that the passage of time or Espinoza's prior employment, as a matter of law, absolves THI of any breach of its duty to hire and retain competent nurses.

[21] Regarding causation, here, Espinoza's conduct, as it pertains to Jacob, is identical to the wrongful conduct he committed in Colorado, i.e., administering Ativan without required approvals. The evidence supports the conclusion that, although Long was aware of Espinoza's stipulated probation order, she never reported ***576** that fact to the Texas nursing authorities, knowing it would affect his employability as a nurse licensed to practice in Texas. The evidence of record further indicates that not only did Long not take precautions to prevent similar conduct from occurring again, she promoted Espinoza to a position of authority with sufficient power to make it relatively easy for him to engage in the same errant behavior.

The jury's findings that THI was negligent in hiring Espinoza and that negligence caused Jacob's injury are not so against the great weight and preponderance of the evidence as to be clearly wrong or manifestly unjust. Accordingly, we cannot say that the evidence was either legally or factually insufficient to support the jury's verdict under Appellees' negligent credentialing/hiring theory of recovery.

2. Medical Malpractice—Negligence

THI next contends the evidence is factually insufficient to support the jury's finding that THI's negligence, through its employees, in administering two doses of Ativan to Jacob proximately caused his death.[51] In support, THI asserts the credentials of its expert, Dr. Hail, are superior to Dr. Haines's credentials and the opinions of its experts, Dr. Hail and Dr. Rice, are entitled to more weight than Dr. Haines's opinions.

[22] **[23]** While proximate cause in a medical malpractice case must be based upon reasonable medical probability; *Park Place Hosp. v. Estate of Milo,* 909 S.W.2d 508, 511 (Tex.1995), "[t]he quantum of proof required is simply 'that it is more likely than not' that the ultimate harm or condition resulted from such negligence." *Kramer v. Lewisville Mem. Hosp.,* 858 S.W.2d 397, 400 (Tex.1993). A plaintiff is not required to exclude every other reasonable hypothesis; *Marvelli v. Alston,* 100 S.W.3d 460, 470 (Tex.App.-Fort Worth 2003, pet. denied), and more than one proximate cause may exist. *Lee Lewis Constr., Inc. v. Harrison,* 70 S.W.3d 778, 784 (Tex.2001) (question is whether the wrongful act "was 'a' proximate cause, not 'the' proximate cause" of decedent's death).

[24] To satisfy the causal element of proximate cause, the wrongful act need only be a substantial factor[52] in bringing about the harm. *Southwest Key Program, Inc. v. Gil–Perez,* 81 S.W.3d 269, 274 (Tex.2002); *Sisters of St. Joseph of Texas, Inc. v. Cheek,* 61 S.W.3d 32, 35 (Tex.App.-Amarillo 2001, pet. denied). Further, whether a particular act of negligence is a cause-in-fact of an injury is a particularly apt question for jury determination. *Farley v. MM Cattle Co.,* 529 S.W.2d 751, 756 (Tex.1975). *See Tex. Dept. of Transp. v. Pate,* 170 S.W.3d 840, 848 (Tex.App.-Texarkana 2005, pet. denied).

[25] **[26]** Any objection to the qualifications or methodology of Appellees' expert witness, Dr. Haines, was waived at trial because THI made no objection to his testimony. To preserve a complaint that scientific evidence is unreliable and thus, no evidence, a party must object to the ***577** evidence before trial or when the evidence is offered. *See Volkswagen of America, Inc. v. Ramirez,* 159 S.W.3d 897, 903 (Tex.2004); *Kerr–McGee Corp. v. Helton,* 133 S.W.3d 245, 252 (Tex.2004). Further, whether

an expert's testimony is credible or not is best left to the jury. *See Pascouet,* 61 S.W.3d at 615–16.

[27] Dr. Haines practiced family medicine for twenty-three years. His practice is comprised of approximately thirty percent of patients over sixty-five years of age. He has cared for patients taking benzodiazepines, the same class of drug as Ativan. He testified that common side effects from Ativan range from sedation and respiratory depression to agitation and confusion. He also testified Ativan's manufacturer listed respiratory depression as the top adverse reaction to the drug [53] and an overdose of Ativan can cause respiratory depression to the extent a person's heart stops.

Although Jacob did not undergo a specific medical test to determine whether he had an allergy to Ativan, Dr. Haines testified Jacob's medical records indicated that he "reacted badly" to Ativan prior to being admitted to Southwest Hospital, i.e., quit breathing after receiving Versed, another benzodiazepine, in preparation for a recent MRI at Covenant and experienced agitation/confusion when medicated by Ativan as illustrated by his physicians' orders labeling Ativan as an allergy for Jacob.

Dr. Haines opined that, after Jacob received the second dose of Ativan in the early morning hours of December 19, he was overdosed. His breathing became increasingly more shallow until there was insufficient oxygen to support the functions of his heart or brain causing his heart to go into arrhythmia until he suffered a cardiac arrest and finally quit breathing altogether due to respiratory depression.

Dr. Hail disagreed. She testified that Jacob died of a heart attack based upon a blood test taken nearly an hour after Jacob was found unresponsive and was transferred to Covenant. She also based her opinion on telemetry strips recorded at Covenant on December 12 (before Jacob was transferred to Southwest Hospital) and on December 19 (after Jacob was returned from Southwest Hospital.) She opined that, based upon her experience in the emergency room, Ativan does not cause respiratory depression and two milligrams of Ativan was not an overdose.

Contrary to Dr. Hail's opinion, however, hospital documentation showed Jacob's heart condition was stable prior to receiving the two doses of Ativan. When Jacob was transferred from Covenant to Southwest Hospital on December 12, his discharge summary noted that he was "released in stable condition, neurologically intact [with] a stable cardiac evaluation." No medical devices were utilized to monitor Jacob's cardiac condition while he was at Southwest Hospital.

Prior to receiving Ativan on December 18, Jacob's Progress Note indicated he was negative for shortness of breath, negative for chest pain, and negative for nausea or vomiting. Although the December 18 Progress Note indicated he was experiencing atrial fibrillation, the Progress Note stated he was "on Coumadin as well as Lorenex, continue these and *recheck 12/20/04.*" (Emphasis added). Further, only hours before receiving either dose of Ativan on December 18 and 19, Nurse Graham checked Jacob's breathing status and vital signs. She noted his oxygen ***578** saturations and respiratory rate and "didn't see anything abnormal."

Approximately six hours after receiving what Dr. Haines termed an overdose of Ativan, Jacob was discovered with no vital signs and unresponsive. On subsequent examination by Dr. Wheeler at Covenant, he noted Jacob was "currently obtunded, probably secondary to [an] Ativan injection." Dr. Wheeler noted that "allergies noted on [Southwest Hospital's] history show morphine and Ativan," and that Jacob had "recently been given Ativan 2 mg IV push q. 4 hours p.r.n., he has received two doses of this over the last 24 hour period." Based upon Jacob's medical records in addition to his experience, Dr. Haines opined that, prior to receiving Ativan, Jacob's medical records did not show he was experiencing irregular heart rhythms that were dangerous or symptoms associated with a heart attack such as chest pains, nausea, or shortness of breath prior to his coding.

Dr. Hail also testified that, if Jacob was having an allergic reaction to Ativan, the manifestation of his symptoms would have occurred within minutes of taking the Ativan rather than hours later. Dr. Haines, on the other hand, testified that Jacob did not go into anaphylactic shock after receiving the Ativan which, in his opinion, could occur within an hour or two of taking the Ativan, but instead suffered from an adverse reaction or side effect due to his sensitivity to Ativan. He testified the effect of the multiple doses of Ativan on Jacob was cumulative, i.e., his respiratory distress or adverse reaction slowly increased as the medication was digested and absorbed into the bloodstream until he was unable to breathe.

Dr. Haines testified that Jacob arrested four hours after the MRI at Covenant on December 3 when, prior to the MRI, he had received Versed, a member of the benzodiazepine family of drugs and faster acting than Ativan. In his opinion, Jacob suffered a similar adverse reaction at Southwest Hospital where he was given multiple two milligram doses of Ativan, one at 4:00 p.m. on December 18 and another at 1:30 a.m. on December 19, and arrested approximately five hours and forty-five minutes after the second dose of Ativan at 7:15 a.m.

Dr. Rice opined that Jacob died of his underlying medical conditions. He pointed to the same blood test and telemetry readings relied on by Dr. Hail. Although he testified there was no scientific evidence that Ativan causes respiratory depression, he conceded that respiratory failure is a side effect of Ativan reported by its manufacturer. He also testified that complications from taking a drug of the benzodiazepine class, which includes Ativan, includes obtundation, as noted by Dr. Wheeler on Jacob's admission on December 19, i.e., "a level of consciousness before a coma."

Dr. Rice testified that he did not want Jacob to receive Ativan because (1) it was well known in literature that Ativan in geriatric patients or severely ill patients doesn't calm them down like it's supposed to but may make the patient wilder and more agitated; (2) Jacob's son had communicated that Jacob had these reactions to the drug; and (3) he didn't want to raise Jacob's heart rate because he was concerned that the stimulus might cause Jacob to suffer a heart attack. For all these reasons, Dr. Rice simply "didn't want [Jacob] to have it." This testimony supports Dr. Haines's conclusion that the two doses of Ativan caused Jacob to arrest.

[28] The jury has broad latitude to infer proximate cause from the evidence and the circumstances surrounding the injury-producing act especially when it is not possible to produce direct proof of proximate ***579** cause or lack of proximate cause. *J.K. & Susie Wadley Research Inst. & Blood Bank v. Beeson,* 835 S.W.2d 689, 698 (Tex.App.-Dallas 1992, writ denied) (citing *Harris v. Laquinta–Redbird Joint Venture,* 522 S.W.2d 232, 236 (Tex.Civ.App.-Texarkana 1975, writ ref'd n.r.e.).

Here, aided by expert testimony, the jury was free to determine that the administration of Ativan caused Jacob to arrest because he was stable and experiencing no symptoms of a heart attack prior to being injected with the two doses of Ativan, yet arrested only hours after having been given the drug. In addition, that Jacob's vital signs were not being electronically monitored at Southwest Hospital as they had been previously at Covenant, his vital signs were not being taken during nurse shift visitations, and his December 18 progress note indicated it was not necessary to check his heart medications until December 20 prior to receiving the Ativan, were also some evidence from which the jury could reasonably infer that Jacob's heart condition was not critical.

Similarly, scientific principles provided by Dr. Haines establish a traceable chain of causation from the condition —Jacob's arrest—back to the event—the administration of multiple doses of Ativan. Having considered all the evidence, we cannot say that the jury's finding that THI's negligence caused Jacob's injuries or death was so against the great weight and preponderance of the evidence as to be clearly wrong or manifestly unjust. Accordingly, THI's third issue is overruled.

IV. & V. Gross Negligence—Sufficiency of Evidence

Appellees argued to the jury that THI was grossly negligent in causing harm to Jacob through the administration of Ativan by either Nurse Jahomo or Espinoza and THI ratified or approved the act. Appellees further argued that THI was grossly negligent, or reckless, for employing Espinoza because he was unfit.

THI asserts there was no clear and convincing evidence that: (1) Espinoza or Jahomo were aware of the risk involved in administering Ativan to Jacob and chose to proceed in conscious indifference to his safety; (2) THI ratified Espinoza's or Jahomo's conduct, Espinoza was unfit to care for Jacob or THI was reckless in hiring him; or (3) Espinoza's employment proximately caused Jacob's death.

A. Gross Negligence

To recover exemplary damages, a plaintiff must prove by clear and convincing evidence [54] that the plaintiff's harm resulted from, *inter alia,* the defendant's willful act or gross neglect. Tex. Civ. Prac. & Rem. Code Ann. § 41.003(a)(3),

(b) (Vernon Supp. 2009). Gross negligence is statutorily defined as an act or omission:

> (A) which when viewed *objectively* from the standpoint of the actor at the time of its occurrence involves an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and
>
> (B) of which the actor has actual, *subjective* awareness of the risk involved, but nevertheless proceeds with conscious indifference to the rights, safety, or welfare of others.

***580** Tex. Civ. Prac. & Rem. Code Ann. § 41.001(11) (Vernon 2008). (Emphasis added).

[29] Thus, two elements comprise gross negligence. First, viewed objectively from the actor's standpoint, the act or omission complained of must depart from the ordinary standard of care to such an extent that it creates an extreme degree of risk of harming others. *Harrison,* 70 S.W.3d at 784–86; *Universal Servs. Co. v. Ung,* 904 S.W.2d 638, 641 (Tex.1995).[55] Second, the actor must have actual, subjective awareness of the risk involved and choose to proceed in conscious indifference to the rights, safety, or welfare of others. *See Harrison,* 70 S.W.3d at 785; *Ung,* 904 S.W.2d at 641.

B. Standard of Review

1. Legal Sufficiency

In reviewing the legal sufficiency of the evidence under a clear and convincing standard, we look at all the evidence, in the light most favorable to the judgment, to determine whether a reasonable trier of fact could have formed a firm belief or conviction that its finding was true. *Garza,* 164 S.W.3d at 622 (citing *In re J.F.C.,* 96 S.W.3d 256, 266 (Tex.2002)). We presume that the trier of fact resolved disputed facts in favor of its findings if a reasonable trier of fact could do so, and disregarded any evidence a reasonable fact finder could have disbelieved or found to have been incredible. *Id.* at 627; *In the Interest of J.L.,* 163 S.W.3d 79, 85 (Tex.2005). Further, "whenever the standard of proof at trial is elevated, [as here], the standard of appellate review must likewise be elevated." *Southwestern Bell Tel. Co. v. Garza,* 164 S.W.3d 607, 627 (Tex.2004).

a. Subjective Test—Espinoza and Jahomo

[30] **[31]** Focusing on the second, or subjective, component,[56] what separates ordinary negligence from gross negligence is the defendant's state of mind; in other words, the plaintiff must show the defendant knew about the peril, but his acts or omissions demonstrate he or she did not care. *See Diamond Shamrock Ref. Co., L.P. v. Hall,* 168 S.W.3d 164, 172 (Tex.2005); *Burk Royalty Co. v. Walls,* 616 S.W.2d 911, 922 (Tex.1981). It is this mental attitude of reckless indifference that permits a jury to find "that the defendant had decided to ignore the rights of others even in light of probable and threatened injury to them." *Williams v. Steves Indus., Inc.,* 699 S.W.2d 570, 573 (Tex.1985). This subjective component may be established by circumstantial evidence. *See Harrison,* 70 S.W.3d at 785; *Mobil Oil Corp. v. Ellender,* 968 S.W.2d 917, 921 (Tex.1998).

[32] As discussed previously, the jury could reasonably infer from the evidence that Espinoza wrote the Ativan order for Jacob without the approval of either Dr. Rice or Nurse Graham. Viewed from the standpoints of Dr. Haines, Dr. Rice, Nurse Jahomo, and Espinoza, the administration of Ativan to a patient such as Jacob without a physician's approval could cause the patient's death. Dr. Rice testified that a nurse "out there writing orders without permission puts a patient in an extreme risk, [and] if put in an extreme risk, could suffer injury to a patient's life."

***581** The magnitude of the injury, i.e., death, and the probability of that injury—probable enough for Jacob's doctors at Covenant to immediately, repeatedly, and expressly enter into his chart that he had an "allergy" to Ativan to assure that he did not receive the drug, and the myriad of precautions that were supposed to be in place at Southwest Hospital to assure a patient does not receive a drug to which they have an allergy (for example: placing an allergy sticker on the patient's chart, affixing an allergy bracelet to the patient's wrist, multiple entries in the patient's chart, computerized medicine dispensing system with allergy warnings, twice daily entries in the Nurse Documentation Reports)[57]—demonstrate that the administration of Ativan to Jacob without a physician's approval posed an extreme degree of risk. *See Columbia*

Medical Center of Las Colinas v. Bush ex rel. Bush, 122 S.W.3d 835, 855 (Tex.App.-Fort Worth 2003).

In fact, Espinoza agreed that it would be extremely dangerous to administer Ativan to a patient without a doctor's order and, after having been disciplined for an identical incident in Colorado, realized that he would put a patient in extreme risk of death if he were to do so again. Here, the jury could reasonably infer from the evidence that Espinoza prescribed Ativan for Jacob without a physician's orders and Espinoza agreed that, "if he wrote the order [for Ativan], he would be consciously disregarding [Jacob's] health, safety and welfare."

The evidence need not show, as THI contends, that Espinoza had specific knowledge of Jacob's allergy or sensitivity to Ativan. *See Harrison,* 70 S.W.3d at 786. Rather, the evidence need only be such that reasonable inferences of a conscious decision could be made. *Id.* Here, the jury's verdict is supported by evidence that Espinoza consciously countermanded Dr. Rice's order to treat Jacob with Zyprexia by prescribing Ativan knowing his decision could cost Jacob his life after having checked and knowing Jacob was allergic to the drug or not checking and not knowing, i.e., consciously indifferent to whether Jacob was allergic or not.

We find the evidence in this case is legally sufficient to support a finding that Espinoza had actual awareness of an extreme risk involved in prescribing Ativan for Jacob without physician permission, proceeded to act with conscious indifference to that risk, and was, therefore, grossly negligent. [58]

b. Corporate Liability

[33] **[34]** **[35]** **[36]** A corporation may be liable in punitive damages for gross negligence only if the corporation itself commits gross negligence. *Ellender,* 968 S.W.2d at 921. Further, a corporation is grossly negligent if it authorizes or ratifies an agent's gross negligence, or if it is directly negligent in ***582** hiring an unfit agent. *Id.* A corporation may also be grossly negligent through the acts or inactions of a vice-principal. *Id.* at 922. [59] *See Bush,* 122 S.W.3d at 854; *Burk,* 616 S.W.2d at 922 (corporation's "conduct can be active or passive").

[37] **[38]** In determining whether acts are directly attributable to the corporate employer, we do not restrict our review to individual elements or facts but instead consider all the surrounding facts and circumstances to determine whether the corporation itself is grossly negligent. *Ellender,* 968 S.W.2d at 922. These facts and circumstances include reasonable inferences the fact finder can draw from what the corporation did or failed to do and the facts existing at relevant times that contributed to a plaintiff's alleged damages. *Id.* at 924.

[39] From the evidence, the fact finder could reasonably infer that Espinoza was unfit at the time he was recruited by Long, Southwest Hospital's Director of Nursing, in 2002. [60] Espinoza testified that, at the time THI hired him, Long was aware his Colorado nursing license had been suspended for administering Ativan to a patient without a doctor's approval and, despite this knowledge, Espinoza was placed in a position at Southwest Hospital where he supervised nurses and initiated orders for prescribed medications. [61]

Further, Espinoza testified that in early 2005 (after Jacob's death) he informed Long that he was a drug addict and she continued to permit him to work at Southwest Hospital. Thereafter, Espinoza's addiction was permitted to progress until he was reported impaired—sleepy, sleep-walking, running into walls, falling asleep at patients' bedsides. Espinoza was misappropriating morphine and Demerol from Southwest Hospital's computerized medicine dispensing system and taking the medications himself without proper authorization while falsifying the information in the system to make it appear as if patients were taking the medication. Finally, on November 19, 2005, he inserted an external jugular venous catheter in a patient without proper authorization, performing a medical procedure outside the parameters of a nursing license. In late December 2005, Espinoza was finally discharged by Long and Southwest Hospital administrator Graves. [62]

From this evidence, the jury could reasonably infer that Long consciously disregarded the danger she was exposing patients to by permitting a "rogue" nurse, ostensibly unrepentant up to the time of ***583** his trial testimony, [63] to supervise the care of patients in general, and Jacob in particular. Furthermore, when this evidence is coupled with Long's initial decision to

hire Espinoza despite knowing of the suspension of his nursing license in Colorado, the jury could reasonably infer that Long continued a pattern of turning a blind eye toward Espinoza's misconduct, beginning with his original hiring and eventually culminating in his termination in December 2005.

Looking at the evidence in a light most favorable to the judgment, we cannot say that a reasonable trier of fact could not have formed a firm belief or conviction that THI, through Long, was directly negligent in hiring an unfit agent and/or authorized or ratified Espinoza's gross negligence. Accordingly, we find that the evidence was legally sufficient to support the jury's finding of gross negligence.

2. Factual Sufficiency

[40] When the burden of proof is clear and convincing evidence, the distinction between legal and factual sufficiency is very fine. In such a factual sufficiency review we must consider all the evidence the fact finder could reasonably have found to be clear and convincing, and then determine whether any fact finder could reasonably have formed a firm belief or conviction of the truth of the allegations. *See In re J.F.C.,* 96 S.W.3d at 266; *In the Interest of C.H.,* 89 S.W.3d 17, 25, 27–29 (Tex.2002). The difference in applying an elevated test under the clear and convincing standard is that "a higher quality of evidence is necessary to tip the scales." *Garza,* 164 S.W.3d at 625.

We consider whether the disputed evidence is such that a reasonable fact finder could have resolved it in favor of its finding. *See In re J.F.C.,* 96 S.W.3d at 266. If, in light of the entire record, disputed evidence that a reasonable fact finder could not have resolved in favor of the finding is so significant as to prevent a fact finder reasonably from forming a firm belief or conviction of the truth of the finding, then the evidence is factually insufficient. *See id.; In re S.M.L.D.,* 150 S.W.3d 754, 757 (Tex.App.-Amarillo 2004, no pet.).

In a single paragraph, without any citation to specific evidence in the record or its brief, THI asserts in a conclusory fashion that the evidence is factually insufficient to support the jury's findings either that: (1) Espinoza understood the extreme risks involved in administering a medication to a patient without prior approval by a physician but did not care when he prescribed Ativan for Jacob; (2) THI ratified Espinoza's conduct; (3) Espinoza was an unfit employee; or (4) THI was reckless for hiring Espinoza.

Rather than find THI waived these issues, [64] in the interest of justice, having reviewed the evidence cited by THI in support of its legal insufficiency argument on the issue of gross negligence, [65] we conclude ***584** the jury could reasonably have formed a firm belief or conviction that THI was grossly negligent in hiring an unfit agent. Accordingly, we need not reach the other bases of gross negligence raised by Appellees. *See Hogue,* 271 S.W.3d at 253. THI's issues four and five are overruled.

VI. Evidentiary Ruling—THI's Internal Investigation

During discovery, THI asserted various statutory privileges to avoid disclosing any information or documents regarding any in-house investigation undertaken by Southwest Hospital into the circumstances surrounding Jacob's death. [66] During trial, Appellees asked a number of witnesses, without objection, whether they had been approached by Southwest Hospital regarding the circumstances of Jacob's death or were aware of any investigation into his death. The witnesses answered in the negative. [67]

To rebut the potential, yet improper, inference that the absence of an in-house investigation was some sort of corporate ratification of Espinoza's conduct, THI sought to offer the testimony of Dr. Rice concerning the matter. When Appellees objected to Dr. Rice testifying that an in-house investigation had been undertaken by Southwest Hospital, on the basis that THI had asserted its investigative privilege as to that subject during discovery, the trial court warned THI that its line of questioning would require full and complete disclosure of the investigation and its results. After consulting with her client, THI's counsel made the following statement:

> So we no longer have an issue. I will still make my objections to the granting of [Appellees' counsel's] objection, in that she opened the door, and, further, that the response to the interrogatory and request for production was an objection and privilege citation, and, the

> objections were never compelled or ruled on by the Court, which would have to be an action of the Plaintiffs, and we were never asked for a privilege log with respect to that privilege that was asserted.

Because THI chose to close the door on its own inquiry rather than open the door further with respect to the in-house investigation, the trial court never excluded the testimony of Dr. Rice. Accordingly, the trial court did not abuse its discretion by excluding any evidence. THI's issue six is overruled.

VII. Damages

By its seventh and final issue, THI contends the trial court's judgment should be modified to reflect application of the various statutory provisions, found within ***585** chapters 41[68] and 74[69] of the Texas Civil Practices and Remedies Code,[70] which limit the recovery of damages by a claimant. Specifically, THI contends that: (1) § 41.008(b) should be applied to limit Appellees' recovery of exemplary damages, (2) § 74.301(b) should be applied to limit Appellees' recovery of noneconomic damages, and (3) § 74.303 should be applied to limit Appellees' overall recovery in a wrongful death and survival action on a health care liability claim. In response, Appellees contend that: (1) THI waived application of §§ 41.008(b) and 74.301(b) by failing to plead those sections as an affirmative defense, and (2) § 74.301(b) does not apply to a wrongful death claim. In response to Appellees' waiver argument, THI further contends the trial court erred by denying its motion for leave to amend its pleadings. We will address these sub-issues in their logical rather than numeric or sequential order.

A. Applicability of § 74.303—Overall Damages Limitation

While the briefs filed by both THI and Appellees seem to indicate that the trial court did apply the § 74.303 limitation of damages provision in arriving at the dollar amount of the judgment entered, without a detailed explanation of the trial court's calculations, the mathematic and legal damage limiting principles applied by the trial court in the entry of its judgment are lost on this Court. Because this Court ultimately remands this case to the trial court for the entry of a judgment in accordance with this opinion, we deem it judicially appropriate to address the application of § 74.303 to the judgment to be entered in this cause.

Section 74.303 provides that:

> (a) In a wrongful death or survival action on a health care liability claim where final judgment is rendered against a physician or health care provider, the limit of civil liability for all damages, including exemplary damages, shall be limited to an amount not to exceed $500,000.00 for each claimant, regardless of the number of defendant physicians or health care providers against whom the claim is asserted or the number of separate causes of action on which the claim is based.
>
> (b) When there is an increase or decrease in the consumer price index with respect to the amount of that index on August 29, 1977, the liability limit described in Subsection (a) shall be increased or decreased, as applicable, by a sum equal to the amount of such limit multiplied by the percentage increase or decrease in the consumer price index, as published by the Bureau of Labor Statistics of the United States Department of Labor, that measures the average changes in prices of goods and services purchased by urban wage earners and clerical workers' families and single workers living alone (CPI–W: Seasonally adjusted U.S. City Average–All items), between August 29, 1977, and the time at which damages subject to such limits are awarded by final judgment or settlement.
>
> (c) Subsection (a) does not apply to the amount of damages awarded on a health care liability claim for the expenses of necessary medical, hospital, and custodial ***586** care received before judgment or required in the future for treatment of the injury.

THI contends Appellees should be considered a single claimant for purposes of their health care liability claim. *See* Tex. Civ. Prac. & Rem. Code § 74.001(a)(2). We find no case law that interprets the applicability of § 74.001(a)(2) in the context of the limitation of damages in a wrongful death and survival action on a health care liability claim where multiple persons are claiming to have sustained damages as the result of the bodily injury or death of a single person. Section 74.001(a)(2) provides that:

> "Claimant" means a person, including a decedent's estate, seeking or who has sought recovery of damages in a health care liability claim. All persons claiming to have sustained damages as the result of the bodily injury or death of a single person are considered a single claimant.

[41] A plain reading of this statute clearly supports THI's contention. Therefore, for purposes of § 74.303, the estate of Jacob Perea, and his four sons, Mario, Max, Tony, and George, i.e., Appellees herein, are a single claimant, entitled to recover for all damages, including exemplary damages, but not including expenses of necessary medical, hospital, and custodial care, an amount not to exceed $500,000, as adjusted in accordance with the provisions of § 74.303(b). Based on the applicable consumer price index (CPI), on June 9, 2008, the § 74.303 cap was $1,737,272.00.[71] Because the judgment entered by the trial court did not exceed that cap, the trial court did not err in the application of the § 74.303 damage cap.

B. Applicability of § 74.301(b)—Noneconomic Damages Limitation

THI contends the trial court erred in failing to properly apply the statutory limitation of noneconomic damages found in § 74.301(b). Section 74.301(b) provides:

> In an action on a health care liability claim where final judgment is rendered against a single health care institution, the limit of civil liability for noneconomic damages inclusive of all persons and entities for which vicarious liability theories may apply, shall be limited to an amount not to exceed $250,000 for each claimant.

Appellees contend the rules of statutory construction dictate that § 74.301(b) does not apply in this case based upon the general principle that specific statutory provisions should govern over general provisions. Specifically, Appellees contend that the more specific provisions of § 74.303 (which is specifically applicable to a wrongful death or survival action) apply to the exclusion of more general provisions of § 74.301(b) (which is generally applicable to health care liability claims). *See Horizon/CMS Healthcare Corp. v. Auld,* 34 S.W.3d 887, 901 (Tex.2000) (determining that the judgment cap provisions of section 11.02 of article 4590i prevail over the general prejudgment interest provisions of article 5069–1.05);[72] *cf.* ***587** Tex. Gov't Code § 311.026 (Vernon 2005) (providing that, when construing code provisions that are irreconcilable, "the special or local provision prevails as an exception to the general provision").

[42] When we construe a statute, our primary goal is to ascertain and give effect to the Legislatures intent in enacting it. Tex. Govt Code Ann. 312.005 (Vernon 2005); *In re Canales,* 52 S.W.3d 698 (Tex.2001). An appellate court must not interpret the statute in a manner that renders any part of the statute meaningless or superfluous, *City of Marshall v. City of Uncertain,* 206 S.W.3d 97, 105 (Tex.2006) (citing *City of San Antonio v. City of Boerne,* 111 S.W.3d 22, 29 (Tex.2003)), and where general and special provisions are both applicable, those "provisions shall be construed, if possible, so that effect is given to both." Tex. Gov't Code Ann. § 311.026(a) (Vernon 2005).

Because a health care liability claim includes a cause of action against a health care provider (including a health care institution) for conduct which proximately results in the death of a claimant, arguably both statutory provisions can be applicable to the facts of this case. The question is, is it possible to give effect to both provisions?

[43] **[44]** We find no cases which directly decide this issue. However, because the two statutory provisions do not conflict on their face, in order to give full effect to the intent of the Legislature, we see no reason why one cap should apply to the exclusion of the other cap. Neither the express wording of the applicable statutes, nor their legislative history indicates that the Legislature intended anything other than to apply both caps. Therefore, we conclude that both caps can be applied, and should be applied. Because Appellees constitute a single claimant, unless otherwise inappropriate, the trial court should have limited THI's civil liability for noneconomic damages to $250,000.

[45] Appellees also contend that THI waived the protections of § 74.301(b) by failing to affirmatively

plead their application to the facts of this case. THI has responded to this argument by contending that: (1) statutory damage caps are not affirmative defenses, and/or (2) the trial court erred by not granting its motion to amend its pleadings. Although the Texas Supreme Court has not directly decided whether a statutory damage caps is an affirmative defense, it has recently held that the statutory damage caps contained in § 41.008(b) "requires a reduction of punitive damages as a matter of law." *In re Columbia Medical Center of Las Colinas,* 306 S.W.3d 246, 248 (Tex.2010). *But see Wackenhut Corr. Corp. v. de la Rosa,* 305 S.W.3d 594 (Tex.App.-Corpus Christi 2009, no pet.) (holding that the cap is an affirmative defense which must be specifically pleaded by the defendant for it to apply). Although in *In re Columbia Medical Center* the Supreme Court equivocates somewhat by adding the phrase "when the parties raise the issue," 306 S.W.3d at 248, we find that the parties here have sufficiently raised the issue before both the trial court and this Court. Therefore, we find that § 74.301(b) requires reduction of noneconomic damages as a matter of law and, as such, it is not an affirmative defense. Accordingly, we find the trial court erred in not applying the provisions of § 74.301(b) to limit THI's civil liability for noneconomic damages to $250,000.

*588 C. Applicability of § 41.008(b)—Exemplary Damages Limitation

THI also contends the trial court erred by failing to apply the § 41.008(b) limitation provisions to the jury's exemplary damages award. Again, Appellees counter by contending the limitation is an affirmative defense which THI waived by failing to plead and THI has responded by contending that: (1) statutory damage caps are not affirmative defenses, and/or (2) the trial court erred by not granting its motion to amend its pleadings.

Section 41.008(b) provides:

> Exemplary damages awarded against a defendant may not exceed an amount equal to the *greater* of:
>
> (1)(A) two times the amount of economic damages; plus
>
> (B) an amount equal to any noneconomic damages found by the jury, not to exceed $750,000; or
>
> (2) $200,000.

[46] Based upon the same analysis we applied to § 74.301(b), we find the exemplary damages cap provided by § 41.008(b) is not an affirmative defense, but must instead be applied as a matter of law. The question then becomes, do the specific provisions of § 74.303 control over the general provisions of § 41.008(b), or should a trial court seek to apply both limitations?

[47] Again, we find no case law answering this question, and again we observe that, on their face, the two provisions do not seem to conflict. One caps exemplary damages in all suits, while the other caps all damages in wrongful death and survival actions. Because the two statutes are not irreconcilable, the statutes can be harmonized by applying the exemplary damages cap first, and then applying the overall cap second. Therefore, once again, in order to give full effect to the intent of the Legislature, we believe both provisions should be applied.

Having determined that § 41.008(b) does apply, because the limit of exemplary damages is, in part, determined by the amount of noneconomic damages, a court must further determine whether to apply the noneconomic damages limitations of § 74.301(b) to the determination of the exemplary damages cap provided by § 41.008(b). Again, we have found no cases directly determining this issue and, once again, we find that, on their face, the two statutory provisions do not conflict. Accordingly, as before, we believe both provisions should be given effect.

Because we have found that § 41.008(b) should have been applied, we find that the trial court erred in not applying that limiting provision. Furthermore, in the application of that cap, we find the trial court should apply the noneconomic damages limitation provisions of § 74.301(b) in determining the cap under § 41.008(b). Accordingly, Appellees' recovery of exemplary damages should have been limited to $285,053.94. [73]

D. Correction of Judgment

[48] Here, the jury awarded Jacob's estate economic damages of $17,526.97 and noneconomic damages of $40,000.00. The jury also awarded Mario, Max, Tony, and George noneconomic damages of $100,000.00 each, for a combined total of $400,000.00. The jury further awarded Appellees exemplary damages of *589 $1,250,000.00.

Furthermore, in addition to actual damages, Appellees were entitled to recover pre-judgment interest on their actual damages. *See* Tex. Fin.Code Ann. § 304.102 (Vernon 2006). [74] Prejudgment interest is an element of recoverable actual damages. *See Embrey v. Royal Indem. Co.,* 986 S.W.2d 729, 732 (Tex.App.-Dallas 1999), *affd,* 22 S.W.3d 414 (Tex.2000). Because prejudgment interest is a part of Appellees' damages, it is subject to the overall damage limit imposed by § 74.303. *Columbia Hosp. Corp. v. Moore,* 92 S.W.3d 470, 475 (Tex.2002) (interpreting subchapter K of former article 4590i); *Horizon/CMS Healthcare Corp.,* 34 S.W.3d at 892.

The trial court entered judgment in favor of Appellees and against THI in the sum of $1,696,895.50, plus costs of court. To the extent the trial court failed to properly apply the overall damages cap under § 74.303, the noneconomic damages cap under § 74.301(b), and/or the exemplary damages cap under § 41.008(b), the trial court erred. THI's seventh issue is sustained.

Because the jury apportioned the negligence causing the "injury in question" 90% to THI and 10% to Pharmasource Healthcare, and because Pharmasource Healthcare entered a "settlement agreement" for the sum of $63,343.44, plus costs of court, and because Pharmasource Healthcare has not appealed the judgment of the trial court, and because we do not know which election THI would make under § 33.012(c) of the Texas Civil Practice and Remedies Code, we are unable to determine the judgment that should be entered in this cause. Accordingly, we remand this cause to the trial court for the rendition of a judgment applying all applicable damages caps, the determination of applicable credits, and the apportionment of the recovery among Appellees. Tex.R.App. P. 43.3.

CONCLUSION

The trial court's judgment is reversed and the cause is remanded to the trial court for entry of a judgment in accordance with this opinion.

CAMPBELL, J., concurring and dissenting.

JAMES T. CAMPBELL, Justice, concurring and dissenting.

I agree with the Court's discussion of appellant THI of Texas at Lubbock I, LLC's issues challenging denial of its proposed jury instruction on negligence (issue one); the trial court's allowing the Pereas to amend their petition during trial (issue two); exclusion of THI's proffered testimony (issue six) and the trial court's failure to apply liability caps on damages set out in sections 41.008(b) and 74.301(b) of the Civil Practice and Remedies Code (issue seven). With regard to its issues challenging the sufficiency of the evidence supporting the jury's findings of negligence and gross negligence (issues three, four and five), I agree with the Court that legally and factually sufficient evidence supports the jury's negligence finding with regard to the negligence of THI's nurses. I disagree, however, that any evidence supports the Pereas' "negligent credentialing/hiring" theory of THI's negligence.

As the Court holds, expert testimony was required to establish that THI failed to act as a reasonably prudent hospital would act in the same or similar circumstances with regard to its decision to hire Leonard Espinoza. The Court relies primarily ***590** on the testimony of Dr. Haines with regard to the hospital's hiring actions. He said that, when hiring nurses, administrators "should look at" the applicant's past employment record and determine whether the applicant "had problems or troubles at prior nursing facilities," and that administrators "had a duty to research the background of people they hired."

But neither Dr. Haines nor any other expert testified that THI did not take those actions when it hired Espinoza. No one said that THI's nursing director Connie Long or any other THI administrator hired Espinoza without review of his employment record or a determination whether he had "problems or troubles" during a prior employment. The record contains no expert testimony of THI's breach of the standard of care Dr. Haines described. *See Garland Cmty. Hosp. v. Rose,* 156 S.W.3d 541, 545–46(Tex.2004) (negligent credentialing). The Court seems to assume that no reasonably prudent hospital would have hired Espinoza as a registered nurse knowing of his discipline by the Colorado authorities under his licensure in that state as a licensed vocational nurse, but no expert said as much. Nor did any expert testify that THI's breach of a duty to act as a reasonably prudent hospital when it hired Espinoza proximately caused the injury to Mr.

Perea. *See, e.g., Denton Regional Med. Ctr. v. LaCroix,* 947 S.W.2d 941, 950 (Tex.App.-Fort Worth 1997, no pet.). To the degree the Court concludes otherwise, I respectfully dissent.

For the same reason, I must dissent from the Court's conclusion sufficient evidence supported the jury's finding THI was "reckless in employing" Espinoza, and thus was grossly negligent. [1] The jury heard no expert testimony demonstrating that THI was reckless in employing Espinoza. No expert was even asked to express an opinion whether THI acted in a less than prudent manner by hiring him.

Despite my disagreement with my colleagues on the "negligent credentialing/hiring" issue, I concur with Court's judgment affirming the award of punitive damages against THI, because I agree that such an award is supported by evidence THI's acknowledged vice-principal, director of nursing Connie Long, ratified or approved Espinoza's negligent act. *See Shamrock Communs., Inc. v. Wilie,* No. 03–99–00852–CV, 2000 WL 1825501, *5, 2000 Tex.App. LEXIS 8284, *14 (Tex.App.-Austin 2000, pet. denied.) (mem. op.) (not designated for publication), *citing Prunty v. Arkansas Freightways, Inc.,* 16 F.3d 649, 653 (5th Cir.1994) (case law provides that ratification may occur when the employer confirms, adopts, or fails to repudiate the acts of its employee). The record includes Espinoza's assertion he was never disciplined for authorizing the administration of Ativan to Mr. Perea and Long's admission that Espinoza remained employed for the year following this incident. Such testimony is evidence of Long's failure to repudiate Espinoza's negligent act of authorizing administration of Ativan.

Accordingly, I dissent from the Court's discussion of the plaintiffs' "negligent credentialing/hiring" theory but concur in the judgment.

All Citations

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Footnotes

1 John T. Boyd, Chief Justice (Ret.), Seventh Court of Appeals, sitting by assignment. Tex. Govt Code Ann. 75.002(a)(1) (Vernon 2005).

2 The trial court applied the statutory damage cap in § 74.303 of the Texas Civil Practice and Remedies Code. *See* Tex. Civ. Prac. & Rem. Code Ann. § 74.303 (Vernon 2005). THI asserts the trial court should have also applied the exemplary damage cap provided by § 41.008(b) and the noneconomic damage cap provided by § 74.301(b) of the Texas Civil Practice and Remedies Code. *See* Tex. Civ. Prac. & Rem. Code Ann. §§ 41.008(b) (Vernon Supp. 2009) & 74.301(b) (Vernon 2005).

3 Michael Rice, M.D., was named as a defendant in Appellees' Original Petition but was not named in subsequent amended original petitions.

4 Appellees' expert, Joe Haines, M.D., testified Ativan is a tranquilizer in the benzodiazepine class prescribed as a sedative to help people sleep, for anti-anxiety, and persons with panic attacks. Ativan is a controlled substance.

5 Jacob's final diagnosis on discharge was confusion/dementia, respiratory failure, severe coronary artery disease with old myocardial infarction, history of congestive heart failure, chronic renal failure/acute renal failure, mitral insufficiency of 2+, diabetes, and pneumonia.

6 Versed is in the same drug family as Ativan, i.e., benzodiazepine, and is faster acting than Ativan.

7 Nurse Angie Jahomo, a charge nurse at Southwest Hospital, testified at trial that Lorazepam is the generic name for Ativan and, as such, is recognizable by all medical professionals.

8 Nurse Jahomo testified at trial that the bracelet is the last thing a nurse looks at before giving medication to a patient. She also testified that "[a] nurse would not think an allergy bracelet was a piece of jewelry, general practice is to look at the bracelet before giving the medication." If a nurse gave a patient medication without looking at the allergy bracelet, Nurse Jahomo testified the nurse would be negligent. She testified it would be extremely dangerous for a nurse to give medication to a patient without a doctor's prior approval and the nurse would lose his/her license. If she observed such an incident, she would report the errant nurse. Further, if a bracelet or chart sticker came off, she testified a nurse would be negligent for not replacing it.

9 Nurse Jahomo testified she gave a copy of Dr. Rice's orders to the pharmacy and notified them of Jacob's allergies. She expected the pharmacy to enter the information in the computerized medicine dispensing system. If a patient is allergic

to a particular medication and a nurse attempts to dispense that medication through the computerized system, the nurse will get a flashing screen indicating the patient has an allergy to the medication. Although Jacob's allergies were listed on Covenant's Medical Administration Record (MAR), his allergies were not listed on Southwest Hospital's MAR. Rather, at the top of Southwest Hospital's MAR, it stated: “Allergies: NKA (no known allergies).” At trial, Nancy Dipprey, the pharmacist on duty when Jacob was admitted, testified she believed the allergies were not written on Nurse Jahomo's admitting orders received by the pharmacy. She also testified she received a copy of the admitting orders and, because they were not official records, the records had been destroyed. Nurse Jahomo testified she received an incorrect MAR from the pharmacy that day but failed to notice the error. She accepted responsibility for not correcting the pharmacy.

10 After speaking with Mario, Dr. Rice wrote in Jacob's chart that Mario had reported Jacob “had a paradoxical reaction to Ativan, becomes agitated but does not have a true allergy.” Dr. Rice testified that a side effect was different than an allergy. Nevertheless, Dr. Rice testified he did not want Jacob to receive Ativan. He testified that, when the issue came up, he informed the nurse that Jacob should have no medication from the benzodiazepine class. Dr. Rice also testified it is well described in literature that Ativan in geriatric patients or a severely ill patient does not calm them down like it is supposed to but actually causes them to become wilder and more agitated. Because of what Jacob's son said, the possibility of a C2 fracture, Jacob had a bad heart and underlying disorders, Dr. Rice did not want any stimulus that might cause him to have a heart attack or complicate his condition. Accordingly, Dr. Rice prescribed Zyprexia, a sedative or antipsychotic drug of a different drug class than benzodiazepine that is used to calm persons who have sensitivity to Ativan.

11 Dr. Joe Haines, appellees' expert, testified that, once Dr. Rice had noted Jacob was allergic to morphine and Ativan, a second order by Dr. Rice or another doctor would be necessary to countermand Dr. Rice's initial order to permit Jacob to receive Ativan.

12 An NDR is patient specific and routinely filled out by the nurse caring for the patient during a particular shift. The first entry on the NDR is typically an acknowledgment by the nurse on the subsequent shift that he or she received and reviewed the NDR written by the nurse on the prior shift.

13 A Nurse Practitioner's license permits the nurse to write prescriptions.

14 Jacob's Progress Note for December 18 indicated he was on Zyprexia for agitation and was negative for shortness of breath, negative chest, negative nausea, or vomiting. The Note's Assessment and Plan stated the following: “1. Status post C-spine fracture, continue Minerva brace and follow-up with Dr. Willis; 2. Fall, diligent fall precautions; 3. End stage renal disease—continue prn dosing as well and monitor; 5. Atrial fibrilliation—patient on Coumadin as well as Lorenex, continue these and recheck on 12/20/04.”

15 The NDR from the prior shift ending at 7:00 a.m. indicated Jacob had allergies to Ativan and morphine. Although Nurse Rosales's NDR indicates she received the prior NDR showing Jacob had allergies to Ativan and morphine, her subsequent NDR given to Nurse Joiner at the 7:00 p.m. shift indicates “NKA” or no known allergies.

16 Dr. Rice and Graham both denied giving any order to Espinoza approving administration of Ativan to Jacob.

17 A CARDEX is a short form listing the relevant medical information for a patient including an update from the prior nurse. Nurse Rosales testified Jacob's CARDEX should have included a summary of his allergies, condition, procedures, etc. Nurse Rosales could not remember Jacob's CARDEX and it was not entered into evidence.

18 Nurses Rosales's and Joiner's NDR both indicated Jacob had no known allergies.

19 Nurse Joiner testified Southwest Hospital's bands were red and white. He also testified he did not attend to the band because he thought it was a piece of jewelry or religious artifact.

20 Mario testified he observed the allergy band he first observed at Covenant, and later at Southwest Hospital, on his father's wrist when he arrived at Covenant's emergency room where a nurse cut the band off for him. The band was admitted at trial and indicated Jacob had allergies to morphine and Ativan. Dr. Rice testified he discovered Jacob had received Ativan and was angry because his written order had been ignored. He subsequently took the matter up with Southwest Hospital Administrator, Deanna Graves, and she agreed to do something about their systems.

21 Dr. Hail, THI's expert, defined “obtunded” as “a word that can mean confused or unconscious. It can be a spectrum, altered mental status ... in this case, with it being after [Jacob] coded at Southwest [Hospital], [Dr. Wheeler] is referring to the brain death or getting close to that.” Dr. Hail further testified that, by the phrase “secondary to Ativan injection,” Dr. Wheeler “is hypothesizing that the cause of [Jacob's] obtundation is from the Ativan....”

22 Dr. Haines explained that a drug such as Ativan, which normally sedates a patient, might also cause agitation and confusion in some people, representing what is termed a “paradoxical reaction,” i.e., “where you get the opposite of what you are trying to achieve.”

23 Dr. Hail testified “[t]elemetry is just essentially an EKG over a period of time.” On cross-examination, however, Dr. Hail conceded that a hospital usually pulls only those strips that are abnormal and agreed with counsel that she had left many

strips behind because an entire day's reading would comprise thousands of such strips. She also conceded that doctors at Covenant had also looked at the strips and no one diagnosed Jacob as having a heart attack. Jacob was not connected to any monitoring devices while at Southwest Hospital.

24 Dr. Hail testified a troponin blood test is specific to having a heart attack.

25 " 'Perhaps' and 'possibly' indicate conjecture, speculation, or mere possibility rather than qualified opinions based on reasonable medical probability." *Columbia Medical Center of Las Colinas, Inc. v. Hogue,* 271 S.W.3d 238, 247 (Tex.2008).

26 On cross-examination, Dr. Haines testified that the patient who received the eight milligram dose of Ativan was a sixteen year old who was suffering from a bad LSD trip.

27 End stage renal disease, congestive heart failure, stroke, and diabetes.

28 Dr. Rice testified an elevated BMP is a "marker for high probability or risk of death. It is also a marker for congestive heart failure or ventricular strain." He further testified that, in patients with underlying cardiac disease coupled with end stage renal disease or diabetes, BMP levels of the magnitude of Jacob's are a very high indicator for likely death, "a marker for mortality."

29 Espinoza's testimony subsequently equivocated on the timing of this disclosure to Long. After testifying Long was aware of his drug addiction in early 2005, he later testified she was not aware until September 2005.

30 As to Southwest Hospital, "negligence" and "proximate cause" were defined as follows:

> "Negligence" when used with respect to the conduct of Southwest Regional Specialty Hospital means failure to use ordinary care, that is, failing to do that which a hospital of ordinary prudence would have done under the same or similar circumstances or doing that which a hospital of ordinary prudence would not have done under the same or similar circumstances.
>
> "Proximate Cause" when used with respect to the conduct of Southwest Regional Specialty Hospital means that cause which, in natural and continuous sequence, produces an event, and without which cause such event would not have occurred. In order to be a proximate cause, the act or omission complained of must be such that a hospital using ordinary care would have foreseen the event, or some similar event, might reasonably result therefrom. There may be more than one proximate cause of an event.

STATE BAR OF TEX., TEXAS PATTERN JURY CHARGES—GENERAL NEGLIGENCE; INTENTIONAL PERSONAL TORTS, PJC 2.4 (2008).

31 The jury found Pharmasource Healthcare, Inc. and Omnicare Inc., d/b/a Pharmasource Healthcare, Inc. (Pharmasource), ten percent negligent and Southwest Hospital ninety percent negligent.

32 The jury awarded the estate the sum of $40,000 for pain and mental anguish, $107,228.15 for medical expenses and $12,490.25 for funeral and burial expenses. In the entry of its judgment, the trial court reduced the recovery of medical expenses to $5,036.72 pursuant to the "paid or incurred" limitation contained in § 41.0105.

33 The judgment also ordered that Appellees recover the sum of $63,343.44 from Pharmasource. Pharmasource did not appeal.

34 In the Fifth Amended Original Petition, Jacob's estate sought damages for personal injury including physical pain and suffering, physical impairment, mental anguish, reasonable and necessary medical expenses, and funeral and burial expenses.

35 In the Fifth Amended Original Petition, Jacob's sons sought damages for the loss of Jacob's love, counsel, companionship, and care, i.e., mental anguish, emotional pain, torment, and mental suffering.

36 In Texas, a cause of action for negligence requires three elements: (1) a legal duty owed by one person to another; (2) breach of that duty; and (3) damages proximately caused by the breach. *D. Houston, Inc. v. Love,* 92 S.W.3d 450, 454 (Tex.2002).

37 Rule 277 of the Texas Rules of Civil Procedure provides that "the court shall, whenever feasible, submit the cause upon broad-form questions." Tex.R. Civ. P. 277. In *Texas Dep't of Human Services v. E.B.,* 802 S.W.2d 647 (Tex.1990), the Texas Supreme Court interpreted the phrase "whenever feasible" as mandating broad-form submission "in any and every instance in which it is capable of being accomplished." *Id.* at 649.

38 Southwest Hospital's objection to the charge at trial was that, if the jury believed the hospital caused an injury to Jacob but not his death, "the wrongful death beneficiaries would not be entitled to recover." Question 3(c) asked what sum of money would compensate Jacob for damages he would have for funeral and burial expenses, while Questions 4 through 7 asked what sum of money "would fairly and reasonably compensate [Jacob's sons] for [their] damages, *if any, resulting from the death of Jacob Perea.*" (Emphasis added). Thus, although the jury may have found Southwest Hospital negligently caused Jacob's injury, these damage instructions reminded the jury that they were limited to damages resulting from Jacob's death.

39 During THI's examination, Espinoza testified he "[could] not think of a time he ever wrote an order for a controlled substance such as Ativan when he had not first gotten the order from a doctor." Appellees sought to impeach this testimony with the stipulated order wherein he had been disciplined by the Colorado Board of Nursing in 1996 for administering Ativan to a patient without a physician's order.

40 *See also Allstate Prop. & Cas. Ins. Co. v. Gutierrez,* 281 S.W.3d 535, 539 (Tex.App.-El Paso 2008, no pet.); (a trial amendment may be prejudicial on its face, "but this does not make it prejudicial as a matter of law"); *American Title Company of Houston v. Bomac Mortgage Holdings, L.P.,* 196 S.W.3d 903, 909 (Tex.App.-Dallas 2006, no pet.) (decision to permit or deny trial amendment rests in sound discretion of trial court if amendment asserts new cause of action or defense); *Deutsch v. Hoover, Bax & Slovacek, L.L.P.,* 97 S.W.3d 179, 186 (Tex.App.-Houston [14th Dist.] 2002, no pet.) ("An amended pleading asserting a new defense is not prejudicial as a matter of law; the amendment must be evaluated in the context of the entire case.").

41 THI contends surprise was asserted when its counsel attempted to exclude the testimony of Deanna Graves, Southwest Hospital Administrator, on the issue of negligent credentialing because she was not on Appellees' witness list. THI's objection to Graves testifying was made pursuant to Rule 193.6 of the Texas Rules of Civil Procedure, not Rule 66. Further, the trial court had already held a hearing on Appellees' motion to amend and granted the Rule 66 motion prior to THI's Rule 193.6 objection. Moreover, Appellees' attorney informed THI four days prior to calling Graves to testify that she intended to call Graves to discuss Espinoza's employment file, and Graves was listed as a potential witness on Pharmasource's witness list for trial.

42 When both legal and factual sufficiency challenges are raised on appeal, the reviewing court must first examine the legal sufficiency of the evidence. *See Glover v. Tex. Gen. Indemnity Co.,* 619 S.W.2d 400, 401 (Tex.1981).

43 "[T]he test for legal sufficiency should be the same for summary judgment, directed verdicts, judgments notwithstanding the verdict and appellate no-evidence review." 168 S.W.3d at 823.

44 Evidence does not exceed a scintilla if it is "so weak as to do no more than create a mere surmise or suspicion" that the fact exists. *Ford Motor Co. v. Ridgway,* 135 S.W.3d 598, 601 (Tex.2004).

45 A "health care liability claim" is as follows:

> [A] cause of action against a health care provider or physician for treatment, lack of treatment, or other claimed departure from accepted standards of medical care, or health care, or safety or professional or administrative services directly related to health care, which proximately results in injury or death of a claimant, whether the claimant's claim or cause of action sounds in tort or contract.

Tex. Civ. Prac. & Rem. Code Ann. § 74.001(13) (Vernon 2005).

46 "The competent selection and review of medical staff is precisely the type of professional service a hospital is licensed and expected to provide, for it is in the business of providing medical care to patients and protecting them from unreasonable risk of harm while receiving medical treatment ... [T]he competent performance of this responsibility is 'inextricably interwoven' with delivering competent quality medical care to hospital patients. *Diversicare,* 185 S.W.3d at 853 (quoting *Bell v. Sharp Cabrillo Hosp.,* 212 Cal.App.3d 1034, 260 Cal.Rptr. 886, 896 (Cal.Ct.App.1989)). "It follows that proper staffing for the care and protection of patients is related to and part of the rendition of health care." *Holguin v. Laredo Regional Medical Center,* 256 S.W.3d 349, 356 (Tex.App.-San Antonio 2008, no pet.). "Without safe, reliable staffing, health care would obviously be compromised because 'training and staffing policies and supervision and protection' of patients 'are integral components of ... health care services.' " *Id.* (quoting *Diversicare,* 185 S.W.3d at 850) (collected cases cited therein)).

47 Southwest Hospital does not assert that it lacked a duty to hire and supervise competent nurses.

48 An employer owes a duty to its other employees and to the general public to ascertain the qualifications and competence of the employees it hires, especially when the employees are engaged in occupations that require skill or experience and that could be hazardous to the safety of others. *JTM Materials, Inc.,* 78 S.W.3d at 50 (citing *Wise v. Complete Staffing Servs., Inc.,* 56 S.W.3d 900, 902 (Tex.App.-Texarkana 2001, no pet.)). *See LaBella,* 942 S.W.2d at 137 ("Texas courts have long recognized a master's duty to make inquiry into the competence and qualifications of those he considers for employment.").

49 Espinoza testified he did not disclose the Colorado Board of Nursing's disciplinary proceedings or their order to Texas authorities. Under the Texas Nursing Practice Act, a person is subject to "denial of license or to disciplinary action ... for ... revocation, suspension, or denial of ... the person's license or privilege to practice nursing in another jurisdiction." Tex. Occ.Code Ann. § 301.452(b)(8) (Vernon 2004).

50 Espinoza testified that he went to work for Highland in May of 1997. Although the Colorado stipulated probation order was not issued until September 1997, his testimony was unclear as to when proceedings were initiated before the State Board of Nursing in Colorado.

51 THI does not assert that Southwest Hospital's nurses owed no duty to properly care for and treat Jacob or that they did not breach their duty of care.

52 "The word 'substantial' is used to denote the fact that the defendant's conduct has such an effect in producing the harm as to lead reasonable men to regard it as a cause." *Givens v. M & S Imaging Partners, L.P.,* 200 S.W.3d 735, 738–39 (Tex.App.-Texarkana 2006, no pet.) (quoting RESTATEMENT (SECOND) OF TORTS § 431 cmt. a (1965)). *See Healthcare Centers of Texas, Inc. v. Rigby,* 97 S.W.3d 610, 625 (Tex.App.-Houston [14th Dist.] 2002, pet. denied).

53 Nurse Joiner testified Ativan is a Central Nervous System suppressant and the number one side effect of Ativan is decreasing a patient's ability to breathe.

54 Evidence is "clear and convincing" if it "will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established." Tex. Civ. Prac. & Rem. Code Ann. § 41.001(2) (Vernon 2008). "[E]vidence that does more than raise surmise or suspicion will not suffice unless it is capable of producing a firm belief or conviction that the allegation is true." *Garza,* 164 S.W.3d at 621.

55 "Extreme risk" is not "a remote possibility of injury or even a high probability of minor harm, but rather the likelihood of serious injury to the plaintiff." *Transp. Ins. Co. v. Moriel,* 879 S.W.2d 10, 22 (Tex.1994) (quoting *Wal–Mart Stores, Inc. v. Alexander,* 868 S.W.2d 322, 327 (Tex.1993)).

56 THI does not challenge on appeal whether Appellees met the objective component.

57 Dr. Haines testified that Jacob's doctors entered into the medical records and past medical history multiple times that he was allergic to Ativan—"[h]is doctors did not want him to have it. I mean, it's very simple." He further testified that, when a patient reacts to drugs, "you do everything you can do to make sure the patient doesn't get the drug, because that is the worse [sic] thing that can happen. You put somebody in the hospital, to take care of another problem, and then you give them something that kills them. That is the worse [sic] thing you can do, you know."

58 When judgment rests on multiple theories of recovery, we need not address all causes of action if any one theory is valid. *EMC Mortgage Corporation v. Jones,* 252 S.W.3d 857, 870–71 (Tex.App.-Dallas 2008, no pet.) (citing *Checker Bag Co. v. Washington,* 27 S.W.3d 625, 634 (Tex.App.-Waco 2000, pet. denied)). As such, we need not decide whether there was sufficient evidence to support a finding that any act or omission by Nurse Jahomo was grossly negligent.

59 Such vice-principals include corporate officers; those who have authority to employ, direct, and discharge other employees; those engaged in performing the corporation's nondelegable or absolute duties, and those responsible for the management of the whole or a department or a division of the business. *Ellender,* 968 S.W.2d at 921 (citing *Hammerly Oaks, Inc. v. Edwards,* 958 S.W.2d 387, 391 (Tex.1997)).

60 THI does not challenge on appeal whether Long is a vice-principal of Southwest Hospital.

61 Espinoza was the charge, or supervising, nurse over Nurses Rosales and Joiner while they cared for Jacob. As a charge nurse, Espinoza supervised all floor nurses and directed them on how to best manage and care for patients. He assisted floor nurses when they had questions, difficulties, or trouble with patients. If he observed a problem on the floor, he was responsible for bringing the problem to the attention of hospital administrators.

62 Ultimately, in May 2007, Espinoza surrendered his Texas nursing license per an agreed order in a proceeding before the Texas Board of Nursing Examiners premised on these same infractions.

63 Despite the stipulated order in Colorado and subsequent agreed order in Texas with the state boards of nursing, Espinoza's testimony at trial indicated he yet believed he had done nothing wrong and should not have been disciplined in either case.

64 Generally, because THI failed to specifically cite any record evidence in support of these general contentions, these arguments were insufficiently briefed, and therefore, waived. Tex.R.App. P. 38.1(h).

65 In support of its legal sufficiency argument, THI argued: (1) Espinoza testified he received an order prescribing Ativan from Nurse Graham; (2) Espinoza had no specific knowledge Jacob was sensitive or had an allergy to Ativan; (3) Nurse Jahomo had no explanation for why Jacob was not wearing an allergy bracelet on December 18; (4) Nurse Jahomo was unaware that the pharmacy did not have the allergy information on Jacob that was forwarded by Covenant when Jacob was originally transferred to Southwest Hospital; and (5) Nurse Jahomo testified she made a mistake by not reviewing Jacob's MAR and correcting the MAR to show that he, in fact, had an allergy to Ativan.

66 By interrogatory and request for production of documents, Appellees sought information related to any in-house investigation undertaken by THI. THI asserted privilege and refused to answer the interrogatory or produce any

documents. When asked by Appellees' counsel prior to trial, THI's counsel represented she would not be offering any evidence of an in-house investigation into Jacob's death by Southwest Hospital.

67 Pharmacist Dipprey, Nurse Rosales, Nurse Graham, and Espinoza testified that no one at Southwest Hospital questioned them regarding the circumstances of Jacob's death or the order for Ativan and they were unaware of any investigation into Jacob's death. Dr. Haines testified he saw no evidence of an investigation in the records he reviewed and believed the director of nursing at Southwest Hospital should have done some investigation to assure a similar incident did not happen again. THI did not object to this testimony.

68 Tex. Civ. Prac. & Rem. Code Ann. § 41.008(b) (Vernon Supp. 2009).

69 Tex. Civ. Prac. & Rem. Code Ann. §§ 74.301(b) & 74.303 (Vernon 2005).

70 For convenience, throughout the remainder of this opinion, references to simply "section ____" and/or " § ____" are references to the Texas Civil Practice and Remedies Code.

71 According to the U.S. Department of Labor, Bureau of Labor Statistics, Table 5. Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W): Seasonally Adjusted U.S. City Average–All Items, the CPI for June 2008 was 213.337. *See http://www.stats.bls. gov/PDQ/servlet/SurveyOutputServlet* (last visited May 12, 2010). This represents a 247.4544% increase over the CPI for August 1977 (CPI = 61.40). Therefore, on June 9, 2008, the § 74.303 cap was $1,737,272.00 (($500,000 x 2.474544) + $500,000).

72 Former article 4590i, § 11.02(a) provided that "[i]n an action on a health care liability claim where final judgment is rendered against a physician or health care provider, the limit of civil liability for damages of the physician or health care provider shall be limited to an amount not to exceed $500,000."

73 Appellees' economic damages equaled $17,526.97 ($12,490.25 + $5,036.72 = $17,526.97). *See* fn. 32, *supra.* Two times economic damages, plus noneconomic damages, as limited by § 74.301(b), up to $750,000, equals $285,053.94. ((2 x $17,526.97) + $250,000 = $285,053.94).

74 Prejudgment interest may not be assessed or recovered on an award of exemplary damages. *See* Tex. Civ. P. & Rem.Code § 41.007 (Vernon 2008).

1 The jury charge authorized the jury to find THI was grossly negligent because of an act by Espinoza if he was "unfit" and THI "was reckless in employing him," or THI or its vice-principal ratified or approved the act. No objection was raised to this aspect of the jury charge, so we examine the sufficiency of the evidence in light of the unobjected-to charge. *See City of Fort Worth v. Zimlich,* 29 S.W.3d 62, 71 (Tex.2000); *Soto v. Seven Seventeen HBE Corp.,* 52 S.W.3d 201, 204 (Tex.App.-Houston [14th Dist.] 2000, no pet.).

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STATE OF SOUTH CAROLINA **COUNTY OF BEAUFORT**	)	**IN THE COURT OF COMMON PLEAS** **FOURTEENTH JUDICIAL CIRCUIT**
COUNTY OF BEAUFORT, **Plaintiff,** **vs.**	)	
RITE AID OF SOUTH CAROLINA, INC.; PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC N/K/A JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC F/K/A ACTAVIS PLC; ALLERGAN FINANCE LLC F/K/A ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; INSYS THERAPEUTICS, INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN DRUG CORPORATION; SMITH DRUG COMPANY; WAL-MART STORES EAST, LP; WAL-MART STORES, INC.; CVS PHARMACY, INC.; CVS HEALTH CORPORATION; LEAVIS SULLIVAN; BETH TAYLOR; LEIGH VARNADORE; PAUL KITCHIN; AATHIRAYEN THIYAGARAJAH; SPINE AND PAIN CONSULTANTS, PA; MACKIE WALKER; JOHN DOE 1; JOHN DOE 2; JOHN DOE 3; JOHN DOE 4; CLINIC 1; CLINIC 2; CLINIC 3; CLINIC 4; and CLINIC 5, **Defendants.**	)	**SUMMONS** **C.A. No.:**

TO: THE DEFENDANTS ABOVE NAMED:

YOU ARE HEREBY SUMMONED and required to Answer the Complaint in this action, a copy of which is herewith served upon you, and to serve a copy of your Answer thereto upon the undersigned at his office at Post Office Box 24005, Hilton Head Island, South Carolina 29925-4005, within thirty (30) days of the service hereof, exclusive of the date of such service; and if you fail to Answer the Complaint within such time, the Plaintiff in this action, COUNTY OF BEAUFORT, will apply to the Court for the relief demanded therein, and judgment by default will be entered against you.

FINGER, MELNICK & BROOKS, P.A.

s/Terry A. Finger
s/ Benjamin T. Shelton
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Hilton Head, South Carolina
June 18, 2018

STATE OF SOUTH CAROLINA **COUNTY OF BEAUFORT**	**IN THE COURT OF COMMON PLEAS** **FOURTEENTH JUDICIAL CIRCUIT**
COUNTY OF BEAUFORT, **Plaintiff,** **vs.** **RITE AID OF SOUTH CAROLINA, INC.; PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC N/K/A JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC F/K/A ACTAVIS PLC; ALLERGAN FINANCE LLC F/K/A ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; INSYS THERAPEUTICS, INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN DRUG CORPORATION; SMITH DRUG COMPANY; WAL-MART STORES EAST, LP; WAL-MART STORES, INC.; CVS PHARMACY, INC.; CVS HEALTH CORPORATION; LEAVIS SULLIVAN; BETH TAYLOR; LEIGH VARNADORE; PAUL KITCHIN; AATHIRAYEN THIYAGARAJAH; SPINE AND PAIN CONSULTANTS, PA; MACKIE WALKER; JOHN DOE 1; JOHN DOE 2; JOHN DOE 3; JOHN DOE 4; CLINIC 1; CLINIC 2; CLINIC 3; CLINIC 4; and CLINIC 5,** **Defendants.**	**COMPLAINT** **JURY TRIAL DEMANDED** **C.A. No.:**

COMPLAINT

Plaintiff, the County of Beaufort, South Carolina ("Plaintiff" or "the County"), by and through the undersigned attorneys, upon personal knowledge as to its own acts and beliefs, and upon information and belief as to all matters based upon the investigation of counsel, for its Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company; Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc.; Janssen Pharmaceutica, Inc. n/k/a/ Janssen Pharmaceuticals; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis plc; Allergan Finance LLC f/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Insys Therapeutics, Inc.; (collectively, "Manufacturers" or "Defendants"); McKesson Corporation; Cardinal Health, Inc.; Rite Aid of South Carolina, Inc.; AmerisourceBergen Drug Corporation; Smith Drug Company; Wal-Mart Stores East LP; Wal-Mart Stores, Inc.; CVS Pharmacy, Inc.; CVS Health Corporation; (collectively, "Distributor Defendants" or "Defendants"); LeAvis Sullivan; Beth Taylor; Leigh Varnadore; Paul Kitchin; (collectively, "Sales Representative Defendants"); Aathirayen Thiyagarajah; Spine and Pain Consultants, PA; Mackie Walker; John Doe 1; John Doe 2; John Doe 3; John Doe 4; Clinic 1; Clinic 2; Clinic 3; Clinic 4; Clinic 5; (collectively, "Dealer Defendants" or "Defendants") alleges as follows:

INTRODUCTION

1. Plaintiff is a body politic in the State of South Carolina.

2. Plaintiff spends millions of dollars each year to provide or pay for the healthcare, pharmaceutical care, and other necessary services and programs on behalf of indigents and otherwise eligible residents, including payments for prescription opium-like painkillers ("opioids"), which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants.

3. Plaintiff not only provides a wide range of other services on behalf of its residents, including services for families and children, public assistance, and law enforcement, but also depends on the health and productivity of its workforce to generate tax revenue.

4. Opioids include brand-name drugs like OxyContin and Percocet and generics like oxycodone and hydrocodone. These drugs are derived from or possess properties similar to opium and heroin, and, as such, they are highly addictive and dangerous and, therefore, are regulated by the United States Food and Drug Administration ("FDA") as controlled substances.

5. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. Opioids are approved by the FDA for use in the management of moderate to severe pain and their use is typically appropriate for a few days or more. For example, doctors traditionally used opioids to treat acute pain for severe bodily trauma (*e.g.*, gunshot wounds and post-surgical pain). Patients experiencing extreme levels of pain from cancer have also received opioids to make the end of their life as pain free as possible.

6. Defendants, however, have manufactured, promoted, and marketed opioids for the long-term management of chronic pain (*e.g.*, low back pain, knee pain, and neck pain) by misleading consumers and medical providers through misrepresentations and/or omissions regarding the appropriate uses, risks, and safety of opioids.

7. Addiction is a spectrum of substance use disorders that range from misuse and

abuse of drugs to addiction.[1] Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

8. Defendants knew that, barring exceptional circumstances, opioids are too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer ("chronic pain").

9. Defendants knew that, with prolonged use, the effectiveness of opioids wanes over time, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.[2]

10. Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (*i.e.,* not longer than 90 days) in managed settings (*e.g.*, hospitals) where the risk of addiction and other adverse outcomes was significantly minimized.

11. To date, there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.

12. Despite the foregoing knowledge, to expand the market for opioids and realize blockbuster profits, Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and to treat a wider range of problems, including such common aches and pains as lower back pain, arthritis, and headaches.

13. Defendants accomplished that false perception through a coordinated, sophisticated, and highly deceptive marketing campaign that began in the late 1990s, became more aggressive in or about 2006, and continues to the present.

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[1] Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").

[2] *See, e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247–87 (H.L. Fields and J.C. Liebeskind eds., 1994).

14. Defendants accomplished their marketing campaign goal by convincing doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks, and that opioids could be safely used by most patients.

15. Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, patients, governmental units, and others by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

16. Defendants' marketing campaign has been extremely successful in expanding opioid use. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled.[3] In 2010, 254 million prescriptions for opioids were filled in the U.S., which is enough to medicate every adult in America around the clock for a month. Also in that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).[4] While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.[5] By 2014, nearly two million Americans either abused or were dependent on opioids.[6]

17. Defendants' campaign has been extremely profitable. In 2012 alone, opioids generated $8 billion in revenue for drug companies.[7] Of that amount, $3.1 billion went to Purdue for its OxyContin sales.[8]

18. Defendants' marketing campaign has been extremely harmful to Americans,

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[3] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: http://www.cdc.gov/drugoverdose/epidemic/index.html (accessed September 19, 2017) (internal footnotes omitted).
[4] M. Daubresse, et al., Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013).
[5] L. Manchikanti, et al., Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten- Year Perspective, 13 Pain Physician 401-435 (2010).
[6] CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids. Available at: http://www.cdc.gov/drugoverdose/opioids/prescribed.html (accessed September 19, 2017).
[7] B. Meier & B. Marsh, *The Soaring Cost of the Opioid Economy*, N.Y. Times (June 22, 2013).
[8] K. Eban, *Purdue Pharma's Painful Medicine*, Fortune Magazine (Nov. 9, 2011).

including the citizens of and visitors to Beaufort County, South Carolina. Nationwide, overdoses from prescription pain relievers are a driving factor in a fifteen-year increase in opioid overdose deaths. Deaths from prescription opioids have also quadrupled since 1999. From 2000 to 2014 nearly half a million people died from such overdoses. According to the CDC, on average, 115 Americans die every day from an opioid overdose.[9]

19. In 2012, an estimated 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.[10] Between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.[11]

20. Opioid addiction and overdoses have reached epidemic levels over the past decade. On March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."[12]

21. In 2016, approximately 64,000 people died from drug overdoses in the United States, more than the peak yearly death tolls from car crashes, HIV deaths, or gun deaths.[13] Sixty-six percent of the drug overdose deaths in 2016 involved opioids, with the total deaths involving opioids taking more lives than breast cancer.[14] The total overdose deaths in 2016 were 10,000 more than in 2015. The graph below shows the trend relating to overdose deaths since

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[9] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

[10] Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H- 46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

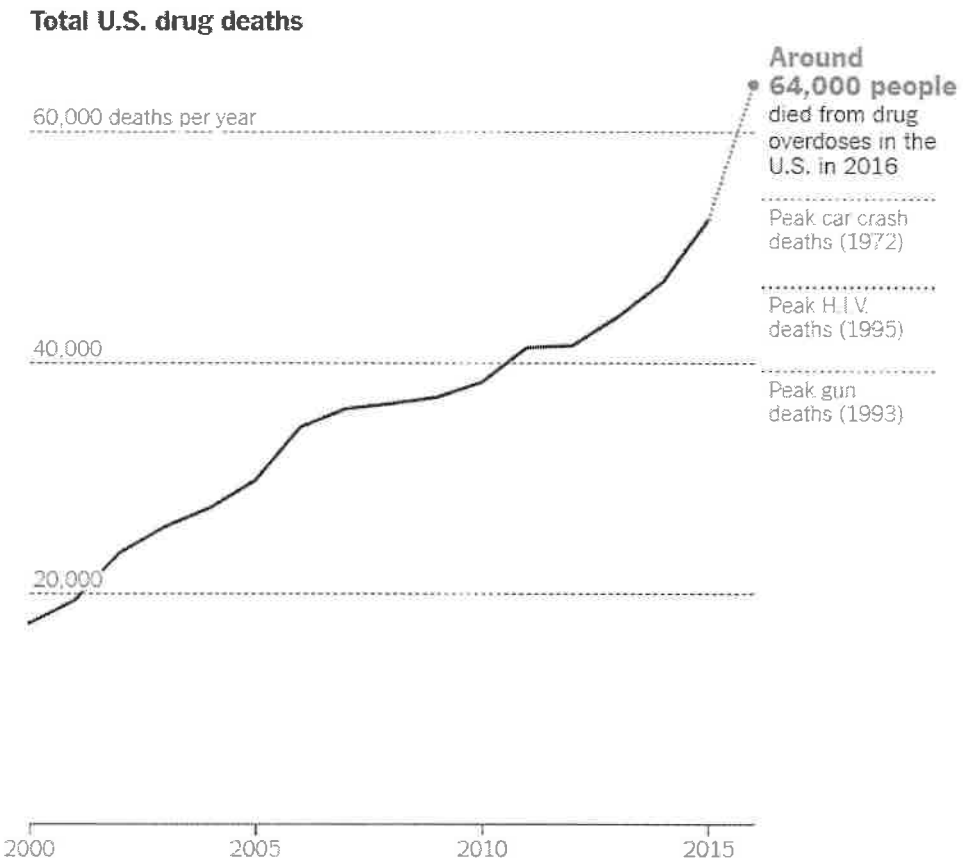
[11] J. Boscarino et al., Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system, 105(10) Addiction 1776 (2010); J. Boscarino et al., Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria, 30(3) Journal of Addictive Diseases 185 (2011).

[12] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed September 19, 2017).

[13] Katz, Josh, *The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years*, https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html (published September 2, 2017, accessed October 27, 2017).

[14] Kounang, Nadia, *Opioids now kill more people than breast cancer*, http://www.cnn.com/2017/12/21/health/drug-overdoses-2016-final-numbers/index.html (accessed December 29, 2017).

2000:[15]



22. Despite the record profits being generated from their efforts, Defendants' marketing campaign has failed to achieve any material healthcare benefits. Since 1999, there has been no overall change in the amount of pain that Americans report.[16]

23. The National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive*

[15] Katz, Josh, *The First County of Fentanyl Deaths in 2016: Up 540% in Three Years*, *Supra.*
[16] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra.*

marketing by pharmaceutical companies."[17] As shown below, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes " are not really independent causative factors but are in fact the direct result of "the aggressive marketing by pharmaceutical companies."

24. The rising numbers of persons addicted to opioids have led to significantly increased healthcare costs as well as a dramatic increase of social problems, including drug abuse and diversion[18] and the commission of criminal acts to obtain opioids throughout the United States, including in South Carolina and Beaufort County. Consequently, public health and safety throughout the United States, including in Beaufort County, has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, ultimately leading to widespread inappropriate use of these drugs.

25. Opioid abuse is widespread across the State of South Carolina. In South Carolina, for each year from 2012 through 2016, there has been more than one opioid prescription for every resident of the state. And, in 2016, South Carolina ranked ninth in the nation in opioid prescribing rates.[19]

26. In 2016, 876 drug overdose deaths occurred in South Carolina, increased from 789 deaths in 2015 (11% increase). Six hundred and sixteen (616) deaths involved opioids, increased from 565 in 2015 (9% increase). Additionally, 70.3% of all drug overdose deaths involved opioids.[20]

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[17] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse (accessed September 19, 2017) (emphasis added).

[18] According to the CDC, when prescription medicines are obtained or used illegally, it is called "drug diversion."

[19] South Carolina Department of Health and Environmental Control. http://scopioidsummit.org/wp content/uploads/2017/09/Data-Presentation.pdf (Accessed December 21, 2017).

[20] Id.

27. In the last five years, more than 3,000 residents of South Carolina have died from overdoses of prescription opioids. Heroin overdoses in the state have increased by 57% from 2014 to 2015 as a result of individuals who cannot get access to prescription opioids and turn to heroin. Heroin and prescription opioid overdose deaths in South Carolina combined exceeded the number of homicides in South Carolina in 2015.[21]

28. Within the Medicaid population in South Carolina, in 2013, there were 3,500 Medicaid enrollees reported with an opioid addiction, 319 per 100,000 persons.[22]

29. Overall sales of opioids in South Carolina have skyrocketed. In 2016, nearly 5 million opioid prescriptions were dispensed in the state, a larger number than the total state population. South Carolina ranked ninth in the nation in opioid prescribing rates in 2016. The South Carolina State Health Plan's compensation to Purdue increased from under $3 million per year in 2010 to over $4.3 million in 2014. Prescriptions for Purdue's opioids likewise increased from 7,000 per year in 2010 to over 11,000 in 2014.[23]

30. Aside from deaths, in South Carolina, addiction and misuse have resulted in increased emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone, the antidote to opioid overdose. In South Carolina, administrations of naloxone (or Narcan) rose from 4,187 in 2015 to 6,427 in 2016.[24]

31. The abuse of opioids has caused additional medical conditions that harm South Carolina residents and require care paid for by taxpayers. For example, the number of chronic

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[21] Id.

[22] "Medicaid and the Opioid Epidemic: Enrollment, Spending, and the Implications of Proposed Policy Changes" July 14, 2017. Kathering Young and Julia Zur. https://www.kff.org/medicaid/issue-brief/medicaid-and-the-opioid-epidemic-enrollment-spending-and-the-implications-of-proposed-policy-changes/

[23] http://www.nsc.org/RxDrugOverdoseDocuments/Prescription-Nation-2016-American-Drug-Epidemic.pdf. (Accessed December 21, 2017.)

[24] Gregory Yee. "Narcan use on the rise in South Carolina amid ongoing Opioid Epidemic." The Post and Courier. January 29, 2017. https://www.postandcourier.com/news/narcan-use-on-the-rise-in-south-carolina-amid-ongoing/article_212301b2-d784-11e6-9e85-c3d1d8b9bf5a.html. (Accessed December 21, 2017).

Hepatitis C patients in South Carolina grew from 3,258 in 2011 to 4,668 in 2015. This increase is largely a result of intravenous drug use stemming from the opioid epidemic.[25]

32. In South Carolina, the abuse of opioids has also harmed children and infants. Neonatal Abstinence Syndrome ("NAS") is a condition where babies are born addicted to drugs because they were exposed to drugs in the womb before birth. NAS most often is caused when a woman takes opioids during pregnancy, and a baby born with NAS may experience withdrawal after birth. The incidence of NAS in South Carolina quadrupled between 2000 and 2013 from roughly 1 infant per 1,000 hospital births to 4 per 1,000, which would amount to 221 infants in 2013.[26]

33. The National Institute on Drug Abuse, a federal government research institute, determined that the average hospital cost for a newborn with NAS is $66,700, compared to $3,500 for the typical, healthy newborn.[27] After birth, children born into families struggling with opioid addiction or who fall into opioid addiction frequently end up in the foster care system.

34. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts in South Carolina have migrated to heroin. Roughly 80% of heroin users previously used prescription opioids. Statewide, overdoses involving heroin increased by 57% from 2014 to 2015. A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, is now making its way into South Carolina communities through

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[25] https://www.cdc.gov/hepatitis/statistics/2011surveillance/pdfs/2011hepsurveillanceprt.pdf. (Accessed December 21, 2017).

[26] Mary Katherine Wildeman, "Charleston Hospitals inundated with requests from volunteers to cuddle infants, partly due to increase of NAS cases" *The Post and Courier.* February 19, 2017. https://www.postandcourier.com/features/charleston-hospitals-inundated-with-requests-from-volunteers-to-cuddle-infants/article_d96b551c-f458-11e6-a927-1f1499a61773.html (Accessed December 21, 2017).

[27] National Institute on Drug Abuse, *Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome*, https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome, (accessed October 25, 2017).

trafficking.[28]

35. Beaufort County has not been an exception to the suffering caused by the opioid epidemic. The amount of reported deaths in Beaufort due to opioid overdoses doubled from four in 2015 to eight in 2016. According to Capt. Bob Bromage, the Beaufort County Sheriff's Office has seen a surge in opioid-related overdoses in the Beaufort community, particularly since the fall of 2016. Bromage has reported that of the 85 known overdose cases since December 2016, more than 90 percent (90%) of the cases where the substance was identified were caused by opioids. Bromage has also noted that these are only the reported cases, many cases go unreported. The County officers have received training on how to use Naloxone.[29] The number of times Naxolone was administered by county changed 20.93% from 2015 to 2016, with 42 uses in 2015 to 52 in 2016.[30]

36. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has been required to spend millions of dollars each year in its efforts to combat the public nuisance created by Defendants' deceptive marketing campaign. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and its residents.

37. Additionally, the average opioid user in Beaufort County was prescribed between

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[28] Anna Lee. "Greenville's Opioid Epidemic Brought to the Forefront at Public Hearing." *Greenville News.* July 12, 2017. http://www.greenvilleonline.com/story/news/2017/07/13/greenvilles-opioid-problem-brought-forefront-public-hearing/469547001/. (Accessed December 21, 2017).

[29] Amy Rigard. "Opioid Epidemic Hits Beaufort County" *The Island News.* August 24, 2017. http://www.yourislandnews.com/opioid-epidemic-hits-beaufort-county/. (Accessed December 21, 2017).

[30] https://www.scdhec.gov/Health/Opioids/OpioidStatistics/. (Accessed December 21, 2017).

474 and 589 mg in 2016.[31] An average of between 326 and 526 mg of opioids were dispensed per Beaufort County resident in 2016.[32]

38. The increase in opioid related drug use has been met with an increase in drug-related crime as well. Oconee County Sheriff, Mike Crenshaw reported: "Ninety-five plus percent of all property crimes is either directly or indirectly connected to illegal drug use."[33] In 2015, Beaufort County had 633 drug/narcotic offenses committed, an increase from 534 drug/drugs equipment offenses in 2011.[34] The increased criminal activity causes financial strain on every aspect of the County criminal justice system.

39. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has been required to spend millions of dollars each year in its efforts to combat the public nuisance created by such wrongful conduct. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse, including, but not limited to, healthcare costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' wrongful conduct proximately caused injury to Plaintiff and its residents.

40. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*: (1) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing

[31] Division of Medicaid Policy Research at the USC Institute for Families in Society, *SC Medicaid Enrollees Within the Growing Opioid Crisis*, http://www.schealthviz.sc.edu/Data/Sites/1/media/2017_scmedicaidopioidreport.pdf, August 2017 accessed January 4, 2017).

[32] Id.

[33] Jennifer Phillips. "Beaufort Co. Sheriff Hopes New Drug Patch will Deter Crime." *Fox Carolina*. February 10, 2017. http://www.foxcarolina.com/story/34525139/Beaufort-county-sheriff-supports-new-drug-patch-to-deter-crime (Accessed January 4, 2018.)

[34] South Carolina Law Enforcement Division and Department of Public Safety, *Crime in South Carolina*, http://www.sled.sc.gov/documents/CrimeReporting/SCCrimeBooks/2010/2010%20Crime%20in%20South%20Carolina.pdf (accessed January 4, 2017).

treatment, counseling, and rehabilitation services; (3) costs for providing treatment to infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; (5) and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered, directly by the Plaintiff. In sum, Plaintiff seeks to recover funds needed for efforts to clean up the disastrous epidemic caused by Defendants, which has infected nearly every aspect of civic life, and the funds required to repair and stop the damage moving forward.

41. Plaintiff also seeks the means to abate the Defendants' wrongful and/or unlawful conduct, which created this public health crisis.

JURISDICTION AND VENUE

42. This Court has jurisdiction over this action pursuant to SC Const. art. VIII §17; SC Const. art. V §11; SC Code Ann. §§ 15-72-10; 14-1-80; 4-9-25; 4-9-670; and 36-2-803.

43. This Court has personal jurisdiction over Defendants because they conduct business in South Carolina and Beaufort County; purposefully direct or directed their negligent and injurious actions toward South Carolina and Beaufort County; consensually submitted to the jurisdiction of South Carolina when obtaining a manufacturer or distributor license; have headquartered in South Carolina; have taken actions within Plaintiff's jurisdictional boundaries that have foreseeably caused injury to Plaintiff; and/or have the requisite minimum contacts with South Carolina and Beaufort County necessary to constitutionally permit the Court to exercise jurisdiction.

44. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity, and

mortality has created a serious public health and safety crisis and is a public nuisance, and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

45. Venue is proper in Beaufort County pursuant to S.C. Code Ann. §§ 15-7-20, 15-7-30, 39-5-50, and 35-1-603 because the transactions and occurrences that give rise to the claims asserted in this Complaint occurred in Beaufort County.

46. This action is non-removable because there is incomplete diversity of citizenship and no substantial federal question is presented.

PARTIES

47. Plaintiff Beaufort County is a South Carolina County with a population of approximately 171,420 residents as of the 2010 Census. Plaintiff has a duty to provide a wide range of services to its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

48. Defendant Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of the State of Delaware with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

49. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

50. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

51. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture,

promotion, distribution, and sale of opioids nationally and in Beaufort County, including OxyContin (Oxycodone hydrochloride extended release), MS Contin (Morphine sulfate extended release), Dilaudid (Hydromorphone hydrochloride), Dilaudid-HP (Hydromorphone hydrochloride), Butrans (Byrenorpine), Hysingla ER (Hyrdrocodone bitrate), and Targiniq ER (Oxycdone hydrocholoride and Naloxone hydrochloride), all of which except Butrans are Schedule II.[35] Purdue is subject to a Consent Judgment in South Carolina dated May 15, 2007.

52. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (i.e., painkillers).

53. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation with its United States Headquarters located at 1090 Horsham Road, North Wales, Pennsylvania 19454.

54. Defendant Cephalon, Inc. is a Delaware corporation with its headquarters at 1090 Horsham Road, North Wales, Pennsylvania 19454. In 2011, Teva Ltd. acquired Cephalon, Inc.

55. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of the opioids

[35] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. Of the Purdue drugs listed above, Butrans is the only Schedule III drug.

nationally and in Beaufort County, including Actiq (Fentanyl citrate) and Fentora (Fentanyl citrate tablet), which are both Schedule II drugs.

56. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in Beaufort County.

57. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its headquarters located at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933.

58. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation that registered its headquarters with the Pennsylvania Department of State at 1125 Bear Harbor Road, Titusville, New Jersey, 08560 and is a wholly owned subsidiary of J&J.

59. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

60. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation that registered its headquarters with the Pennsylvania Department of State at 1125 Bear Harbor Road, Titusville, New Jersey, 08560.

61. Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation that registered its headquarters with the Pennsylvania Department of State at 1125 Bear Harbor Road, Titusville, New Jersey, 08560.

62. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals stock. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

63. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of

opioids nationally and in Beaufort County, including Duragesic (Fentanyl), Nucynta (Tapentadol), and Nucynta ER (Tapentadol extended release), all of which are Schedule 2 drugs.[36]

64. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

65. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its headquarters at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

66. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its headquarters at 1400 Atwater Drive, Malvern, Pennsylvania.

67. EHS and EPI (collectively, "Endo") manufacture, promote, distribute and sell opioids nationally and in Beaufort County, including Opana ER (Oxymorphone hydrochloride extended release), Opana (Oxymorphone hydrochloride), Percodan (Oxymorphone hydrochloride and aspirin), and Percocet (Oxymorphone hydrochloride and acetaminophen).

68. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

69. Allergan Plc is a public limited liability company incorporated in Ireland with its principal place of business at Clonshaugh Business & Technology Park, Coolock, Dublin 17. Actavis Plc acquired Allergan Plc in March 2015, and the combined company changed its name to Allergan Plc in March 2015.

[36] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

70. Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012; the combined company changed its name to Actavis, Inc. in January 2013. Actavis, Inc. is now known as Allergan Finance LLC. Allergan Finance LLC is a Nevada Corporation with its corporate headquarters located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

71. Watson Laboratories, Inc. is a Nevada corporation with its headquarters at 132 Business Center Drive, Corona, California and is a wholly owned subsidiary of Allergan Plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

72. Actavis Pharma, Inc. f/k/a Actavis, Inc. is a Delaware corporation with its headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, and was formerly known as Watson Pharma, Inc.

73. Actavis LLC is a Delaware limited liability company with its headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

74. Each of the defendants in ¶¶ 70–74 is owned by Allergan Plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan Plc exercises control over these marketing and sales efforts; profits from the sale of Allergan/Actavis products; and ultimately benefits from them (Allergan Plc, Actavis Plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter collectively are referred to as "Actavis.").

75. Actavis manufactures, promotes, distributes, and sells the branded opioids Kadian (morphine sulfate extended release) and Norco nationally and within Beaufort County. Kadian is a Schedule II drug. Actavis also sells a generic version of Kadian, Duragesic, and Opana. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008

and began marketing Kadian in 2009.

76. Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

77. Insys has manufactured, promoted, distributed, and sold the branded Schedule II opioid Subsys (fentanyl sublingual spray) since 2012, both nationally and within Beaufort County, South Carolina. According to its Form 10-K filing for 2015, Insys reported revenues of $329.5 million from sales of Subsys. Although Subsys was approved solely for treatment of breakthrough pain ("BTP") in cancer patients already receiving opioids for persistent cancer-related pain, Insys illegally and deceptively marketed Subsys for chronic pain conditions.

78. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its headquarters at One Post Street, San Francisco, California, 94104.

79. McKesson promotes, distributes, and sells opioids manufactured by Manufacturers across the country and, upon information and belief, within South Carolina and Beaufort County to pharmacies and institutional providers. McKesson had a net income of over $1.5 billion in 2015.

80. Defendant Cardinal Health Inc. ("Cardinal") is an Ohio corporation with its headquarters at 7000 Cardinal Place, Dublin, Ohio, 43017.

81. Defendant Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including, on information and belief, within South Carolina and Beaufort County.

82. Defendant Rite Aid of South Carolina, Inc., ("Rite Aid") was incorporated in South Carolina in 1977 and has various locations throughout South Carolina, including within Beaufort County, and acts as a subsidiary of Rite Aid Corporation.

83. Defendant Rite Aid distributes opioids to consumers within South Carolina and Beaufort County.

84. Defendant Wal-Mart Stores East, LP was incorporated in Delaware with its principal place of business in Bentonville, Arkansas, doing business as Wal-Mart Pharmacy Warehouse #46. Wal-Mart is registered to do business in South Carolina and distributes opioids to consumers within South Carolina and Beaufort County.

85. Defendant Wal-Mart Stores, Inc. was incorporated in Delaware and is registered to do business in South Carolina and distributes opioids to consumers within South Carolina and Beaufort County. It acts as the parent company of Wal-Mart Stores East, LP (collectively, "Wal-Mart"). Its headquarters are at 702 SW 8th Street, Bentonville, AR 72716.

86. Defendant CVS Pharmacy, Inc. was incorporated in Rhode Island and is registered to do business in South Carolina and distributes opioids to consumers within South Carolina and Beaufort County.

87. Defendant CVS Health Corporation is incorporated in Delaware and serves as the parent corporation for CVS Pharmacy, Inc. (collectively, "CVS"). Its headquarters are at One CVS Drive, Woonsocket, Rhode Island 02895.

88. Upon information and belief, Defendant AmerisourceBergen Drug Corporation ("Amerisource") is a Delaware corporation with its headquarters at 1300 Morris Drive, Chesterbrook, Pennsylvania, 19087.

89. Defendant Amerisource does substantial business as a pharmaceutical distributor to retail pharmacies and institutional providers in the State of South Carolina and Beaufort County.

90. The Distributor Defendants failed to detect and report actions by the Dealer

Defendants and others, which caused the opioid epidemic plaguing Beaufort County. The data which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential Automation of Reports and Consolidated Orders System (ARCOS) database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). All potential Distributor Defendants conceal and prevent the discovery of necessary information to confirm their identities. Neither the DEA[37] nor the wholesale distributors[38] will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for naming all Distributor Defendants responsible.

91. Defendant Smith Drug Company ("Smith") is a South Carolina Corporation with its headquarters at 9098 Fairforest Rd, Spartanburg, SC 29301.

92. Defendant Smith distributes opioids to consumers within South Carolina and Beaufort County.

93. Three of the Distributor Defendants, Cardinal, Amerisource, and McKesson are three of the largest opioid distributors in Beaufort County.

94. Defendant LeAvis Sullivan is a resident and citizen of South Carolina. During the relevant time period, Defendant Sullivan was a Sales Representative and served as a District Manager for Defendant Purdue Pharma, L.P. in South Carolina.

95. Defendant Beth Taylor is a resident and citizen of South Carolina. During the relevant time period, Defendant Taylor was a Sales Representative, Analgesia Specialist for the

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[37] *See* Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI,
Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

[38] *See* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

Southeast Region, and served as a District Field Sales Trainer for Defendant Purdue Pharma, L.P. in South Carolina.

96. Defendant Leigh Varnadore is a resident and citizen of South Carolina. During the relevant time period, Defendant Varnadore was a Sales Representative and served as a District Manager for Defendant Purdue Pharma, L.P. in South Carolina.

97. Defendant Paul Kitchin is a resident and citizen of South Carolina. During the relevant time period, Defendant Kitchin was a Sales Representative and served as a District Manager for Defendant Purdue Pharma, L.P. in South Carolina.

98. Collectively, the Sales Representative Defendants were chiefly responsible for the sale of opioid medications across the entire state of South Carolina for Purdue, and they were also responsible for the training, management, and direction of any new members of Purdue's salesforce in the state.

99. Defendant Aathirayen Thiyagarajah is, ostensibly, a physician licensed to practice medicine in South Carolina and has his primary place of business in Greenville County, South Carolina, is a citizen of South Carolina, and dedicates a large portion of his practice to prescribing opioid medications for nonmedical purposes. Defendant Thiyagarajah distributed and dispensed opioids outside the usual course and scope of professional practice and not for a legitimate medical purpose. His actions have led to opioids being sold illegally in Beaufort County, South Carolina and have led to overdoses within Beaufort County. He greatly contributed to the diversion of opioids across South Carolina and in Beaufort County, causing great economic loss to Plaintiff.

100. Defendant Spine and Pain Consultants, PA is a South Carolina legal entity which ostensibly operates as a medical provider in Greenville County and Anderson County. This clinic

defendant is operated by, employs, and/or is affiliated with Defendant Thiyagarajah. The acts and/or omissions of this clinic defendant greatly contributed to the illegal diversion of opioids across South Carolina and Beaufort County, and opioids placed into the public by this clinic defendant directly resulted in overdoses and diversion of opioids within Beaufort County, causing great economic loss to Plaintiff. Defendant Spine and Pain Consultants, PA greatly contributed to the diversion of opioids across South Carolina and in Beaufort County

101. Defendant Mackie Walker was, ostensibly, a podiatrist licensed to practice medicine in South Carolina and had his primary place of business in Aiken County, South Carolina, is a citizen of South Carolina, and dedicated a large portion of his practice to prescribing opioid medications for nonmedical purposes. Defendant Walker distributed and dispensed opioids outside the usual course and scope of professional practice and not for a legitimate medical purpose. His actions have led to opioids being sold illegally in Beaufort County, South Carolina and have led to overdoses within Beaufort County. He greatly contributed to the diversion of opioids across South Carolina and in Beaufort County, causing great economic loss to Plaintiff.

102. Defendants John Doe 1, John Doe 2, John Doe 3, John Doe 4, and John Doe 5 are ostensibly physicians licensed to practice medicine in South Carolina, have their primary place of business in Beaufort County, South Carolina, are citizens of South Carolina, and dedicate a large portion of the practice to prescribing opioid medications. On information and belief, these physicians distributed and dispensed opioids outside the usual course and scope of professional practice and not for a legitimate medical purpose. Their actions have led directly to opioids being sold illegally in Beaufort County, South Carolina and to overdoses within Beaufort County. They greatly contributed to the diversion of opioids across South Carolina and in Beaufort County

causing great economic loss to Plaintiff. After the Complaint is filed and initial limited discovery is held, John Doe 1, John Doe 2, John Doe 3, John Doe 4, and John Doe 5 will be named through the appropriate motion to amend this initial Complaint.

103. Defendants Clinic 1, Clinic 2, Clinic 3, Clinic 4, and Clinic 5 are South Carolina legal entities which ostensibly operate as medical providers in Beaufort County. The Clinic Defendants are operated by, employ, and/are affiliated with the Doe Defendants. The Clinic Defendants' acts and/or omissions greatly contribute to the illegal diversion of opioids across South Carolina and Beaufort County, and opioids placed into the public by the Clinic Defendants directly result in overdoses and diversion of opioids within Beaufort County, causing great economic loss to Plaintiff.

GENERAL FACTUAL ALLEGATIONS

A. THE PAIN-RELIEVING AND ADDICTIVE PROPERTIES OF OPIOIDS

104. The pain-relieving properties of opium have been recognized for millennia. Likewise, the magnitude of opium's potential for abuse and addiction has been well-known for ages and has led to its strict regulation world-wide. Opioids, similar to the illegal drugs opium and heroin, are substances that act on opioid receptors to produce morphine-like effects.

105. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain, particularly on the battlefield, and they were popularly used in a wide variety of commercial products such as pain elixirs, cough suppressants, and beverages. By 1900, an estimated 300,000

people were addicted to opioids in the United States,[39] and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

106. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression" as the result of an excessive dose.

107. Studies and articles from the 1970s and 1980s also made clear the reasons to avoid opioids: scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' functioning; greater pain complaints as most patients developed a tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments such as physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

108. In 1986, Dr. Russel Portenoy, M.D., who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[40]

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[39] Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

[40] R. Portenoy & K. Foley, Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases, 25(2) Pain 171 (1986).

109. Writing in 1994, Dr. Russel Portenoy, described the prevailing attitudes regarding the dangers of long-term use of opioids:

> ***The traditional approach to chronic non-malignant pain does not accept the long- term administration of opioid drugs.*** **This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life.** ***Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.***[41]

According to Dr. Russel Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[42]

110. For all the reasons outlined by Dr. Russel Portenoy, and in the words of one researcher from the University of Washington in 2012, and quoted by a Harvard researcher the same year, "it did not enter [doctors'] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them."[43]

111. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include severe

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[41] R. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).
[42] *Id.*
[43] J. Loeser. Five crises in pain management, Pain Clinical Updates. 2012;20 (1):1–4(cited by I. Kissin, Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety? 6 J. Pain Research 513, 514 (2013)).

anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

112. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction to which he has become accustomed, up to and including doses that are "frighteningly high."[44] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

113. Opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

114. Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic pain.

115. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death." The FDA further warned that "[e]ven proper

[44] M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate."[45] The FDA required that, going forward, opioid makers of long-acting formulations clearly communicate these risks in their labels.

116. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.[46]

117. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants in the 1990s when their deceptive marketing began.

B. OPIOID THERAPY MAKES PATIENTS SICKER WITHOUT LONG TERM BENEFITS

118. There is no scientific evidence supporting the safety or efficacy of opioids for long-term use. Defendants are (and have been) well aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, Defendants failed to disclose the lack of evidence to support their use long-term and intentionally failed to disclose the substantial scientific evidence demonstrating that chronic opioid therapy actually worsens patients' health.

119. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function on a long-term basis. For

[45] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing,* Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013) (emphasis in original).

[46] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed September 19, 2017).

example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that the evidence did not allow judgments regarding long-term use.

120. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.[47]

121. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater healthcare utilization.

122. Although opioids may work acceptably well during a limited, short period of time, long-term usage results in marked declines in patient's ability to function, their general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.[48]

123. The foregoing is true both generally and for specific pain-related conditions. Studies of the long-term use of opioids for chronic lower back pain have failed to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not permit patients to return to work or physical activity. This failure is due in part to addiction and other side effects.

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[47] A. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. K. Seal, *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012).

[48] *See* A. Rubenstein, *Are we making pain patients worse?* Sonoma Medicine (Fall 2009).

124. For example, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Yet, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment, and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other, non-opioid medications.

C. DEFENDANTS' SCHEME TO CHANGE PRESCRIBER HABITS AND PUBLIC PERCEPTION

125. Prior to the Defendants' marketing campaign and other wrongful conduct complained of herein, generally accepted standards of medical practice dictated that opioids should only be used on a short-term, temporary basis in order to treat acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those limited instances, the risks of addiction are considered low or of little significance.

126. By its very nature, the market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. Defendants recognized that if they could sell their opioid products for both short term pain relief and for the treatment of long-term, chronic pain, they could achieve blockbuster levels of sales while exponentially increasing their profits. Further, Defendants recognized that the elevated risk of addiction associated with the long-term use of their highly-addictive, opioid products would virtually guarantee that their blockbuster profits would continue indefinitely.

127. Defendants knew that to increase their profits from the sale of opioids they would need to convince doctors and patients that long-term opioid therapy was safe and effective. In other words, Defendants needed to persuade physicians to abandon their long-held apprehensions

about prescribing opioids and instead prescribe opioids for durations previously understood to be unsafe.

128. Defendants knew that their goal of increasing profits by promoting the prescription of opioids for chronic pain would directly lead to an increase in healthcare costs for patients, healthcare insurers, and healthcare payors such as Plaintiff.

129. Marshalling help from consultants and public relations firms, Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain and improve patient quality of life, however, Defendants instead sought to distort and pervert medical and public perception of existing scientific data.

130. As explained more fully herein, Defendants, collectively and individually, poured vast sums of money into generating articles, continuing medical education courses ("CMEs"), and other "educational" materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, all of which was intended to, and which did, create a new but patently false "consensus" supporting the long-term use of opioids.

D. DEFENDANTS USED "UNBRANDED" MARKETING TO EVADE REGULATIONS AND CONSUMER PROTECTION LAWS

131. The promotional activity of pharmaceutical companies can be branded or unbranded; unbranded marketing typically focuses on education regarding a particular disease state or treatment rather than promoting a specific drug product. By using unbranded marketing in their communications, drug companies avoid the extensive regulatory framework governing branded communications.

132. A drug company's branded marketing, which identifies and promotes a specific

drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[49] The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of prescribing those drugs to their patients.

133. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") places additional restrictions on branded marketing. It prohibits the sale, in interstate commerce, of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[50] "Labeling" includes more than just the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[51] The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.[52] Thus, Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

134. Branded promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated. If, upon review, the FDA determines that a drug's marketing materials are misleading, it can issue either an untitled letter or a warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions

[49] 21 U.S.C. 352(a); 21 CFR 202.1(e)(6); 21 CFR 202.1(e)(3); 21 CFR 1.21(a)
[50] 21 U.S.C 352(f); 21 U.S.C. 352(q); *U.S. v. Sullivan*, 68 S.Ct. 331, 335 (1948)
[51] 21 U.S.C.A. § 321(m)
[52] *Kordel v. U.S.*, 69 S. Ct. 106, 110 (1948)

involving safety or health risks and indicate the FDA may take further enforcement action.

135. Defendants generally avoided using branded advertisements to spread their deceptive messages and claims regarding opioids. Defendants intentionally avoided branded promotional materials for the express purpose of escaping regulatory review of their claims.

136. Instead, Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated and unbranded marketing materials—materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, Defendants presented information and instructions concerning opioids generally that were false and misleading.

137. By acting through third parties, Defendants were able to give the false appearance that their messages reflected the views of independent third parties. Later, Defendants would cite to these sources as "independent" corroboration of their own statements. Further, as one physician adviser to Defendants noted, third-party documents not only had greater credibility, but also broader distribution, as doctors did not "push back" at having such materials—for example, literature from the non-profit American Pain Foundation ("APF")—on display in their offices, as they would with drug company pieces.

138. As part of their marketing scheme, Defendants spread and validated their deceptive messages through the following unbranded vehicles ("the Vehicles"): (i) so-called "key opinion leaders" ("KOLs") (i.e., physicians who influence their peers' medical practice, including but not limited to prescribing behavior), who wrote favorable journal articles and delivered supportive CMEs; (ii) a body of biased and unsupported scientific literature, ghostwritten by Manufacturer Defendants and published by KOLs; (iii) treatment guidelines ghostwritten by Manufacturer Defendants and published as a direct result of KOLs reputation

and involvement with the publishing organizations, which were distributed within Beaufort County causing injury within the County; (iv) CMEs by KOLs, deliberately conducted within South Carolina and attended by Beaufort County physicians, causing tortious injury within the County; and (v) unbranded patient education materials disseminated within South Carolina and Beaufort County through groups purporting to be patient-advocacy and professional organizations ("Front Groups"), which were deliberately influenced by Defendant-controlled KOLs, exercising their influence both directly and indirectly because they served in leadership roles in these organizations.

139. Defendants disseminated many of their false, misleading, imbalanced and unsupported messages through the Vehicles because they appeared to uninformed observers to be independent. Through unbranded materials, Defendants presented information and instructions concerning opioids generally that were false and misleading.

140. Even where such unbranded messages were disseminated through third-party Vehicles, including the KOLs, Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials, which all Defendants knew were false, misleading, unsubstantiated, unbalanced, and incomplete from the very outset of the message's "creation" by the purportedly independent KOLs. As described herein, Defendants' sales representatives distributed deceptive third-party marketing material to Defendants' target audience.

141. Defendants took an active role in writing, guiding, reviewing, and approving many of the misleading statements issued by third parties, including the KOLs' statements, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, Defendants exercised control over their deceptive

messages and acted in concert with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain. The process described in this paragraph is commonly referred to as "ghostwriting."

142. The unbranded marketing materials that Defendants assisted in creating and distributing either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks. All of these unbranded marketing materials were falsely promoted by the KOLs from the very outset as independent statements. The KOLs' false promotion of independence provided the unbranded marketing materials utilized by Manufacturer Defendants the credibility required to fraudulently induce physicians within South Carolina and Beaufort County to prescribe opioids for chronic pain.

a. ***Manufacturer Defendants' Misuse of KOLs***

143. The Manufacturer Defendants cultivated a select circle of doctors who were chosen and sponsored by Manufacturer Defendants solely because they promoted the aggressive treatment of chronic pain with opioids in return for the payment of vast sums of money by the Manufacturer Defendants. Pro-opioid KOLs have been at the hub of Defendants' promotional efforts, presenting a false appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of opioid therapy for chronic pain. They have served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to exert control over each of these modalities through the KOLs, who all accepted money to promote Defendants' false marketing claims.

144. In return for their successful pro-opioid advocacy, KOLs received money, prestige, recognition, research funding, and avenues to publish. The more successfully the KOLs were in their deceptive promotion of opioids for chronic pain, the more they were rewarded by the Manufacturer Defendants.

145. Defendants cited and promoted the KOLs and studies or articles by the KOLs to broaden the chronic opioid therapy market. In contrast, Defendants did not support, acknowledge, or disseminate the publications of truly independent doctors who criticized the use of chronic opioid therapy.

146. Defendants carefully vetted their KOLs to ensure that they would remain on-message and supportive of the agenda to falsely promote opioids as safe for the treatment of chronic pain. Defendants also kept close tabs on the content of the materials published by the KOLs, and in some instances Defendants authored, edited, and/or revised them in their entirety prior to publication.

147. In their promotion of the use of opioids to treat chronic pain, the KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit the Defendants.

b. ***Defendants' Corruption of Scientific Literature through KOLs***

148. Rather than actually test the safety and efficacy of opioids for long-term use, Defendants, instrumentally relying on KOLs, misled physicians, patients, and healthcare payors into believing that such tests had already been done. As set forth herein, Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers,

patients, and payors. This literature was, in fact, marketing material intended to persuade doctors and consumers that the benefits of long- term opioid use outweighed the risks.

149. To accomplish their goal, Defendants—sometimes through third-party consultants and/or front groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals authored by KOLs.

150. Defendants' plans for these materials did not originate in the departments within their organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in Defendants' marketing departments and with Defendants' marketing and public relations consultants, ultimately being published and promoted by KOLs.

151. In these materials, Defendants (and their KOL surrogates) often claimed to rely on "data on file" or presented posters, neither of which are subject to peer review. Still, Defendants presented these materials to the medical community as scientific articles or studies, despite the fact that Defendants' materials were not based on reliable data and were not subject to the scrutiny of others who are experts in the same field.

152. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature and by KOLs, even when Defendants knew that the articles distorted the significance or meaning of the underlying study. Most notably, Purdue frequently cited a 1980 item published in the well-respected New England Journal of Medicine, J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) (the "Porter & Jick Letter"), in a manner that makes it appear that the item reported the results of a peer reviewed study. It was also cited in two CME programs sponsored by Endo where KOLs were presenters. Defendants and the KOLs acting on their behalf failed to reveal that this

"article" was actually a letter-to-the-editor, not a study, much less a peer-reviewed study. The Porter & Jick Letter, reproduced in full below, states that the authors examined their files of hospitalized patients who had received opioids:

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

153. The patients referred to in the Porter & Jick Letter were all treated prior to the letter's publication in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids would have been limited to acute or end-of-life situations, not chronic pain, making the data useless for any generalization regarding the safety or efficacy of opioids for treating chronic pain. Even aside from chronic pain treatment, the letter notes that when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor, indeed, is there any indication whether the patients were followed after they were discharged from the hospital or, if they were followed, for how long. None of these

serious limitations were disclosed when Defendants and KOLs acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

154. Dr. Jick has complained that his letter has been distorted and misused—as indeed it has.

155. Defendants not only created and promoted favorable studies in the literature through the paid efforts of KOLs but, in order to discredit or suppress negative information, funded studies and articles that targeted articles contradicting Defendants' claims or raising concerns about chronic opioid therapy. In order to do so, Defendants, often with the help of KOLs, used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

156. Defendants' strategy—to create, fund, plant, and promote supportive literature for citation as pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted their claims—was flatly inconsistent with their legal obligations. Defendants' strategy was intended to alter, and did alter, prescribing and consumer patterns, including those in Beaufort County, by distorting the truth regarding the risks and benefits of using opioids for chronic pain relief.

c. *Defendants' Misuse of Treatment Guides*

157. Treatment guidelines authored with KOLs' influence but under the direction and control of Manufacturer Defendants have been particularly important in securing acceptance for chronic opioid therapy. The guidelines are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are generally not experts, and who generally have no special training, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific

literature and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

i. FSMB

158. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

159. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 edition of the guidelines, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies" and taught that opioids were "essential" for the treatment of chronic pain, including as a first prescription option, rather than that opioids could be appropriate in limited cases after other treatments had failed.

160. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including those in Beaufort County.

161. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications."

162. In 2007, Cephalon sponsored and distributed through its sales representatives FSMB's *Responsible Opioid Prescribing*, which was drafted by Dr. Scott Fishman, M.D, a KOL. Dr. Fishman was frequently hired by a consulting firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Dr. Fishman's work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

163. *Responsible Opioid Prescribing* was a signature piece of Dr. Fishman's work and contained a number of deceptive statements. This publication claimed that, because pain had a negative impact on a patient's ability to function, relieving pain—alone—would "reverse that effect and improve function." However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction.

164. Defendants relied on 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

ii. AAPM/APS GUIDELINES

165. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding

from Defendants from 2009 to 2013.

166. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[53] The chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue, and the sole consultant to the committee was a KOL named Dr. Russel Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

167. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine, M.D., received support from Defendants Janssen, Cephalon, Endo, and Purdue.

168. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated in Beaufort County during the relevant time period, and were and are available online.

169. Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

iii. GUIDELINES THAT DID NOT RECEIVE DEFENDANTS' SUPPORT

170. The extent of Defendants' influence on treatment guidelines is demonstrated by

[53] Haddox J., et al., The Use of Opioids for the Treatment of Chronic Pain – A Consensus Statement from the American Academy of Pain Medicine and the American Pain Society, 6(1) Pain Forum 77-79 (1997)

the fact that independent guidelines (the authors of which did not accept drug company funding) reached very different conclusions.

171. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects."[54]

172. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence."[55]

173. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain,

[54] Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

[55] *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids* (2011).

issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.[56]

d. ***Defendants' Misuse of CMEs***

174. A CME (an acronym for "Continuing Medical Education") is a professional education program provided to doctors. As a condition of their licensure, doctors are required to attend a certain number and, often, type of CME programs each year. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine and/or to deepen their knowledge in specific areas of practice.

175. With the support of Defendants, the KOLs become highly respected in their fields and, as a result, they typically teach CMEs. These programs are thought to be independent, objective reflections of these physicians' medical expertise. As a result, CMEs can be especially influential with doctors. In fact, the Defendants used KOL-taught CMEs in South Carolina to influence the prescribing habits of doctors within South Carolina and Beaufort County, ultimately inducing Beaufort County to provide health insurance for its workforce and treatment to its citizens that allowed the prescribing of opioids for chronic pain, ultimately costing lost revenue.

176. The countless doctors and other healthcare professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one

[56] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_fulltext.pdf (accessed September 19, 2017).

target, Defendants, through KOLs, aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

177. Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

178. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[57]

179. KOL Dr. Fine authored a CME, sponsored by Cephalon, titled *Opioid-Based Management of Persistent and Breakthrough Pain*, with KOLs Dr. Christine A. Miaskowski, M.D., and Michael J. Brennan, M.D. Cephalon paid to have this CME published in a supplement of Pain Medicine News in 2009.[58] It instructed prescribers that "clinically, broad classification of pain syndromes as either cancer or non-cancer related has limited utility" and recommended dispensing "rapid onset opioids" for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," Actiq, and "fentanyl buccal table," Fentora, including in

[57] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).
[58] Fine, Perry, et al., *Opioid-Based Management of Persistent and Breakthrough Pain*, Pain Medicine News (2009), https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain (accessed December 29, 2017).

patients with chronic non-cancer pain. Dr. Miaskoski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines, that she served on Cephalon's speaker's bureau.[59] Dr. Fine also received funding from Cephalon for consulting services.

180. Beaufort County physicians attended or reviewed Defendants' sponsored CMEs during the relevant time period and were misled by them.

181. By sponsoring CME programs put on by Front Groups (i.e., groups purporting to be patient-advocacy and professional organizations) such as APF, AAPM and others, Defendants could rely on instructors to deliver messages favorable to them, as these organizations were dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

e. ***Defendants' Misuse of Patient Education Materials and Front Groups***

182. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[60] Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not

[59] 14 of 21 panel members who drafted the AAPM/APS Guidelines received support from Janssen, Cephalon, Endo, and Purdue.

[60] Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 Albany L. Rev. 299, 308 (2013).

approved.[61] Recognizing this phenomenon, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

183. Defendants entered into arrangements with numerous Front Groups (i.e., groups purporting to be patient-advocacy and professional organizations) to promote the prescription of opioids for the treatment of chronic pain. Each one of these Front Groups depends largely, if not exclusively, upon Defendants for significant funding and, in some cases, they depend wholly upon Defendants' funding for their continued survival. In addition to generating Defendants' promotional materials and programs supporting chronic opioid therapy to be provided to doctors and patients, the Front Groups also assisted Defendants' marketing efforts by responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on the use of opioids to treat chronic pain. Defendants created a symbiotic relationship with the Front Groups whereby Defendants funded them in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages. In turn, the supportive messages drove prescriptions and profits for Defendants and ensured continued funding of the Front Groups.

i. AMERICAN PAIN FOUNDATION

184. The most prominent and effective of Defendants' Front Groups was the American

[61] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al.*, *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

Pain Foundation ("APF"), which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.

185. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain treatment and minimized their risks, specifically the risk of addiction. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to "educate" patients about their "right" to pain treatment with opioids. All of the programs and materials were intended to, and did, reach a national audience, including residents of Beaufort County.

186. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. APF board member, Dr. Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

187. While APF held itself out as an independent patient advocacy organization, it simultaneously engaged in grassroots lobbying against various legislative initiatives that might regulate the prescription of opioids and protect patients from the risks associated with the unnecessary prescription of highly addictive and ineffective drugs. In stark contrast to its stated purpose, APF functioned principally as an advocate for the interests of Defendants, not patients.

188. In practice, APF operated in close collaboration with Defendants. APF submitted grant proposals seeking to fund activities and publications suggested by Defendants. APF also assisted in marketing projects for Defendants.

189. The intimate relationship between APF and Defendants demonstrates APF's clear lack of independence in its finances, management, and mission, and its willingness to allow Defendants to control its activities and messages strongly indicates that each Defendant that provided it with funding was able to exercise editorial control over its publications.

190. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links—financial and otherwise—between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately,"[62] proving the degree of its dependence upon Defendants' financing as well as their control over it.

ii. THE AMERICAN ACADEMY OF PAIN MEDICINE

191. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and sponsored and hosted CMEs essential to Defendants' deceptive marketing scheme.

192. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

193. The conferences sponsored by AAPM heavily emphasized CME sessions on

[62] William Heisel, USC Annenberg Center for Health Journalism, Antidote: Investigating Untold Health Stories, *Journalists Bag a Big One: The American Pain Foundation*, https://www.centerforhealthjournalism.org/blogs/2012/05/14/journalists-bag-big-one-american-pain-foundation (accessed September 19, 2017).

opioids: 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs, Dr. Fine, Dr. Portenoy, and Dr. Lynn Webster, who was elected president of AAPM while under a DEA investigation. Another past AAPM president, KOL Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are … small and can be managed."[63]

194. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

E. DEFENDANTS ACTED THROUGH KOLs AND FRONT GROUPS TO CREATE, PROMOTE, AND CONTROL UNBRANDED MARKETING

195. Like the tobacco companies that engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the industry-funded and directed Front Groups and KOLs to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superior efficacy of opioids to treat chronic pain.

196. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Despite knowing that this information was false and misleading, Defendants, Front Groups, and KOLs disseminated these misrepresentations nationwide, including to Beaufort County prescribers and patients.

197. One Vehicle for Defendants' marketing collaboration was the Pain Care Forum

[63] *Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine*, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829 (accessed September 19, 2017).

("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

198. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue), doctors and nurses in the field of pain care, professional organizations (including AAPM, APS, and American Society of Pain Educators); patient advocacy groups (including APF and American Chronic Pain Association ("ACPA")), and other like-minded organizations, almost all of which received substantial funding from Defendants.

199. For example, PCF developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.[64] This was critical because a REMS that went too far in narrowing the uses or benefits or in highlighting the risks of chronic opioid therapy would undermine Defendants' marketing efforts and adversely affect profits. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, rather than undermine, their deceptive marketing of opioids for chronic pain treatment.

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[64] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

F. DEFENDANTS' MISREPRESENTATIONS

200. Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace and disseminated to the public, including to prescribers, patients, and payors in Beaufort County. These promotional messages were intended to and did encourage patients to request, doctors to prescribe, and payors to pay for chronic opioid therapy.

201. Recognizing that doctors are the gatekeepers for controlling access to prescription drugs, not surprisingly, Defendants focused the bulk of their marketing efforts and multi-million dollar budgets on the professional medical community. As controlled substances with significant regulatory barriers limiting access, Defendants knew doctors would not prescribe opioids to patients with common chronic pain complaints unless doctors were convinced that opioids had real benefits and minimal risks. Accordingly, Defendants concealed from prescribers, patients, and the public that evidence in support of their promotional claims was inconclusive, non-existent, or unavailable. Instead, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, Beaufort County doctors began prescribing opioids on a long-term basis to treat chronic pain, a treatment choice that most (if not all) never would have considered prior to Defendants' campaign.

202. Drug company marketing materially impacts doctors' prescribing behavior.[65] Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their products, and they are influenced by their patients' requests for particular drugs and payors' willingness to pay for those drugs. Evidence shows that doctors who would otherwise not have prescribed opioids were, in fact, induced by Defendants' deceptive marketing to prescribe opioids for chronic pain as a result of Defendants' deceptive marketing.

203. Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, 88% of the practitioner respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities.[66] These results are the direct consequence of Defendants' fraudulent marketing campaign.

204. As described in detail below, Defendants:

i. Misrepresented the truth about how opioids lead to addiction;

ii. Misrepresented that opioids improve function;

iii. Misrepresented that addiction risk of opioids can be managed;

[65] See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); *see also* A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

[66] Research Letter, Prescription Drug Abuse: A National Survey of Primary Care Physicians, JAMA Intern. Med. (Dec. 8, 2014), E1-E3.

iv. Misled doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"

v. Falsely claimed that withdrawal is simply managed;

vi. Misrepresented that increased doses pose no significant additional risks to patients; and

vii. Falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

205. Defendants' misrepresentations were aimed at doctors, patients, and payors.

206. Underlying each of Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Defendants' collective effort to hide from the medical community the fact that there exist no adequate and well-controlled studies of opioid use longer than 12 weeks.[67]

a. *Defendants, Acting Individually and Collectively, Misrepresented the Truth About How Use of Opioids Leads to Addiction.*

207. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. Through their well-funded, comprehensive, and aggressive marketing efforts, Defendants succeeded in changing the perceptions of many physicians, patients, and healthcare payors and persuaded them that opioid addiction rates are low and that addiction is unlikely to develop when opioids are prescribed for chronic pain. As both an intended and foreseeable result, doctors in Beaufort County prescribed more opioids to more patients, thereby enriching Defendants.

208. Each of the Defendants claimed that the potential for addiction from its drugs was relatively small or non-existent, despite the complete lack of supporting scientific evidence.

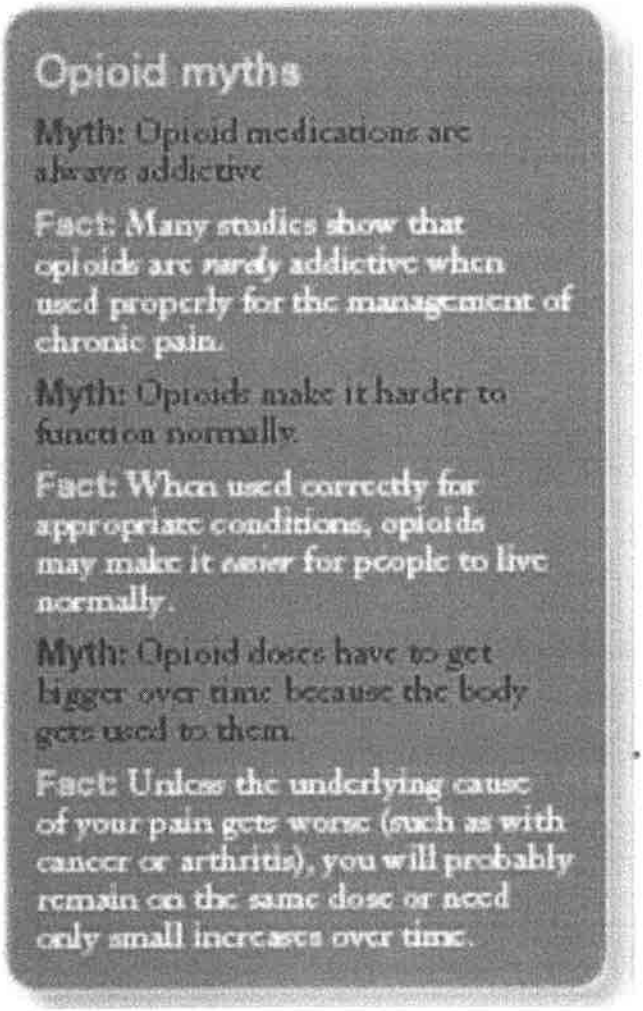
[67] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing,* Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).

209. For example, Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which fraudulently claimed that addiction is rare and limited to extreme cases of unauthorized dose escalations, opioid prescription fraud, or theft.

210. Similarly, Endo sponsored a website, www.painknowledge.com, through APF, which falsely claimed that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that the long-term use of opioids presents minimal risk of addiction to patients if the opioids are properly prescribed by a physician.

211. Additionally, Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that patients prescribed opioids for *genuine* pain will not become addicted, a claim which is both unsupported and known to be false.

212. Likewise, Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF, which, as set forth in the excerpt below, described the fact that opioids are addictive as a "myth" and falsely asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."



Although the term "rarely" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that the long-term use of opioids presents minimal risk of addiction to patients if the opioids are properly prescribed by a physician, which is untrue. The guide states as a "fact" that "[m]any studies" show that opioids are *rarely* addictive when used for chronic pain. In fact, no such studies exist.

213. For another example, Purdue sponsored and Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught, "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation

suggests that the rate is so low as to be immaterial.

214. For yet another example, Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids would become addicted.[68] This publication also falsely asserted that pain is undertreated due to "misconceptions about opioid addiction."

215. In addition, in the 1990s, Purdue amplified the pro-opioid message with promotional videos featuring Dr. Portnoy and other doctors in which it was claimed, "the likelihood that treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[69]

216. As yet another example from the industry, Actavis's strategy and pattern of deceptive marketing is similarly evident in its internal training materials. A sales education module titled "Kadian Learning System" trained Actavis's sales representatives on the marketing messages described above—including deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal—that sales representatives were directed and required, in turn, to pass on to prescribers, nationally and in Beaufort County.

217. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Complaint, starting with the promise of improved function. The sales training module instructed Actavis sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," when, in reality, available data demonstrate that patients on chronic opioid therapy are *less likely* to participate in daily activities like work.

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[68] In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain.

[69] Excerpts from one such video, including the statement quoted here, may be viewed at http://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (accessed September 19, 2017).

218. Actavis sales training materials also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted several important facts about the increased risks of high dose opioids. First, Actavis taught its sales representatives, who would pass the message on to doctors, that pain patients would not develop tolerance to opioids, which would have necessitated increasing doses: "Although tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with [chronic pain]." Second, Actavis instructed its sales personnel that opioid "[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose." Actavis failed to inform doctors, via its sales representatives, of the greater risks associated with opioids at high doses.

219. The Kadian Learning System module dates from July 2010, but Actavis sales representatives were passing deceptive messages on to prescribers before that date. A July 2010 "Dear Doctor" letter issued by the FDA indicated that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]." Certain risks that the FDA noted were misrepresented include the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid agonists have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion." The FDA also took issue with an advertisement for misrepresenting Kadian's ability to help patients "live with less pain and get adequate rest with less medication," when the supporting study did not represent "substantial evidence or substantial clinical experience."

220. Finally, the internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the

AAPM/APS Guidelines with doctors during detailing visits. These guidelines deceptively concluded that the risk of addiction is manageable for patients, regardless of past abuse histories, amongst other deceptive statements as described above.

221. Rather than honestly disclose the risk of addiction, Defendants attempted to portray those who were concerned about addiction as callously denying treatment to suffering patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables: they suggested that doctors who *failed* to treat their patients' chronic pains with opioids were failing their patients and risking professional discipline, while doctors who prescribed long-term opioid therapy were following the compassionate (and professionally less risky) approach. Defendants claimed that "exaggerated" concerns about the risk of addiction resulted in patients' pain being under-treated while opioids were over-regulated and under-prescribed.

222. For example, the Treatment Options guide funded by Purdue and Cephalon claims that "[d]espite the great benefits of opioids, they are often underused." And, the APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, laments that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include . . . misconceptions about opioid addiction."[70]

223. *Let's Talk Pain*, sponsored by APF, AAPM and Janssen, likewise warns that "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program goes on to say, "[b]ecause of the potential for abusive and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their

[70] This claim also appeared in a 2009 publication by APF, *A Reporter's Guide*.

patients.... This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States."

b. *Defendants, Acting Individually and Collectively, Misrepresented that Opioids Improve Function*

224. Defendants produced, sponsored, or controlled materials with the expectation that, by instructing patients and prescribers that opioids would improve patient functioning and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy for patients in the belief that lack of improvement in quality of life could be alleviated by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

225. Although opioids may initially improve patients' function by providing pain relief in the short term, no controlled studies of the use of opioids beyond 12 weeks has ever shown that opioids improve patients' function in the long-term. On the contrary, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[71] Despite this lack of evidence of improved function, and the existence of evidence to the contrary, Defendants consistently promoted opioids as capable of improving patients' function and quality of life without disclosing the lack of evidence for this claim.

226. Claims that opioids improve patients' function are misleading because such claims have "not been demonstrated by substantial evidence or substantial clinical experience."[72]

227. The Federation of State Medical Boards' Responsible Opioid Prescribing (2007),

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[71] Jeffrey Dersh, et al., Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders, 33(20) Spine 2219-27 (Sept. 15,2008).

[72] Letter from Thomas W. Abrams, RPh., MBA, Dir., Div. of Marketing, Advertising and Communications to Brian A. Markison, Chairman, *King Pharmaceuticals*, Re: NDA21-260 (March 24, 2008).

sponsored by drug companies including Cephalon, Endo, and Purdue, deceptively taught that relief of pain in itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."

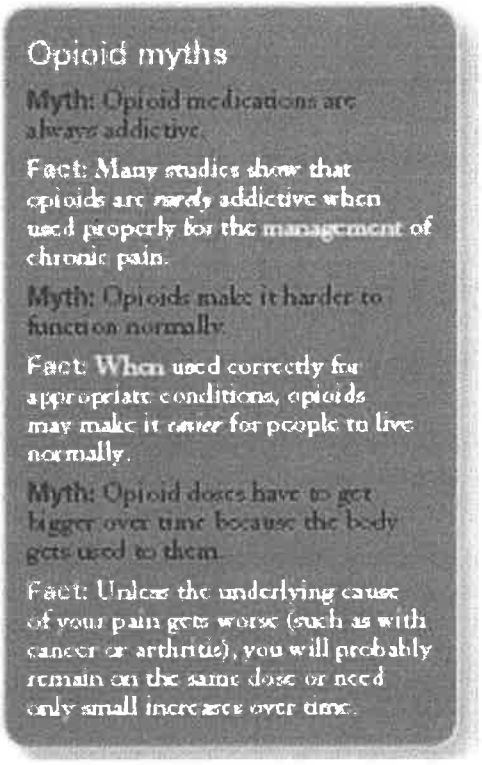
228. Cephalon and Purdue sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." The Treatment Options guide notes that non-steroidal anti-inflammatory drugs (e.g., aspirin or ibuprofen) have greater risks with prolonged duration of use, but there was no similar warning for opioids. The APF distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report, and it is currently still available online.

229. Through the APF, Endo sponsored a website, painknowledge.com, which claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life as well as "improved function" as benefits of opioid therapy.

230. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA, and APF. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

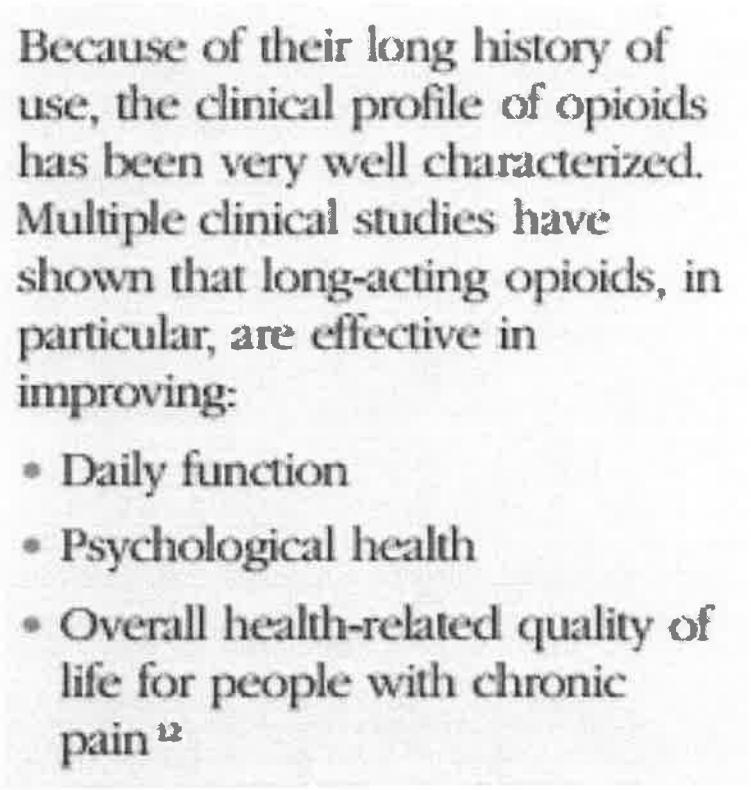
231. As set forth in the excerpt below, the guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative support for the claim that does not exist. The targeting of older adults also

ignored heightened opioid risks in this population.



232. Janssen sponsored a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and American Society for Pain Management Nursing, whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative despite the lack of statistical support.

233. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients," with the implication these studies presented claims of long-term improvement.


Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for people with chronic pain [12]

The sole reference for the functional improvement claim (1) noted the absence of long-term studies and (2) actually stated, "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."

234. Purdue sponsored and Janssen provided grants to APP to distribute *Exit Wounds* to veterans, which taught that opioid medications "increase your level of functioning."

c. ***Defendants, Acting Individually and Collectively, Misrepresented that Addiction Risk can be Effectively Managed***

235. Defendants each continue to maintain to this day that most patients can safely take opioids long-term for chronic pain relief without becoming addicted. Presumably to explain to doctors the high incidence of patient opioid addiction, Defendants have recently acknowledged that some patients could become addicted, but that doctors can effectively avoid or manage that risk by using screening tools or questionnaires. These tools, they claim, identify

those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) and allow doctors to more closely monitor patients at greater risk of addiction.

236. There are three fundamental flaws in Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that the addiction risk screening tools currently available are reliable, effective, capable of being applied correctly and consistently, or invulnerable to patient manipulation. Second, there is no reliable scientific evidence that high-risk or addicted patients identified through the screening tools can take opioids long-term without triggering or worsening addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients identified through such screening tools as "low risk" can take opioids long-term without significant danger of addiction.

237. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools with which to do so. An Evidence Report by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[73] Furthermore, attempts to treat high-risk patients, like those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine

[73] The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain, Agency for Healthcare Res. & Quality (Sept. 19, 2014).

drug screening tests are not proven to work in the real world, even when the most well-intentioned doctors were misled to employ them.[74]

238. Defendants' misrepresentations regarding the risk of addiction from chronic opioid therapy were particularly dangerous because they were aimed at general practitioners or family doctors (collectively, "GPs"), who treat many chronic conditions but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. One study conducted by pharmacy benefits manager Express Scripts concluded, after analyzing 2011–2012 narcotic prescription data of the type regularly used by Defendants to market their drugs, that only 385 of the more than half million prescribers of opioids during that time period were identified as pain specialists.[75]

239. In materials they produced, sponsored, or distributed, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting on opioid therapy for chronic pain.

240. Defendants' marketing scheme contemplated a "heads we win; tails we win" outcome: patients deemed low risk were to receive opioids on a long-term basis without enhanced monitoring, while patients deemed high risk were also to receive opioids on a long-term basis but with more frequent visits, tests and monitoring—with those added visits, tests, and monitoring to be paid for or reimbursed by payors, including Plaintiff. This, of course, led to a

[74] M. Von Korff, et al., *Long-term opioid therapy reconsidered*, 15595, Annals Internal Med. 325 (Sept. 2011); L. Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment*, 15 Pain Physician S1 (2012).
[75] Express Scripts Lab, A Nation in Pain: Focusing on U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain (December 2014).

"heads you lose; tails you lose" outcome for patients (all of whom are subjected to an unacceptable risk of addition) and for payors, including Plaintiff.

241. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which falsely reassured patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."

242. Endo paid for a 2007 supplement available for continuing education credit in the Journal of Family Practice written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* created by KOL Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

243. Purdue sponsored a 2011 webinar taught by Dr. Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

d. *Defendants, Acting Individually and Collectively, Misled Physicians, Patients, and Payors Through the Use of the Term "Pseudoaddiction"*

244. Defendants instructed patients and prescribers that signs of addiction are actually the product of untreated pain, thereby causing doctors to prescribe ever more opioids despite signs that the patient was addicted. The word "pseudoaddiction" was concocted by KOL Dr. J. David Haddox, who later went to work for Purdue, and was popularized in opioid therapy for chronic pain by KOL Dr. Portenoy, who consulted for Defendants Cephalon, Endo, Janssen,

and Purdue. Much of the same language appears in other Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction," as if patients could not experience both.

245. In the materials they produced, sponsored, or controlled, Defendants misrepresented that the concept of "pseudoaddiction" is substantiated by scientific evidence.

246. Cephalon and Purdue sponsored the Federation of State Medical Boards' Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are in fact signs of genuine addiction, are all really signs of "pseudoaddiction."

247. Purdue did not mention that the author who concocted both the word and the phenomenon it purported to describe became a Purdue Vice President, nor did Purdue disclose the lack of scientific evidence to support the existence of "pseudoaddiction."[76]

248. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, PartnersAgainstPain.com, in 2005, and upon information and belief circulated this pamphlet after 2007. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but rather was indicative of "pseudoaddiction" caused by untreated pain. It also stated, "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is untreated . . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

[76] J. David Haddox & David E. Weissman, *Opioid pseudoaddiction – an iatrogenic syndrome*, 36(3) Pain 363 (Mar. 1989).

e. *Defendants, Acting Individually and Collectively, Claimed Withdrawal is Simply Managed*

249. In an effort to underplay the risk and impact of addiction, Defendants claimed that, while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed, if and when pain relief is no longer desired, by gradually tapering patients' dosage to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—an adverse effect that also makes it less likely that patients will be able to stop using drugs.

250. In materials Defendants produced, sponsored, and/or controlled, Defendants made misrepresentations to persuade doctors and patients that withdrawal from their opioids was not a problem and they should not be hesitant about prescribing or using opioids. These claims were not supported by scientific evidence.

251. A CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering a patient's opioid dose by 10% to 20% per day for ten days. This claim was misleading because withdrawal in a patient already physically dependent would take longer than ten days—when it is even successful at all.[77]

252. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

f. *Defendants, Acting Individually and Collectively, Misrepresented that Increased Doses Pose no Significant Additional Risks*

[77] See Jane Ballantyne, *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain with Opioids*, 21(5) Pain Clinical Updates (Dec. 2013).

253. Defendants claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses.

254. In materials Defendants produced, sponsored, or controlled, Defendants instructed patients and prescribers that patients could remain on the same dose indefinitely, assuaging doctors' concerns about starting patients on opioids or increasing their doses during treatment, or about discontinuing their patients' treatment as doses escalated. These claims were not supported by scientific evidence.

255. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claimed that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide taught that opioids differ from NSAIDs in that they have "no ceiling dose" and are, therefore, the most appropriate treatment for severe pain. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose when the true figure was closer to 3,200 at the time.[78]

256. Cephalon sponsored a CME written by KOL Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

[78] Robert E. Tarone, et al., Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

257. Endo sponsored a website, *painknowledge.com*, through APF, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

258. Endo also distributed a patient education pamphlet edited by KOL Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was published on Endo's website. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. … You won't 'run out' of pain relief."

259. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinite ones, but did not disclose the risks from high-dose opioids. This publication is still available online.

260. Purdue sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME was edited by KOL Dr. Portenoy, and, among others, taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

g. *Defendants, Acting Individually and Collectively, Deceptively Omitted or Minimized the Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment*

261. In materials they produced, sponsored, or controlled, Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs. None of these claims was supported by scientific evidence.

262. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[79] hormonal dysfunction;[80] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[81] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety. Post-traumatic stress disorder and anxiety also often accompany chronic pain symptoms.[82]

263. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are, therefore, the most appropriate treatment for severe pain. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose when the figure is closer to 3,200.[83] *Treatment Options* also warned that risks of NSAIDS increase if "taken for more than a period of months," but provided no corresponding warning about opioids.

264. Endo sponsored a website, painknowledge.com, through APF, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects that omitted significant adverse effects including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

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[79] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing,* Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).
[80] H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001).
[81] Bernhard M. Kuschel, The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study, Eur. J. Pub. H. (July 31, 2014).
[82] Karen H. Seal, Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan, 307(9) J. Am. Med. Ass'n 940- 47 (2012).
[83] Robert E. Tarone, et al., Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

265. Janssen and Purdue sponsored and Endo provided grants to APF to distribute *Exit Wounds (*2009), which omits warnings of the risk of potentially fatal interactions between opioids and certain anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder.

266. As a result of Defendants' campaign of deception, promoting opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[84]

G. DEFENDANTS' PROMOTION OF THEIR BRANDED DRUGS WAS ALSO DECEPTIVE

267. While Defendants worked in concert to expand the market for opioids generally, they also worked to maximize their individual shares of that market. Each Defendant promoted opioids for chronic pain through sales representatives (which Defendants called "detailers" to deemphasize their primary sales role) and small group speaker programs to reach out to individual prescribers nationwide and in Beaufort County. By establishing close relationships with doctors, Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to allay individual prescribers'

[84] M. Daubresse, *et al.*, *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010,* 51*(10)* Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits and referrals to physical therapy remained steady. *See also* J. Mafi, *et al.*, *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

concerns about prescribing opioids for chronic pain.

268. Defendants developed sophisticated methods for selecting doctors for sales visits based on the doctors' prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health, a healthcare data collection, management, and analytics corporation. This data allows Defendants to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above throughout the United States, including to doctors in Beaufort County.

H. DEFENDANTS KNEW THAT THEIR MARKETING OF CHRONIC OPIOID THERAPY WAS FALSE, UNFOUNDED, AND DANGEROUS AND WOULD HARM PLAINTIFF AND ITS RESIDENTS

269. Defendants made, promoted, and profited from their misrepresentations—individually and collectively—knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading.

270. For example, Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct.

271. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths, all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers.

272. Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and payors to pay for their opioids for chronic pain.

273. When they began their deceptive marketing practices, Defendants recklessly

disregarded the harm that their practices were likely to cause. As their scheme was implemented, and as reasonably foreseeable harm began to occur, Defendants were well aware that it was occurring. Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon—overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CME programs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to, and carefully monitored, government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

274. To provide a particularly egregious example, Insys engaged in an extended campaign of blatant fraud and deception to market its sublingual fentanyl medication Subsys for chronic pain.

275. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain."[85] The indication also specifies that "SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." Subsys is contraindicated for, among other ailments, the "[m]anagement of acute or postoperative pain including headache/migraine and dental pain." It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg dosage strengths.

[85] The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer."

276. Insys's revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, Insys reported revenues of $331 million. Of that total, $329.5 million was derived from sales of Subsys. The majority of Insys's sales of Subsys are through wholesalers including Defendants AmerisourceBergen, McKesson, and Cardinal Health. In 2015, those wholesalers respectively comprised 20%, 17%, and 14% of Insys's total gross sales of Subsys.

277. On information and belief, Subsys was prescribed to and/or consumed by Beaufort County residents.

278. According to Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing and chief medical officer of the Phoenix House Foundation, fentanyl products are "'the most potent and dangerous opioids on the market.'"[86]

279. The dangers associated with Subsys are reflected by its extremely limited and specific indication. Subsys is approved solely for breakthrough pain ("BTP") in cancer patients already receiving opioids for persistent cancer-related pain.

280. Despite Subsys's limited indication and the potent danger associated with fentanyl, Insys falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain, neck pain, and other off-label pain conditions.[87] Moreover, as of June 2012, Insys defined BTP in cancer patients to include mild pain: a "flare of mild-to-severe pain in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by KOL Dr. Portenoy.[88] Insys trained and instructed its sales representatives to use the false definition of

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[86] Dina Gusovsky, *The pain killer: A drug company putting profits above patients, CNBC*, http://www.cnbc.com/2015/11/04/thedeadly-drug-appeal-of-insys-pharmaceuticals.html, (published Nov. 5, 2015, 10:13 AM).

[87] In the Matter of Insys Therapeutics, Inc., Notice of Unlawful Trade Practices and Proposed Resolution, https://www.documentcloud.org/documents/2195731-insysdoj.html, (dated July 10, 2015).

[88] Russell K. Portenoy & Neil A. Hagen, *Breakthrough pain: Definition, prevalence and characteristics*, 41(3) Pain 273-81 (July 1990). (featured in the 1990 issue of Pain, the article actually defined breakthrough pain as "a transitory increase in pain to greater than moderate intensity (that is, to an intensity of 'severe' or 'excruciating') . . . on a baseline pain of moderate intensity or less.")

breakthrough pain and specifically to use a core visual aid, including the improper definition, whenever they detailed Subsys to a healthcare provider's office.

281. According to a 2014 article in The New York Times, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others written by other specialists including dentists and podiatrists.[89]

282. For example, Dealer Defendant Thiyagarajah is a physiatrist in South Carolina, distributing Subsys for nonmedical purposes within Greenville County and Anderson County, ultimately causing diversion across South Carolina and in Beaufort County.

283. On December 8, 2016, several former Insys executives were arrested and indicted for conspiring to bribe practitioners in numerous states, many of whom operated pain clinics, in order to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers of Subsys prescriptions for patients, most of who were not diagnosed with cancer.[90]

284. The indictment alleged that the former executives conspired to mislead and defraud health insurance providers, who were reluctant to approve payment for Subsys when it was prescribed for patients without cancer. The former executives established a "reimbursement unit" at Insys, which was dedicated to assisting physicians by obtaining prior authorization for prescribing Subsys directly from insurers and pharmacy benefit managers. Insys's reimbursement unit employees were told to inform agents of insurers and pharmacy benefit

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[89] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. Times, https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html?action=click&contentCollection=Business%20Day&region=Footer&module=MoreInSection&pgtype=Blogs&_r=2, (published May 13, 2014).

[90] Press Release, U.S. Attorney's Office for the District of Massachusetts, Pharmaceutical Executives Charged in Racketeering Scheme (Dec. 8, 2016), https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeeringscheme (hereinafter "Insys Indictment Press Release")); Ex. 95 (United States v. Babich, et al., No. 1:16-cr-10343-ADB, Dkt. No. 1 (D. Mass. Dec. 6, 2016), https://www.justice.gov/usao-ma/press-release/file/916681/download (hereinafter "Insys Indictment")).

managers that they were calling "from" or that they were "with" the doctor's office, or that they were calling "on behalf of" the doctor.

285. The executive defendants named in the indictment include Insys's former CEO and president, former vice president of sales, former national director of sales, former vice president of managed markets, and several former regional sales directors. The charges include alleged violations of the federal Anti-Kickback Law, the federal Racketeer Influenced and Corrupt Organizations ("RICO") statute, and conspiracy to commit wire and mail fraud, as well as allegations of bribery and defrauding insurers.

286. The indictment details a coordinated, centralized scheme by Insys to illegally drive profits. The company defrauded insurers from a call center at corporate headquarters where Insys employees, acting at the direction of Insys's former CEO and vice president of managed markets, disguised their identity and the location of their employer and lied about patient diagnoses, the type of pain being treated, and the patient's course of treatment with other medication.

287. Insys targeted and bribed practitioners in a number of ways. Insys bribed Subsys prescribers through strategic hires, employing sales representatives and other employees at practitioners' behest and with the expectation that such hires would provide inroads with key practitioners. Further, the indictment alleges that Insys bribed practitioners through a sham speakers' bureau that was purportedly intended to increase brand awareness using peer-to-peer educational lunches and dinners. Insys engaged in this behavior within South Carolina and within Beaufort County.

288. Additionally, the indictment alleges that in June 2012, former executives began using in-person meetings, telephone calls, and texts to inform Insys sales representatives that the

key to sales was using the speakers' bureau to pay practitioners to prescribe Subsys. As one of the company's vice presidents for sales texted one of his sales representatives about potential physicians for the speakers' bureau: "[t]hey do not need to be good speakers, they need to write a lot of [Subsys prescriptions]." The former Insys executives actively recruited physicians known to have questionable prescribing habits for these speakers' bureaus.[91]

289. The indictment also alleges that speakers' bureaus were often just social gatherings at high-priced restaurants involving neither education nor presentations. Frequently, they involved repeat attendees, including physicians not licensed to prescribe Subsys. Many of the speakers' bureaus had no attendees; sales representatives were instructed to falsely list names of attendees and their signatures on Insys's sign-in sheets.

290. Insys made thousands of payments to physicians nationwide, including to Beaufort physicians in South Carolina and within Beaufort County, for participating on these speakers' bureaus and for other services. One such example is Defendant Thiyagarajah, who received over $190,000 between 2014 and 2015 alone for speaking, training, education, and consulting with Insys.

291. Insys' top sales representative, Brett Szymanski, earned up to $250,000 per quarter covering one doctor in Michigan. The physician entered into a plea agreement on November 8, 2016. As set forth in the indictment, at one national speakers' bureau in or about 2014, Insys' then-vice president of sales stated:

> **"These [doctors] will tell you all the time, well, I've only got like eight patients with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic]. Doc, I'm not talking about any of those patients. I don't want any of those patients. That's, that's small potatoes. That's nothing. That's not what I'm here doing. I'm here selling [unintelligible] for the breakthrough pain. If I can successfully sell you the**

[91] Insys Indictment Press Release, supra n.85

> **[unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. That leaves me with at least five hundred patients that can go on this drug."**[92]

292. The indictment also alleges that, when agents of insurers or pharmacy benefit managers asked if a patient was being treated for BTP in cancer patients, Insys' reimbursement unit employees were instructed to answer using a written script, sometimes called "the spiel": "'The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable).'"[93]

293. The indictment further alleges that Insys's former executives also tracked and internally circulated the number of planned and completed speakers' bureau events for each speaker, as well as the number of Subsys prescriptions each speaker wrote, the percentage of such prescriptions compared to those written for Subsys' competitor drugs, the total amount of honoraria paid to each speaker, and, for a period of time, an explicit calculation of the ratio of return on investment for each speaker. When a speaker did not write what Insys considered to be an appropriate number of Subsys prescriptions, the number of future events for which that speaker would be paid would be reduced unless and until he or she wrote more Subsys prescriptions.

294. In a press release issued when the indictment was announced, the Massachusetts U.S. Attorney, Carmen M. Ortiz, stated: "'I hope that today's charges send a clear message that

[92] Insys Indictment, supra n.85, at 15.
[93] *Id.* at 44

we will continue to attack the opioid epidemic from all angles, whether it is corporate greed or street level dealing.'"[94]

295. In the same press release, the FBI Special Agent in Charge of the Boston Field Division, Harold H. Shaw, linked the allegations to the national opioid epidemic:

> **"As alleged, top executives of Insys Therapeutics, Inc. paid kickbacks and committed fraud to sell a highly potent and addictive opioid that can lead to abuse and life threatening respiratory depression . . . . In doing so, they contributed to the growing opioid epidemic and placed profit before patient safety. These indictments reflect the steadfast commitment of the FBI and our law enforcement partners to confront the opioid epidemic impacting our communities, while bringing to justice those who seek to profit from fraud or other criminal acts."[95]**

296. In the press release, the Special Agent in Charge at the Defense Criminal Investigative Service in the Northeast Field Office, Craig Rupert, focused specifically on the effect the criminal activities had on members of the military: "Causing the unnecessary use of opioids by current and retired U.S. military service members shows disregard for their health and disrespect for their service to our country . . . ."[96]

I. DEFENDANTS FRAUDULENTY CONCEALED THEIR MISREPRESENTATIONS

297. Defendants took steps to avoid detection of, and to fraudulently conceal, their deceptive marketing and conspiratorial behavior.

298. Defendants disguised their own roles in the deceptive marketing by funding and working through Front Groups purporting to be patient advocacy and professional organizations and through paid KOLs. Defendants purposefully hid behind the assumed credibility of the front organizations and KOLs and relied on them to vouch for the accuracy and integrity of Defendants' false and misleading statements about opioid use for chronic pain. While

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[94] Insys Indictment Press Release, *Supra* n.85
[95] *Id.*
[96] *Id.*

Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. Defendants exerted their considerable influence on these purportedly "educational" or "scientific" materials in private emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies.

299. In addition to hiding their own role in generating the deceptive content, Defendants manipulated their promotional materials and the scientific literature to make it appear these items were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of materials they cited and offered them as evidence for propositions the materials did not support. The true lack of support for Defendants' deceptive messages was not apparent to the vast majority of the medical professionals who relied upon them in making treatment decisions. The false and misleading nature of Defendants' marketing was not known to, nor could it reasonably have been discovered by, Plaintiff or its residents.

300. Defendants also concealed their participation by extensively using the public relations companies they hired to work with Front Groups to produce and disseminate deceptive materials.

301. Defendants concealed from the medical community, patients, and healthcare payors facts sufficient to arouse suspicion of the existence of claims that Plaintiff now asserts. Plaintiff did not discover the existence and scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through the public statements, marketing, and advertising, Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

J. THE DISTRIBUTOR DEFENDANTS INTENTIONALLY FAILED TO TAKE ANY ACTION TO STOP THE MISUSE OF OPIOIDS, IN VIOLATION OF STATE AND

FEDERAL LAWS AND REGULATIONS

302. The Distributor Defendants purchased opioids from manufacturers, such as the named Manufacturer Defendants herein, and sold them to pharmacies throughout Beaufort County.

303. The Distributor Defendants played an integral role in the chain of opioids being distributed throughout Beaufort County.

304. The South Carolina Poisons, Drugs, and Other Controlled Dangerous Substances Act, S.C. Code Ann., §§ 44-53-10 *et seq.*, incorporates 21 CFR § 1301.74(b) at S.C. Code Ann. § 44-53-340.

305. Federal regulations, incorporated as stated above, similarly impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

306. "Suspicious orders" include orders of an unusual size, orders of unusual frequency, or orders deviating substantially from a normal pattern. *See* 21 CFR 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether an order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an

order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

307. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

308. These prescription drugs are regulated for the purpose of providing a "closed" system **intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[97]

309. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[98]

310. As the DEA advised the Distributor Defendants in a letter to them dated September

[97] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[98] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/ about/mission/ (last visited Aug. 21, 2017).

27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[99]

311. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.[100]

312. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, ***in addition*** to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[101] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[102] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[103]

313. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[104] This letter reminds the Distributor Defendants of their statutory and regulatory duties

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[99] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

[100] *See* Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

[101] Rannazzisi Letter, *supra*, at 2.

[102] *Id.* at 1.

[103] *Id.* at 2.

[104] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin.,

to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[105] The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.
>
> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as

U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

[105] *Id.*

> suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[106]

314. Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[107]

315. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[108]

316. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders.

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[106] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), *Supra*.

[107] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), *Supra*.

[108] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *2 [hereinafter Brief of HDMA].

317. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[109]

318. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Beaufort County and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Beaufort County.

319. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[110]

320. The sheer volume of prescription opioids distributed to pharmacies in Beaufort County, and/or to pharmacies from which the Distributor Defendants knew the opioids were

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[109] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

[110] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

likely to be diverted into Beaufort County, is excessive for the medical need of the community and facially suspicious; some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[111]

321. Additionally, the Distributor Defendants' grossly negligent distribution to pharmacies outside the County also caused an influx of illicit diversion of opioids within Beaufort County.

322. The Distributor Defendants failed to report "suspicious orders" originating from Beaufort County, or which the Distributor Defendants knew were likely to be diverted to Beaufort County, to the federal and state authorities, including the DEA and/or the State Board of Pharmacy.

323. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders that deviated substantially from a normal pattern and/or orders of unusual frequency in Beaufort County, and/or in areas from which the Distributor Defendants could foreseeably anticipate that opioids were likely to be diverted to Beaufort County.

324. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates originating from Beaufort County, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Beaufort County.

325. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

326. The Distributor Defendants breached their duty to "design and operate a system to

[111] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities, including the South Carolina Department of Health, of suspicious orders when discovered, in violation of their duties under federal and state law.

327. The Distributor Defendants failed to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific, and industrial channels.[112]

328. The federal and state laws at issue here are public safety laws.

329. The unlawful conduct by the Distributor Defendants is purposeful and intentional.

330. The Distributor Defendants refuse to abide by the duties imposed on them by federal and state law, which are required to legally acquire and maintain a license to distribute prescription opiates.

331. The Distributor Defendants acted with actual malice and have consciously disregarded the rights and safety of other persons, and said actions have caused substantial harm.

332. The Distributor Defendants' repeated shipments of suspicious orders over an extended period, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

333. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

334. The Distributor Defendants have refused to recognize any duty beyond *reporting*

[112] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

suspicious orders. For example, in the *Masters Pharmaceuticals* case, the HDMA, a trade association run by the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

i. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[113]

ii. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."[114]

iii. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[115]

iv. The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[116]

v. The Associations alleged (inaccurately) that "DEA's regulations [sensibly impose] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[117]

vi. Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the

[113] Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *4–5.
[114] Brief for HDMA and NACDS, *supra*, 2016 WL 1321983 at *8.
[115] *Id.* at *14
[116] *Id.* at *22
[117] *Id.* at *24-25

> necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[118]

335. The positions taken by the trade groups are emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of these dangerous drugs.[119]

336. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharms., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). In that case, the D.C. Circuit Court upheld the revocation of Masters Pharmaceuticals Inc.'s license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id.* at 212. Masters Pharmaceuticals was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstances prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

337. Recently, wholesale distributor McKesson was forced to admit to a breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017), it "did not identify or report to

[118] *Id.* at *26

[119] *See* Brief of HDMA, *supra*, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

[the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[120]

338. Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[121] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers," including the McKesson Distribution Centers located in twelve different locations, any of which could have foreseeably caused the diversion of opioids into Beaufort County.[122] Due to these violations, McKesson agreed that its authority to distribute controlled substances from these twelve facilities would be partially suspended.[123]

339. As punishment for its wrongdoing, McKesson agreed to pay a $150 million fine and suspend the sale of controlled substances from distribution centers in several states.[124]

340. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the

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[120] Department of Justice, Administrative Memorandum of Agreement, January 17, 2017, https://www.justice.gov/opa/press-release/file/928476/download, (accessed October 27, 2017).
[121] Department of Justice, *Administrative Memorandum of Agreement* at 4, *Supra*.
[122] *Id.*
[123] *Id.* at 6.
[124] *Id.* at 8.

DEA.[125] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed in its obligations.[126] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[127]

341. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws.

342. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[128] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[129] These actions include the following:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen

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[125] *Id.* at 4.
[126] *Id.*
[127] *Id.*
[128] U.S. Dep't of Justice, Evaluation and Inspections Div., Office of the Inspector Gen., *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf, (accessed October 27, 2017).
[129] *Id.*

entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against facilities it owned in South Carolina, Florida, New York, and Washington.

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

343. Defendant Rite Aid had a duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates originating from Beaufort County, South Carolina.

344. In January 2009, Rite Aid agreed that it failed to comply by these requirements after a pattern of failing to meet its duty was discovered by the Department of Justice.[130] Rite Aid ultimately agreed to pay $5 million for breaching its duty to report any "suspicious orders" of prescription opiates to the DEA and/or the South Carolina Board of Pharmacy between 2006 to the present.

345. Rite Aid similarly breached its duty by failing to report any suspicious orders of prescription opiates originating in Beaufort County and South Carolina between 2006 to the present. Rite Aid's failure contributed to the excessive non-medical opioid prescriptions filled in Beaufort County from 2006 until present. Rite Aid, operating within South Carolina and

[130] Department of Justice, *Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act*, https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations (Published January 12, 2009).

Beaufort County, must have neglected its duties, given that retail opioid prescriptions dispensed were 65 per 100 persons in Beaufort County in 2016, meaning there were enough opioids prescribed within the County for every man, woman, and child to receive a handful.

346. Additionally, the allegations below detailing the exploits of the South Carolina Dealer Defendants show instances of suspicious orders that should have been detected and reported by distributors like Rite Aid. Suspicious orders continue currently and are made by the Dealer Defendants as detailed below, and have been left unreported by Rite Aid.

347. Rite Aid's failures are a direct and proximate cause of the diversion of prescription opiates for nonmedical purposes in Beaufort County and across South Carolina, causing opioid abuse, addiction, and deaths in Beaufort County and across the state.

348. Defendant Smith had a duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates originating from Beaufort County, South Carolina.

349. Smith breached this duty when it failed to report any "suspicious orders" of prescription opiates originating from Beaufort County to the DEA and/or the South Carolina Board of Pharmacy between 2006 to present. Smith's failure contributed to the excessive non-medical opioid prescriptions filled in Beaufort County from 2006 until present. Smith, operating within South Carolina and Beaufort County, must have neglected its duties, given that retail opioid prescriptions dispensed were 65 per 100 persons in Beaufort County in 2016, meaning there were enough opioids prescribed within the County for every man, woman, and child to receive a handful.

350. Additionally, the allegations below detailing the exploits of the South Carolina Dealer Defendants show instances of suspicious orders that should have been detected and

reported by distributors like Smith. Suspicious orders continue currently and are made by the Dealer Defendants as detailed below, left unreported by Smith.

351. Smith's failures are a direct and proximate cause of the diversion of prescription opiates for nonmedical purposes in Beaufort County and across South Carolina, causing opioid abuse, addiction, and deaths in Beaufort County and across the state.

352. Defendant CVS has paid over $40 million in fines as the result of opioid prescription investigations by the DEA and the United States Department of Justice. Yet, CVS continues to dispense opioids in quantities significantly higher than medically necessary to residents of Beaufort County. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the Department of Justice that its stores and pharmacists had been violating their duties under the Controlled Substances Act, by filling prescriptions with no legitimate medical purpose.[131] CVS has settled similar cases with Florida, Oklahoma, Massachusetts, New Hampshire, and Rhode Island for filling forged prescriptions for addictive painkillers and filling prescriptions with no legitimate medical purpose.

353. Operating within South Carolina and Beaufort County, the Distributor Defendants must have neglected their duties given that 65 retail prescriptions were dispensed per 100 residents of Beaufort County in 2016.[132] This total allows for each man, woman, and child within the County to have ingested a pill. The Distributor Defendants failed to detect and report actions by the Dealer Defendants and others, which caused the opioid epidemic plaguing Beaufort County.

354. The data which reveals and/or confirms the identity of each wrongful opioid

[131] Press Release, Drug Enf't Admin., DEA Reaches $8 million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances (Feb. 12, 2016.) https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled (Accessed February 20, 2018).

[132] Centers for Disease Control, *U.S. County Prescribing Rates*, https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html (2016)

distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). All potential Distributor Defendants conceal and prevent their discovery of necessary information to confirm their identities. Neither the DEA[133] nor the wholesale distributors[134] will voluntarily disclose the data necessary to identify with specificity the transactions which will for the evidentiary basis for naming all Distributor Defendants responsible. All of the Distributor Defendants named in this lawsuit have been identified by publicly disclosed ARCOS data as distributors that have contributed to flooding the market with opioid medications, causing a wave of addiction.[135]

355. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any

[133] *See* Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

[134] *See* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

[135] Kanawha County Commission v. Rite Aid of Maryland, Inc., et al., Case 2:17-cv-01666, (Document 1) (filed 3/9/2017); Cabell County Commission v. Amerisourcebergen Drug Corporation, et al, Case 3:17-cv-01665 (Document 1) (filed 3/9/17).

violations of law before a suspension order can be issued.[136]

356. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

357. For example, a Cardinal Health executive claimed that Cardinal Health uses "advanced analytics" to monitor its supply chain and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[137] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results in favor of profits.

358. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[138] Again, given

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[136] Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aca2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.61697ec67e05; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-aa05d3c21f7cf_story.html?utm_term=.014176059151; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, http://www.100daysinappalachia.com/2017/02/22/dea-agent-no-leadership-west-virginia-amid-flood-pain-pills/, Charleston Gazette-Mail, Feb. 18, 2017, (all accessed October 27, 2017).

[137] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10c79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.6d9936e87c93, (accessed October 27, 2017).

[138] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.0b845f727e2c, (accessed October 27, 2017).

McKesson's historical conduct, this statement is either false or the company ignored outputs of its monitoring program.

359. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

360. Meanwhile, the opioid epidemic rages unabated in the nation, in the State of South Carolina, and in Beaufort County.

361. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility. Despite the charges, fines, and penalties brought against the Distributor Defendants in the past, they continued to fail to report suspicious orders and/or prevent the flow of prescription opioids, including into Beaufort County and elsewhere, harming Plaintiff.

362. Between the years in question, including 2007 through 2016, the Distributor Defendants shipped millions of doses of highly addictive controlled opioid pain killers into Beaufort County and elsewhere, causing diversion of opioid pain killers within Beaufort County.

363. Many of these orders should have been stopped or, at the very least, investigated as potential suspicious orders.

364. The sheer volume of the increase in opioid pain medications, including

oxycodone, being distributed to retailers should have put the Distributor Defendants on notice to investigate and report such orders.

365. The Distributor Defendants delivered an excessive and unreasonable amount of opioid pain medications to retailers in Beaufort County and elsewhere.

366. Upon information and belief, the Distributor Defendants did not refuse to ship or supply any opioid medications to any pharmacy in Beaufort County from 2007 to the present.

367. The Defendant Distributors knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of Beaufort County.

368. The Defendant Distributors also paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications within Beaufort County.

369. The Distributor Defendants made substantial profits from the opioids sold in Beaufort County and elsewhere.

370. By the actions and inactions described above, the Distributor Defendants showed a reckless disregard for the safety of the residents of Beaufort County.

371. By the actions and inactions described above, the Distributor Defendants caused great harm to Beaufort County.

372. The Distributor Defendants have abandoned their duties imposed under federal and state law; taken advantage of a lack of DEA law enforcement; and abused the privilege of distributing controlled substances in the State of South Carolina and in Beaufort County.

K. VARIOUS DOCTORS, INCLUDING THE DEALER DEFENDANTS, RECKLESSLY CAUSED THE DIVERSION OF PRESCRIPTION OPIOIDS THROUGHOUT

SOUTH CAROLINA AND BEAUFORT COUNTY

373. The Manufacturer and Distributor Defendants' negligent, deceptive, reckless, and/or willful and wanton actions, as described in detail throughout this Complaint, caused and created the market for the illegal diversion of opioids for nonmedical purposes by the various Dealer Defendants.

374. For example, one doctor, Dr. Hershline, operated an office in Hilton Head, South Carolina that functioned as a "Pill Mill" by vastly overprescribing opioid medications without a legitimate medical purpose.

375. Dr. Hershline wrote thousands of opioid prescriptions without the appropriate physical examination or medical need to profit from this activity, causing diversion of opioid medications throughout South Carolina and Beaufort County.[139]

376. Dr. Hershline conspired with others to distribute and dispense outside the usual course and scope of professional practice and not for a legitimate medical purpose, oxycodone and methadone.

377. Another doctor, Dr. D. Vincent Rhodes, participated in a prescription drug ring, prescribing prescription opioids without the appropriate physical examination or medical need to profit from this activity, causing diversion of over ten thousand opioid medications across South Carolina and within Beaufort County.[140]

378. Dr. Hershline and Dr. Rhodes had many patients that traveled from all of the State of South Carolina including Beaufort County, for the primary purpose of obtaining prescription opioids.

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[139] Davis, Kelly, *Doctor sentenced to 41 months in prison*, http://www.thestate.com/news/local/crime/article14379230.html (accessed December 21, 2017).

[140] Moody, Erin, *Beaufort doctor sentenced to 1 year for role in cocaine, prescription drug ring*, http://www.islandpacket.com/news/local/community/beaufort-news/article33613854.html (accessed December 21, 2017).

379. Subsequent to Dr. Rhodes' and Dr. Hershline's actions, other healthcare providers in South Carolina wrote thousands of opioid prescriptions without the appropriate physical examination or medical need to profit from this activity, causing diversion of opioid medications throughout South Carolina and Beaufort County.

380. Upon information and belief, John Doe 1, John Doe 2, and John Doe 3 conspired with others to distribute and dispense opioids outside the usual course and scope of professional practice and not for a medical purpose.

381. Upon information and belief, John Doe 1, John Doe 2, and John Doe 3 facilitated a prescription drug ring, prescribing prescription opioids without the appropriate physical examination or medical need to profit from this activity, causing diversion of thousands of opioid medications within Beaufort County and across South Carolina.

382. Upon information and belief, repeatedly, over the course of years, John Doe 1, John Doe 2, and John Doe 3 participated in the illegal diversion of opioids.

383. Upon information and belief, repeatedly, over the course of years, John Doe 1 separately prescribed 90 immediate release oxycodone (aka "Roxycontin" or "Roxies") at a time to an individual resident of the Town of Bluffton, in Beaufort County, South Carolina (herein "Illegal Drug Distributor I") and his girlfriend (herein "Illegal Drug Distributor II"), also a Beaufort County resident, for nonmedical purposes and for resale of Roxycontin on the black market.

384. Upon information and belief, the relationship between Illegal Drug Distributor I and II was obvious; they regularly traveled to and from John Doe 1 and Clinic 1, together, sought the same prescriptions and received the same prescriptions and quantity of prescriptions from John Doe 1 and on Clinic 1's premises.

385. Upon information and belief, after obtaining the Roxycontin, Illegal Drug Distributor II would give her pills to Illegal Drug Distributor I for the purpose of resale on the black market.

386. Upon information and belief, Illegal Drug Distributor I and other illegal drug distributors sold Roxycontin and other opiates obtained through John Doe 1 to multiple individuals addicted to narcotic drugs because of the negligent and deceptive acts of the Manufacturer and Distributor Defendants throughout South Carolina and Beaufort County. Upon information and belief, individuals from several other counties, including Beaufort County, came to Beaufort County to obtain opioids for sale in the black market by John Doe 1.

387. Upon information and belief, among individuals that became addicted due to the Manufacturer and Distributor Defendant actions was Witness 1, a resident of Beaufort County, who for years purchased Roxycontin placed into the marketplace by John Doe 1 from Illegal Drug Distributor I.

388. Upon information and belief, monthly, after obtaining Roxycontin from John Doe 1, Illegal Drug Distributors I and II traveled to the Atlanta, Georgia area and obtained additional Roxycontin from a different physician for the purpose of distributing on the black market.

389. Upon information and belief, John Doe 1 failed to exercise the nonmedical, administrative, ministerial, and routine duty owed to Plaintiff and the public of preventing the diversion of opioids into the black market as he wrote prescriptions for nonmedical purposes outside of a bona fide practitioner-patient relationship, in violation of S.C. Code Ann. §§ 44-53-360(c) and 44-53-360(h), and failed to conform with the record-keeping requirements of S.C. Code Ann. §§ 44-53-340 and 44-53-390(a)(4).

390. Upon information and belief, John Doe 1 failed to exercise the nonmedical,

administrative, ministerial, and routine duty of determining whether Illegal Drug Distributors I and II obtained Roxycontin from another physician between visits in violation of S.C. Code Ann. § 44-53-1645.

391. Upon information and belief, Clinic 1, the premises where John Doe 1 operated, failed to implement reasonable protocols and procedures to prevent the diversion of opioids into the black market across South Carolina and in Beaufort County in violation of S.C. Code Ann. §§ 44-53-360(c), 44-53-360(h), 44-53-340, and 44-53-390(a)(4).

392. Upon information and belief, Clinic 1 failed to exercise the nonmedical, administrative, ministerial, and routine duty owed to Plaintiff and the public of determining whether Illegal Drug Distributors I and II obtained Roxycontin from another physician between visits in violation of S.C. Code Ann. § 44-53-1645.

393. Upon information and belief, John Doe 1 and Clinic 1 routinely and repeatedly failed to exercise the nonmedical, administrative, ministerial, and routine duty owed to Plaintiff and the public of preventing the diversion of opioids into the black market (and in fact did place opioids directly into the black market), resulting in thousands of opioids being sold on the street and abused in Beaufort County, South Carolina.

394. Placing opioids directly into the hands of an illegal distributor on the black market, outside of a bona fide practitioner-patient relationship, does not constitute the practice of medicine. Defendants John Doe 1, John Doe 2, John Doe 3, Clinic 1, Clinic 2, Clinic 3, and Clinic 4 all engaged in this activity. John Doe 2 operates Clinic 2 and Clinic 3. John Doe 3 operates Clinic 4.

395. Upon information and belief, in 2013, Witness 1 experienced a family trauma leading to depression.

396. Upon information and belief, in 2013, Witness 1 was prescribed Lortab (a combination of acetaminophen and hydrocodone) by a physician for treatment purposes. Hydrocodone is a narcotic, synthetic "opioid" sold and distributed by the Manufacturer and Distributor Defendants.

397. Upon information and belief, after being prescribed Lortab, Witness 1, became addicted, and began recreational use of Roxycontin.

398. Upon information and belief, in 2015, Witness 1 overdosed on Roxycontin obtained from John Doe 1 and Illegal Drug Distributors I and II, nearly dying. He was transported by EMS, lost work, wages, and received care from County responders and providers.

399. After his first overdose, upon information and belief, Witness 1 went to an inpatient treatment center in Georgia. He missed work, lost wages, and his rehabilitation was supported by South Carolina residents' tax dollars.

400. Upon information and belief, in the years of 2014 through 2015, Witness 1 saw John Doe 4, a supervising physician at Clinic 5,[141] in Bluffton, South Carolina. John Doe 4 and Clinic 5 repeatedly provided Witness 1 with "suboxone" strips for nonmedical purposes. Suboxone is a synthetic opioid designed for use by individuals *not taking other opioids* to facilitate recovery from opioid addiction. However, suboxone is prone for abuse by actively using addicts both to get high and to thwart effects of withdrawal between injections or other use of illicit opioids.

401. At all times during his visits to John Doe 4 and Clinic 5, Witness 1 was still abusing opioids and other drugs. Witness 1 disclosed his ongoing illicit drug use to John Doe 4 multiple times and failed urine screens, yet John Doe 4 continued to supply Witness 1 with

[141] Clinic 4 is a clinic operated by a Nurse Practitioner and not a physician, but which cannot operated under law without an associated physician overseeing the Registered Nurse Practitioner's activities.

suboxone at a high rate. John Doe 4 failed in the duty to Plaintiff and the public to exercise nonmedical, administrative, ministerial, and routine protocols to keep appropriate records and knowingly dispensed suboxone for nonmedical purposes, in violation of S.C. Code Ann. §§ 44-53-360(h), 44-53-340, and 44-53-390(a)(4).

402. During one visit, John Doe 4 admitted to Witness 1 that they needed to cut back on the number of suboxone strips given to Witness 1 because regulatory agencies were "watching [John Doe 4]." Thereafter, John Doe 4 gave Witness 1 no more than seven suboxone strips per visit.

403. Upon information and belief, during a different visit, John Doe 4 lied to a family member of Witness 1 who was concerned that Witness 1 was still abusing opioids. When Witness 1 failed a drug screen requested by the concerned family member, John Doe 4 misrepresented that Witness 1 had passed the drug screen and that he was not taking any opioids illicitly.

404. John Doe 4's acts described herein are for nonmedical purposes. John Doe 4's acts are fraudulent, deceptive, and constitute a knowing violation of the law. John Doe 4 held a duty to the County and the public to refrain from such acts.

405. Upon information and belief, John Doe 4's conduct to Witness 1 was routine and repeated, leading to thousands of fraudulently obtained drugs entering into commerce in Beaufort County and South Carolina.

406. Upon information and belief, John Doe 4 and Clinic 5 derived a financial benefit from their fraudulent, deceptive, and reckless acts.

407. Upon information and belief, during this time, Witness 1 continued to purchase and was taking Roxycontin placed into commerce by John Doe 1.

408. Upon information and belief, instead of treating Witness 1, John Doe 4 facilitated and maintained his addiction through artifice and fraud while deriving a financial benefit therefrom.

409. Upon information and belief, Clinic 5 failed to implement reasonable protocols and procedures to prevent the recklessness and fraud employed by John Doe 4 and to prevent the diversion of opioids into the black market in Beaufort County and South Carolina.

410. Upon information and belief, Clinic 5 owed a duty to the Plaintiff and the Public to exercise nonmedical, administrative, ministerial and routine protocols to keep appropriate records and knowingly dispensed suboxone for nonmedical purposes, in violation of S.C. Code Ann. §§ 44-53-360(h), 44-53-340, and 44-53-390(a)(4).

411. Upon information and belief, Clinic 5 derived a financial benefit from John Doe 4's deceptive acts.

412. Upon information and belief, Clinic 5 did nothing to prevent or stop John Doe 4's deceptive acts.

413. Upon information and belief, John Doe 4 repeated the deceptive acts, and Clinic 5 allowed and condoned the same.

414. Upon information and belief, in late February 2016, approximately a week after Witness 1 was released from in-patient rehabilitation in Greenwood, South Carolina, Witness 1 relapsed and overdosed a second time, nearly dying again from Roxycontin received from John Doe 1, Clinic 1 and Illegal Drug Distributors I and II. Witness 1 was transported again to a healthcare facility by EMS, law enforcement personnel were forced to respond, and Witness 1 lost work, wages, and earnings.

415. Dealer Defendant Aathirayen Thiyagarajah, acting in concert with Dealer

Defendant Spine and Pain Consultants, PA, prescribed Subsys and other opioids off-label within Greenville and Anderson Counties, for nonmedical purposes not indicated by the FDA. These Defendants deliberately addicted patients, trapping them in a vicious cycle and ruining their lives, for the sake of profits while receiving kick-backs and expensive travel from Insys.[142] They operated as *de facto* drug dealers in white coats, greatly contributing to the diversion of opioids and wave of addiction across South Carolina.

416. Defendants Thiyagarajah and Spine and Pain Consultants, PA knew that Subsys was approved by the FDA solely for use in cancer patients, already on opioids, experiencing BTP at the end of their life. Despite this knowledge, these Defendants knowingly and recklessly deceived chronic pain patients into believing Subsys was safe for long term use.

417. As an example, one South Carolina woman reports that she was convinced by these Defendants to take Subsys for chronic abdominal pain from Crohn's disease. She received the drug for years and experienced blackouts, uncontrolled diarrhea, and vomiting. Defendants Thiyagarajah and Spine and Pain Consultants, PA consistently reassured her that it was not the Subsys causing these problems. The South Carolina woman became addicted and, she states, these Defendants ruined her life. At one point, she asked Defendant Thiyagarajah to take her off Subsys, but he angrily insisted that it was Subsys or nothing.[143] Defendants Thiyagarajah and Spine and Pain Consultants, PA knew that if they stopped prescribing Subsys to this South Carolina woman and others, they would stop receiving the lavish kickbacks and trips from Insys.

418. Defendants Thiyagarajah and Spine and Pain Consultants, PA received 50 times more payments from Insys than other similarly situated peers for speaking, training, education,

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[142] Kessler, Aaron, et al., *CNN Exclusive: The more opioids doctors prescribe, the more money they make*, https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html, (updated March 12, 2018, 8:45AM)

[143] *Id.*

and consulting on behalf of Insys.[144]

419. Defendants Thiyagarajah and Spine and Pain Consultants, PA issued opioid prescriptions for nonmedical purposes in addition to Subsys, issuing nearly double the amount of opioid prescriptions *per patient* than other similarly situated physicians. At one point in 2015, a DEA investigation concluded that these defendants were prescribing buprenorphine for nonmedical purposes as well, in violation of state and federal laws.[145]

420. Defendants Thiyagarajah and Spine and Pain Consultants, PA have victimized as many as 12,000 people from across South Carolina.[146]

421. The actions of Defendants Thiyagarajah and Spine and Pain Consultants, PA greatly contributed to the diversion of opioids and the wave of addiction across South Carolina and within Beaufort County.

422. Defendants Thiyagarajah and Spine and Pain Consultants, PA failed to exercise the nonmedical, administrative, ministerial, and routine duty owed to Plaintiff and the public of preventing the diversion of opioids into the black market. Defendant Thiyagarajah wrote prescriptions for nonmedical purposes outside of a bona fide practitioner-patient relationship, in violation of S.C. Code Ann. §§ 44-53-360(c) and 44-53-360(h), and failed to conform with the record-keeping requirements of S.C. Code Ann. §§ 44-53-340 and 44-53-390(a)(4).

423. Defendants Thiyagarajah and Spine and Pain Consultants, PA failed to exercise the nonmedical, administrative, ministerial, and routine duty of determining whether patients obtained opioids from other physicians in violation of S.C. Code Ann. § 44-53-1645.

424. Dealer Defendant Mackie Walker recently pleaded guilty to being the key figure

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[144] Kessler, Aaron, *CNN Exclusive,* Supra.
[145] *Id.*
[146] Patient Fusion, https://www.patientfusion.com/doctor/aathiraven-thiyagarajah-mbbs-md-59869 (accessed March 13, 2018).

in a state-wide opioid diversion ring. Defendant Walker routinely wrote prescriptions for nonmedical purposes to cause and feed opioid addiction statewide. He actively engaged in the diversion of opioid medications (even paying the bond of his "dealers" after they were arrested), ultimately diverting at least 51,000 pills into the black market across South Carolina.[147]

425. The actions of Defendant Walker greatly contributed to the diversion of opioids and the wave of addiction across South Carolina and within Beaufort County.

426. Defendant Walker failed to exercise the nonmedical, administrative, ministerial, and routine duty owed to Plaintiff and the public of preventing the diversion of opioids into the black market as he wrote prescriptions for nonmedical purposes outside of a bona fide practitioner-patient relationship, in violation of S.C. Code Ann. §§ 44-53-360(c) and 44-53-360(h), and failed to conform with the record-keeping requirements of S.C. Code Ann. §§ 44-53-340 and 44-53-390(a)(4).

427. Defendant Walker failed to exercise the nonmedical, administrative, ministerial, and routine duty of determining whether patients obtained opioids from other physicians in violation of S.C. Code Ann. § 44-53-1645.

428. Upon information and belief, scores of other individuals whose addiction to opioids were caused by the deceptive and negligent acts of the Manufacturer and Distributor defendants overdosed and/or became incapacitated and/or unemployed and/or otherwise participated in antisocial behavior in Beaufort County and South Carolina after taking opioids placed into commerce by Dr. Hershline, Dr. Rhodes, and the Dealer Defendants.

429. Upon information and belief, the Dealer Defendants all financially benefited and continue to derive financial benefit from the acts described herein.

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[147] Monk, John, *Judge gives SC doctor, turned drug kingpin, 15-year prison sentence,* http://www.thestate.com/news/local/crime/article210201374.html (published May 1, 2018, accessed May 23, 2018).

430. Dr. Hershline, Dr. Rhodes, and the Dealer Defendants' practices resulted in the additional cost for (among other things) substance abuse treatment, toxicology assessment, emergency hospitalization care, lost tax revenue, economic loss, and foster care to Beaufort County and other South Carolina Counties, costs which continue to be incurred to date.

L. DESPITE KNOWING THE EXCESSIVE RISK OF ADDICTION, MISUSE, AND ABUSE TO THE COUNTY AND SOUTH CAROLINA, THE SALES REPRESENTATIVE DEFENDANTS MISREPRESENTED THE SAFETY OF OPIOIDS FOR TREATING CHRONIC PAIN TO PHYSICIANS

431. At all relevant times, Defendant Sullivan was a Purdue sales detail person and/or district manager in South Carolina and was responsible for the promotion, advertisement, sale, marketing, and/or distribution of OxyContin in South Carolina, including to those who prescribed and/or consumed the drug in the County and across the State.

432. From 1992 until 2017, Defendant Sullivan directed, ratified, trained, supervised, and managed all Purdue sales personnel within the State of South Carolina, including within Beaufort County, to utilize all of the deceptive sales tactics and marketing materials developed by Purdue and described in detail throughout this Complaint.

433. At all relevant times, Defendant Taylor was a Purdue sales detail person, Analgesia Specialist for the Southeast Region, and/or district field trainer in South Carolina and was responsible for the promotion, advertisement, sale, marketing, and/or distribution of OxyContin in South Carolina, including to those who prescribed and/or consumed the drug in the County and across the State.

434. From 1998 until 2015, Defendant Taylor directed, ratified, trained, supervised, and managed all Purdue sales personnel within the State of South Carolina, including within Beaufort County, to utilize all of the deceptive sales tactics and marketing materials developed by Purdue and described in detail throughout this Complaint.

435. At all relevant times, Defendant Varnadore was a Purdue sales detail person and/or district manager in South Carolina and was responsible for the promotion, advertisement, sale, marketing, and/or distribution of OxyContin in South Carolina, including to those who prescribed and/or consumed the drug in the County and across the State.

436. From 1998 until the present, Defendant Varnadore directed, ratified, trained, supervised, and managed all Purdue sales personnel within the state of South Carolina, including within Beaufort County, to utilize all of the deceptive sales tactics and marketing materials developed by Purdue and described in detail throughout this Complaint.

437. At all relevant times, Defendant Kitchin was a Purdue sales detail person and/or district manager in South Carolina and was responsible for the promotion, advertisement, sale, marketing, and/or distribution of OxyContin in South Carolina, including to those who prescribed and/or consumed the drug in the County and across the State.

438. From 1990 until 2009, Defendant Kitchin directed, ratified, trained, supervised, and managed all Purdue sales personnel within the state of South Carolina, including within Beaufort County, to utilize all of the deceptive sales tactics and marketing materials developed by Purdue and described in detail throughout this Complaint.

439. The Sales Representative Defendants owed a duty of care to Plaintiff in the marketing, advertising, sale, and promotion of Purdue's highly dangerous, addictive, and abuse-prone OxyContin.

440. The Sales Representative Defendants owed Plaintiff a duty to use reasonable care because, *inter alia*, it was foreseeable, and in fact known to the Sales Representative Defendants that their conduct would result in injuries and damages to and within the County.

441. The Sales Representative Defendants were aware that OxyContin posed an

excessive risk of harm to South Carolina and Beaufort County, including its risks relating to addiction, abuse, and diversion, all of which were occurring and ongoing in the County and across the State.

442. The Sales Representative Defendants had actual knowledge that the safety, efficacy, addictiveness, abuse, and diversion potential of OxyContin was negligently and recklessly marketed, advertised, promoted, and sold.

443. The Sales Representative Defendants knew that OxyContin was highly susceptible to addiction, misuse, abuse and/or diversion and the risk for each of these factors bore a direct relationship to the amount and volume of opioids being prescribed within South Carolina and Beaufort County, and in fact that OxyContin was being misused, abused and diverted across the country, including across South Carolina and within Beaufort County. For example:

i. The Sales Representative Defendants witnessed first-hand the devastating effects of OxyContin in and around South Carolina and Beaufort County and knew or should have known that OxyContin was being regularly abused, misused, and diverted;

ii. The Sales Representative Defendants were informed, alerted, questioned, and/or made aware by prescribers throughout South Carolina and Beaufort county that OxyContin was being abused, misused, and diverted and, on at least one occasion, that a family member of a prescriber within South Carolina had overdosed on OxyContin in South Carolina;

iii. Memos from sales representatives within South Carolina and/or surrounding areas were distributed and/or discussed between Purdue employees and representatives, including the Sales Representative Defendants, which contained "red flags" about OxyContin and detailed reports from prescribers that their patients were misusing, abusing, and diverting OxyContin; and

iv. The Sales Representative Defendants were made aware of medical literature and studies that concluded OxyContin was more attractive to drug abusers compared to other prescription

pain pills.

444. The Sales Representative Defendants knew or should have known that OxyContin was unreasonably dangerous and highly addictive and highly susceptible to abuse and diversion, yet they knowingly and negligently provided false and/or misleading information to prescribers within South Carolina, including prescribers in Beaufort County, concerning the risk of addiction, abuse, and diversion of OxyContin and false and/or misleading information about the drug's relative safety.

445. The Sales Representative Defendants also represented to prescribers throughout South Carolina and Beaufort County that OxyContin was safe for use in chronic pain patients.

446. Upon information and belief, the Sales Representative Defendants purposefully or negligently caused communities across South Carolina, including Beaufort County, to be flooded with highly dangerous and addictive opioids, even though they knew that these drugs were being misused, abused, and diverted.

447. The Sales Representative Defendants knew or should have known that opioid addiction, abuse, and/or diversion and their related consequences would injure and damage communities across the country, including Beaufort County. Applicable South Carolina laws, and the industry standards applicable to the manufacture, advertising, labeling, distribution, and sale of opioid drugs exist to control addiction, abuse, and/or diversion associated with these dangerous drugs. Moreover, the Sales Representative Defendants were aware of their actions and the effects their actions were having in communities across the country, including Beaufort County. The escalating amounts of highly addictive drugs being prescribed and distributed, and the sheer volume of these prescription opioids, further alerted the Sales Representative

Defendants that over-prescription and addiction were fueling increased addiction, abuse, and diversion, and that legitimate medical purposes were not being served.

448. Despite this knowledge, and in direct disregard of the known and foreseeable harms to Plaintiff, the Sales Representative Defendants negligently and recklessly breached their duties to Plaintiff by, for example:

i. Negligently and recklessly marketing, advertising, and promoting OxyContin in Beaufort County and surrounding areas;

ii. Misrepresenting and misstating the addiction, abuse, and/or diversion potential of OxyContin;

iii. Overstating the benefits of chronic OxyContin therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;

iv. Downplaying and/or obscuring OxyContin's serious risks and adverse outcomes, including the risk of addiction, abuse, diversion, overdose, and death;

v. Overstating OxyContin's superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;

vi. Mischaracterizing the difficulty of withdrawal from OxyContin and the prevalence of withdrawal symptoms;

vii. Marketing OxyContin for indications and benefits that were not supported by substantial evidence; and

viii. Misrepresenting to healthcare providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of misuse or abuse.

449. At all times material herein, the Sales Representative Defendants willingly and knowingly participated in Defendant Purdue's deceptive and misleading marketing scheme, were aware of its existence, and did nothing about it. The Sales Representative Defendants promoted, perpetuated, and furthered Purdue's deceptive and misleading marketing campaign by knowingly

and falsely promoting and marketing OxyContin as less addictive and less subject to abuse and diversion than other opioids.

450. The Sales Representative Defendants had a financial incentive to knowingly provide false information to prescribers within South Carolina and Beaufort County, and their pay and continued employment depended on the volume of sales and prescriptions written within their District and surrounding areas. Upon information and belief, the Sales Representative Defendants received lucrative bonuses, trips, and other items of value as a result of their success in pushing OxyContin into the communities of South Carolina.

451. The Sales Representative Defendants further trained their sales representatives to employ various tactics to evade physicians' questions regarding OxyContin's addictiveness and likelihood of addiction, misuse, abuse, and/or diversion. The Sales Representative Defendants also trained their sales force to misrepresent and conceal facts relating to OxyContin's safety. By way of example, at least one of the Sales Representative Defendants trained her sales representatives to be "Audible Ready" when questioned about opioid street-abuse and to misrepresent OxyContin's addictiveness and likelihood of abuse, diversion, and misuse.

452. Upon information and belief, after receiving reports from prescribers and medical professionals that OxyContin was being abused and diverted in and around Beaufort County, the Sales Representative Defendants instructed their sales team to ride out the controversy, ignore abuse reports, and "sell through it."[148]

[148] Keefer, Patrick, The New Yorker, *The Family that Built and Empire of Pain: The Sackler Dynasty's Ruthless Marketing of Painkillers has Generated Billions of Dollars – and Millions of Addicts*, https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain (published October 30, 2017).

453. Upon information and belief, the Sales Representative Defendants would instruct their sales force to target doctors that data indicated were overprescribing opioid medications, instead of reporting them to authorities.[149]

454. The Sales Representative Defendants knew their marketing and the information they and their sales team provided was a substantial factor in physicians, patients, and others prescribing, purchasing or using opioids in South Carolina and Beaufort County.

455. At all times material herein, prescribers and consumers within South Carolina and in Beaufort County relied upon the representations made by the Sales Representative Defendants and their sales teams, and their reliance was justified.

456. As stated herein, the Sales Representative Defendants' breaches of duties bear a causal connection with and/or proximately resulted in the harm and damages to Plaintiff.

457. As a direct and proximate result of the Purdue Sales Representative Defendants' actions, Plaintiff has suffered and continues to suffer injury and damages, including but not limited to, incurring costs related to diagnosis, treatment, and cure of abuse and/or addiction and costs related to having to provide necessary resources for care, treatment facilities, law enforcement, and other expenses associated with opioid addiction, abuse, and diversion.

FIRST CAUSE OF ACTION
SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT – DECEPTIVE AND UNFAIR ACTS AND PRACTICES
(ALL DEFENDANTS)

458. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

[149] *Id.*

459. At all times relevant to this Complaint, Defendants were engaged in the trade or commerce of manufacturing, marketing, selling, and/or distributing prescription opioid pain medications. For twenty years, Defendants have been the leading force in the prescription opioid market, both nationwide and in South Carolina.

460. By engaging in the acts and practices alleged herein, Defendants made or caused to be made to South Carolina consumers, directly or indirectly, explicitly or by implication, misrepresentations that, reasonably interpreted, are material, false, and likely to mislead.

461. Defendants violated the South Carolina Unfair Trade Practices Act, S.C. Code Ann. §§ 39-5-10 *et seq.* ("SCUTPA"), because they engaged in deceptive acts or practices in the conduct of business, trade or commerce within South Carolina and Beaufort County, including:

i. The Manufacturer Defendants' and Sales Representative Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;

ii. The Manufacturer Defendants' and Sales Representative Defendants' creating, sponsoring, and/or assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

iii. The Manufacturer Defendants' and Sales Representative Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;

iv. The Manufacturer Defendants' and Sales Representative Defendants' distributing brochures to doctors, patients, and the public that included deceptive statements concerning the indicators of possible opioid abuse, indicating that screening tools effectively prevent addiction, and representing that abuse-deterrent opioids reduce tampering and abuse;

v. The Manufacturer Defendants' and Sales Representative Defendants' sponsoring, directly distributing, and/or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

vi. The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of South Carolina and Federal law;

vii. The Manufacturer Defendants' and Sales Representative Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

viii. The Manufacturer Defendants' and Sales Representative Defendants' developing and/or disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

ix. The Manufacturer Defendants' and Sales Representative Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

x. The Manufacturer Defendants' and Sales Representative Defendants' creating, endorsing, and/or supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

xi. The Manufacturer Defendants' and Sales Representative Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

xii. The Manufacturer Defendants' and Sales Representative

Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

xiii. The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating South Carolina and Federal law by not reporting these doctors instead; and,

xiv. The Dealer Defendants' falsely representing to patients and the public that they lawfully prescribed opioids for medical treatment when their practice of prescribing was for nonmedical purposes, violated laws, and was done for the sole purpose of making profit.

462. Defendants knew at the time that they made their misrepresentations and omissions that (1) they were false and (2) they had the tendency to influence the consumer choices of Plaintiff and its residents.

463. Defendants designed their misrepresentations and omissions for the purpose of influencing Plaintiff and its residents into relying upon them.

464. Defendants' acts and practices as alleged in this Complaint had a capacity or tendency to deceive. When considered from the perspective of a reasonable consumer, these acts or practices were likely to mislead South Carolina consumers in Beaufort County.

465. The Manufacturer Defendants' and Sales Representative Defendants' consistent, repeated, deceptive representations that their opioids had properties unsupported by medical literature did in fact deceive Plaintiff and its residents, causing them to both prescribe and consume opioids for the treatment of chronic pain conditions and suffer from addiction when they otherwise would not.

466. The Distributor and Dealer Defendants' consistent, repeated, deceptive representations that they kept records as required by law and were prescribing opioids for legitimate medical purposes did in fact deceive Plaintiff and its residents, resulting in widespread addiction that otherwise would not have occurred.

467. Given the incredible resources the Manufacturer Defendants and Sales Representative Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions, as stated above.

468. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied on the Distributor Defendants to uphold their legal requirements and not commit intentional, material omissions to law enforcement for the sake of profits.

469. Given the efforts taken by the Dealer Defendants to obtain medical licenses, operate businesses, and present the outward appearance of legitimate medical practitioners, Plaintiff and its residents reasonably relied on the Dealer Defendants' representations that they were providing medical treatment and not engaging in unlawful, nonmedical dissemination of opioids to addicts for the sole purpose of profit.

470. Plaintiff and its residents have been injured by reason of Defendants' violations of SCUTPA. Plaintiff's injuries were directly caused by Defendants' deceptive behavior, resulting in lost productivity and tax revenue, as well as increased expenditures on public healthcare services, law enforcement, the justice system, and child and family services. The health and wellbeing of the citizens of Beaufort County, including those who have abused or will abuse

prescription opioids, or were led to their addiction by the acts of Defendants, are matters of vital and legitimate concern to Plaintiff and its citizens.

471. Defendants' conduct was willful or knowing under S.C. Code § 39-5-140.

472. Defendants' acts or practices alleged herein constitute unfair or deceptive acts or practices in violation of SCUTPA and have proximately caused and continue to cause an ascertainable loss of money and property to Plaintiff.

473. Every deceptive, unfair, and/or misrepresentative act by Defendants constitutes a separate and distinct violation of S.C. Code § 39-5-20, capable of repetition and affecting and impacting the public's interest. Defendants' acts in violation of SCUTPA are patently offensive to public policy, unethical, immoral, and oppressive.

474. Plaintiff is informed and believes that it is entitled to actual damages in an amount to be determined by the jury, and that Plaintiff is entitled to an award of treble damages under SCUTPA and an award of reasonable attorney's fees.

SECOND CAUSE OF ACTION
FRAUD
(AGAINST ALL DEFENDANTS)

475. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

476. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:

i. The Manufacturer Defendants' and Sales Representative Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into

using addictive opioids;

ii. The Manufacturer Defendants' and Sales Representative Defendants' creating, sponsoring, and/or assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

iii. The Manufacturer Defendants' and Sales Representative Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;

iv. The Manufacturer Defendants' and Sales Representative Defendants' distributing brochures to doctors, patients, and the public that included deceptive statements concerning the indicators of possible opioid abuse, indicating that screening tools effectively prevent addiction, and representing that abuse-deterrent opioids reduce tampering and abuse;

v. The Manufacturer Defendants' and Sales Representative Defendants' sponsoring, directly distributing, and/or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

vi. The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of South Carolina and Federal law;

vii. The Manufacturer Defendants' and Sales Representative Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

viii. The Manufacturer Defendants' and Sales Representative Defendants' developing and/or disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life,

while concealing contrary data;

ix. The Manufacturer Defendants' and Sales Representative Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

x. The Manufacturer Defendants' and Sales Representative Defendants' creating, endorsing, and/or supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

xi. The Manufacturer Defendants' and Sales Representative Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

xii. The Manufacturer Defendants' and Sales Representative Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

xiii. The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating South Carolina and Federal law by not reporting these doctors instead; and,

xiv. The Dealer Defendants' falsely representing to patients and the public that they lawfully prescribed opioids for medical treatment when their practice of prescribing was for nonmedical purposes, violated laws, and was done for the sole purpose of making profit.

477. Defendants knew at the time that they made their misrepresentations and

omissions that they were false.

478. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.

479. Given the incredible resources the Manufacturer Defendants and Sales Representative Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon (and were right to rely upon) Defendants' misrepresentations and omissions, as stated above.

480. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied upon (and had a right to rely upon) the Distributor Defendants to uphold the legal requirements and not commit intentional, material omissions to law enforcement for the sake of profits.

481. Given the efforts taken by the Dealer Defendants to obtain medical licenses, operate businesses, and present the outward appearance of legitimate medical practitioners, Plaintiff and its residents reasonably relied on the Dealer Defendants' representations that they were providing medical treatment and not engaging in unlawful, nonmedical dissemination of opioids to addicts for the sole purpose of profit.

482. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff had no knowledge of the Defendants' falsehoods and Plaintiff and its residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior resulting in lost productivity and tax revenue, as well as increased expenditures on public healthcare services, law enforcement, the justice system, and child and family services.

483. Defendants' conduct was willful, wanton, and malicious and was directed at the

public generally.

THIRD CAUSE OF ACTION
UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

484. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

485. Plaintiff is entitled to recover the amounts that Defendants have been unjustly enriched at Plaintiff's expense under the doctrine of unjust enrichment.

486. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by Plaintiff and its residents.

487. In exchange for the opioid purchases, and at the time Plaintiff and its residents made these payments, Plaintiff and its residents expected that Defendants had provided all of the necessary and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.

488. Defendants' wrongdoing directly caused Plaintiff to suffer increased expenditures on public healthcare services, law enforcement, the justice system, child and family services, as well as lost productivity and lost tax revenue, without receiving any of the purported benefits deceptively promoted by Defendants.

489. Defendants' acts and practices alleged herein were motivated by a desire to retain and increase market share and profits, and were undertaken in bad faith.

490. Beaufort County has suffered injuries in paying for opioids and the direct costs resulting from opioid use as a result of Defendants' unlawful conduct, and is therefore entitled to restitution or disgorgement.

491. Defendants have been unjustly enriched in the form of increased revenues and profits as a result of their deceptive marketing in violation of the laws of the State of South Carolina. Under equitable principles and due to its unjust enrichment, Defendants should be required to disgorge any profits, plus interest, that were obtained as a result of their misrepresentations.

FOURTH CAUSE OF ACTION
NEGLIGENCE
(AGAINST ALL DEFENDANTS)

492. Plaintiff incorporates the allegations within all prior paragraphs of this Complaint as if they were fully set forth herein.

493. All Defendants have a duty to exercise reasonable care in the distribution and marketing of opioids, as provided by state and federal law, to avoid the undue risk of widespread addiction to opioids.

494. The Manufacturer Defendants and Sales Representative Defendants breached their duties within Beaufort County and South Carolina by:

i. Marketing opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;

ii. Creating, sponsoring, and assisting in the distribution of patient education materials to consumers that contained deceptive statements;

iii. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;

iv. Distributing brochures to doctors, patients, and the public that included deceptive statements concerning the indicators of possible opioid abuse, indicating that screening tools effectively prevent addiction, and representing that abuse-

deterrent opioids reduce tampering and abuse;

v. Sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

vi. Providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of South Carolina and Federal law;

vii. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

viii. Developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

ix. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

x. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

xi. Disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards; and

xii. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

495. The Distributor Defendants breached their duties within Beaufort County and South Carolina (and in many cases have admitted such breaches), by:

i. Failing to design and operate a system to disclose suspicious orders of opioids;

ii. Once compelled to design and operate a system to disclose suspicious orders of opioids, failing to report suspicious orders as required; and,

iii. Failing to avoid filling suspicious orders, which were ultimately diverted to the black market and/or for nonmedical purposes.

496. The Dealer Defendants breached their duties by distributing opioids for nonmedical purposes, serving as drug dealers in white coats.

497. As a direct and a proximate result, Defendants and their agents have caused Plaintiff to suffer damages by (among other things) excessive costs related to the diagnosis, treatment, and cure of addiction or risk of addiction to opioids, Beaufort County has borne the massive costs of opioid-related illnesses and conditions by having to provide necessary resources for care, treatment facilities, law enforcement services, first responder services, and child and family services for county residents and by having to use county resources in relation to opioid use and abuse. Additionally, the County has suffered lost productivity from its workforce, thereby losing tax revenue.

498. In addition to actual damages, Plaintiff is entitled to an award of punitive damages for Defendants' willful and wanton conduct, in an amount to be determined by the jury at the trial of the matter.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(AGAINST ALL DEFENDANTS)

499. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

500. Defendants, individually and acting through their employees and agents, and in

concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail in this Complaint, including:

i. The Manufacturer Defendants' and Sales Representative Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;

ii. The Manufacturer Defendants' and Sales Representative Defendants' creating, sponsoring, and/or assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

iii. The Manufacturer Defendants' and Sales Representative Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;

iv. The Manufacturer Defendants' and Sales Representative Defendants' distributing brochures to doctors, patients, and the public that included deceptive statements concerning the indicators of possible opioid abuse, indicating that screening tools effectively prevent addiction, and representing that abuse-deterrent opioids reduce tampering and abuse;

v. The Manufacturer Defendants' and Sales Representative Defendants' sponsoring, directly distributing, and/or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

vi. The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of South Carolina and Federal law;

vii. The Manufacturer Defendants' and Sales Representative Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

viii. The Manufacturer Defendants' and Sales Representative Defendants' developing and/or disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

ix. The Manufacturer Defendants' and Sales Representative Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

x. The Manufacturer Defendants' and Sales Representative Defendants' creating, endorsing, and/or supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

xi. The Manufacturer Defendants' and Sales Representative Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

xii. The Manufacturer Defendants' and Sales Representative Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

xiii. The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating South Carolina and Federal law by not reporting these doctors instead; and,

xiv. The Dealer Defendants' falsely representing to patients and the public that they lawfully prescribed opioids for medical treatment when their practice of prescribing was for nonmedical purposes, violated laws, and was done for the sole purpose of making profit.

501. Defendants should have known at the time that they made their misrepresentations and omissions that they were false.

502. Defendants should have, at the least, investigated the truth or falsity of their representations to Plaintiff.

503. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.

504. Given the incredible resources the Manufacturer Defendants and Sales Representative Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions, as stated above.

505. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied on the Distributor Defendants to uphold their legal requirements and not commit intentional, material omissions to law enforcement for the sake of profits.

506. Given the efforts taken by the Dealer Defendants to obtain medical licenses, operate businesses, and present the outward appearance of legitimate medical practitioners, Plaintiff and its residents reasonably relied on the Dealer Defendants' representations that they were providing medical treatment and not engaging in unlawful, nonmedical dissemination of opioids to addicts for the sole purpose of profit.

507. By reason of their reliance on Defendants' misrepresentations and omissions of

material fact, Plaintiff and its residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior, resulting in increased expenditures on public healthcare services, law enforcement, the justice system, and child and family services, as well as lost productivity and lost tax revenue.

508. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally. In addition to actual damages, the Plaintiff is entitled to a reasonable amount of punitive damages in an amount to be determined by the jury at the trial of the matter.

SIXTH CAUSE OF ACTION
PUBLIC NUISANCE
(AGAINST ALL DEFENDANTS)

509. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

510. Defendants, through the actions described in this Complaint, have created, or were a substantial factor in creating, a public nuisance by unreasonably interfering with a right common to the general public that worked to hurt, inconvenience, or damage and interfere with the enjoyment of life or property.

511. The County of Beaufort and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience. The interference of this right resulted from Defendants' illegal and deceptive marketing and distribution of opioids.

512. Defendants, individually and acting through their employees and agents, and in concert with each other, made unreasonable and/or unlawful use of their financial resources in an improper, indecent, and unwarranted fashion to wage a massive campaign of misrepresentations and omissions of facts, negligence, and violation of state laws material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail in

this Complaint, including:

i. The Manufacturer Defendants' and Sales Representative Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;

ii. The Manufacturer Defendants' and Sales Representative Defendants' creating, sponsoring, and/or assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

iii. The Manufacturer Defendants' and Sales Representative Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;

iv. The Manufacturer Defendants' and Sales Representative Defendants' distributing brochures to doctors, patients, and the public that included deceptive statements concerning the indicators of possible opioid abuse, indicating that screening tools effectively prevent addiction, and representing that abuse-deterrent opioids reduce tampering and abuse;

v. The Manufacturer Defendants' and Sales Representative Defendants' sponsoring, directly distributing, and/or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

vi. The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of South Carolina and Federal law;

vii. The Manufacturer Defendants' and Sales Representative Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

viii. The Manufacturer Defendants' and Sales Representative Defendants' developing and/or disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

ix. The Manufacturer Defendants' and Sales Representative Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

x. The Manufacturer Defendants' and Sales Representative Defendants' creating, endorsing, and/or supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

xi. The Manufacturer Defendants' and Sales Representative Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

xii. The Manufacturer Defendants' and Sales Representative Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

xiii. The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating South Carolina and Federal law by not reporting these doctors instead; and,

xiv. The Dealer Defendants' falsely representing to patients and the public that they lawfully prescribed opioids for medical treatment when their practice of prescribing was for nonmedical purposes, violated laws, and was done for the

sole purpose of making profit.

513. The activities of Defendants that created a public nuisance worked as an obstruction or injury to Beaufort County and its residents, producing a material annoyance, inconvenience, discomfort, and/or hurt on the County and its residents by causing them to suffer actual damages directly caused by Defendants' deceptive, negligent, and/or unlawful behavior, resulting in increased expenditures on public healthcare services, law enforcement, the justice system, and child and family services, as well as lost productivity and lost tax revenue.

514. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

515. At all times relevant to this Complaint, Defendants exercised control over the instrumentalities constituting the nuisance, Defendants' actions were a substantial factor creating the public nuisance, and the public nuisance was foreseeable to Defendants. Without Defendants' actions, opioid use would not have become so widespread in Beaufort County and the opioid epidemic that now exists would have been averted or would be much less severe.

SEVENTH CAUSE OF ACTION
CONSTRUCTIVE FRAUD
(AGAINST ALL DEFENDANTS)

516. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

517. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:

i. The Manufacturer Defendants' and Sales Representative Defendants' marketing of opioid drugs as safe and effective

for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;

ii. The Manufacturer Defendants' and Sales Representative Defendants' creating, sponsoring, and/or assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

iii. The Manufacturer Defendants' and Sales Representative Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;

iv. The Manufacturer Defendants' and Sales Representative Defendants' distributing brochures to doctors, patients, and the public that included deceptive statements concerning the indicators of possible opioid abuse, indicating that screening tools effectively prevent addiction, and representing that abuse-deterrent opioids reduce tampering and abuse;

v. The Manufacturer Defendants' and Sales Representative Defendants' sponsoring, directly distributing, and/or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

vi. The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of South Carolina and Federal law;

vii. The Manufacturer Defendants' and Sales Representative Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

viii. The Manufacturer Defendants' and Sales Representative Defendants' developing and/or disseminating misleading scientific studies that deceptively concluded opioids are

safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

ix. The Manufacturer Defendants' and Sales Representative Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

x. The Manufacturer Defendants' and Sales Representative Defendants' creating, endorsing, and/or supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

xi. The Manufacturer Defendants' and Sales Representative Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

xii. The Manufacturer Defendants' and Sales Representative Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

xiii. The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating South Carolina and Federal law by not reporting these doctors instead; and,

xiv. The Dealer Defendants' falsely representing to patients and the public that they lawfully prescribed opioids for medical treatment when their practice of prescribing was for nonmedical purposes, violated laws, and was done for the sole purpose of making profit.

518. Defendants should have known at the time that they made their misrepresentations and omissions that they were false.

519. Defendants should have, at the least, investigated the truth or falsity of their representations to Plaintiff.

520. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.

521. Given the incredible resources the Manufacturer Defendants and Sales Representative Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon (and had the right to rely on) the Defendants' misrepresentations and omissions, as stated above.

522. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied on (and had the right to rely on) the Distributor Defendants to uphold their legal requirements and not commit intentional, material omissions to law enforcement for the sake of profits.

523. Given the efforts taken by the Dealer Defendants to obtain medical licenses, operate businesses, and present the outward appearance of legitimate medical practitioners, Plaintiff and its residents reasonably relied on (and had a right to rely on) the Dealer Defendants' representations that they were providing medical treatment and not engaging in unlawful, nonmedical dissemination of opioids to addicts for the sole purpose of profit.

524. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff had no knowledge of the Defendants' falsehoods and Plaintiff and its residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior,

resulting in increased expenditures on public healthcare services, law enforcement, the justice system, and child and family services, as well as lost productivity and lost tax revenue.

525. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally. In addition to actual damages, the Plaintiff is entitled to a reasonable amount of punitive damages in an amount to be determined by the jury at the trial of the matter.

EIGHTH CAUSE OF ACTION
NEGLIGENCE PER SE
(AGAINST ALL DEFENDANTS)

526. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

527. The Federal Food, Drug, and Cosmetic Act ("FDCA") places restrictions on branded marketing. It prohibits the sale, in interstate commerce, of drugs that are "misbranded." A drug is "misbranded" if the label is false or misleading "in any particular."[150] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[151]

528. Furthermore, the FDCA specifies that drug advertisements must include a true statement of information and an advertisement fails to satisfy this requirement if it is: "false or misleading with respect to side effects, contraindications, or effectiveness"[152]; or "[c]ontains a representation or suggestion that a drugs is safer than it has been demonstrated to be by substantial evidence or substantial experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be

[150] 21 U.S.C 352(a)
[151] 21 U.S.C.A. § 321(m)
[152] 21 CFR 202.1(e)(5)(i)

safer than has been demonstrated."[153]

529. The Manufacturer Defendants and Sales Representative Defendants breached their duties within Beaufort County and South Carolina by:

i. Marketing opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;

ii. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

iii. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;

iv. Distributing brochures to doctors, patients, and the public that included deceptive statements concerning the indicators of possible opioid abuse, indicating that screening tools effectively prevent addiction, and representing that abuse-deterrent opioids reduce tampering and abuse;

v. Sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

vi. Providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of South Carolina and Federal law;

vii. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

viii. Developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for

[153] 21 CFR 202.1(e)(6)(iv)

the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

ix. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

x. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

xi. Disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards; and

xii. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

530. The South Carolina Poisons, Drugs, and Other Controlled Dangerous Substances Act, S.C. Code Ann. § 44-53-10 *et seq.*, incorporates 21 CFR § 1301.74(b) at S.C. Code Ann. § 44. These regulations impose a non-delegable duty upon the Distributor Defendants to "design and operate a system to disclose . . . suspicious orders of controlled substances. The [Distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the [Distributor]. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[154] The stated purpose of the statutory scheme is to reduce the widespread diversion of controlled substances, like opioids, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[155]

[154] 21 CFR § 1301.74(b)
[155] 1970 U.S.C.C.A.N. 4566, 4571-72

531. The Distributor Defendants breached their duties within Beaufort County and South Carolina, as provided by state and federal law (and in many cases have admitted such breaches), by:

i. Failing to design and operate a system to disclose suspicious orders of opioids;

ii. Once compelled to design and operate a system to disclose suspicious orders of opioids, failing to report suspicious orders as required; and

iii. Failing to avoid filling suspicious orders that were ultimately diverted.

532. The South Carolina Poisons, Drugs, and Other Controlled Dangerous Substances Act requires medical practitioners to keep adequate records that are accurate[156] and verify the prescription history of patients receiving opioids.[157] Furthermore, the Act makes it illegal for medical practitioners to distribute opioids for nonmedical purposes outside a bona-fide practitioner-patient relationship.[158]

533. The Dealer Defendants breached their duties to Beaufort County and South Carolina as specified by the South Carolina Poisons, Drugs, and other Controlled Dangerous Substances Act by:

i. Distributing opioids for nonmedical purposes;

ii. Distributing opioids for nonmedical purposes outside a bona-fide practitioner-patient relationship;

iii. Failing to keep adequate records on patients being prescribed opioids;

iv. Failing to keep accurate records on patients being prescribed opioids; and

v. Failing to verify the prescription history of those whom

[156] S.C. Code Ann. §§ 44-53-340 and 44-53-390(a)(4)
[157] S.C. Code Ann. § 44-53-1645
[158] S.C. Code Ann. § 44-53-360(c) and 44-53-260(h)

they prescribed opioids.

534. All of the aforementioned statutory provisions are designed to protect both individuals and the community-at-large, like Beaufort County and the State of South Carolina, from the addictive properties of opioids and the damages caused by opioid addiction, which includes the current opioid epidemic caused by Defendants that Plaintiff is forced to cope with and ameliorate by use of public funds.

535. As a direct and a proximate result of Defendants' acts and omissions that violated the listed statutory provisions, Defendants and their agents have caused Plaintiff to suffer damages by (among other things) incurring costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids. Beaufort County has borne the massive costs of opioid-related illnesses and conditions by having to provide necessary resources for care, treatment facilities, law enforcement services, first responder services, and child and family services for County residents and by having to use County resources in relation to opioid use and abuse. Additionally, the County has suffered lost productivity from its workforce, thereby losing tax revenue.

536. The Defendants' acts are willful and wanton. In addition to actual damages, the Plaintiff is entitled to a reasonable amount of punitive damages in an amount to be determined by the jury at the trial of the matter.

PRAYER FOR RELIEF

WHEREFORE Plaintiff demands judgment against Defendants, jointly and severally, awarding Plaintiff:

i. Compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;

ii. Treble damage under the SCUTPA;

iii. Damages, costs, and reasonable attorney's fees;

iv. A reasonable amount of punitive damages to be determined by the jury at the trial of the matter;

v. Interest, costs, and disbursements;

vi. An injunction forcing Defendants to abate the opioid epidemic ravaging South Carolina and Beaufort County and enjoining the Defendants from marketing opioids as safe for use in chronic pain patients, carrying a low risk of addiction in long term use, and needed in patients exhibiting signs of "pseudoaddiction"; and

vii. Such other and further relief as this Court deems just and proper.

Dated: June 18, 2018

Respectfully Submitted,

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/s/ Benjamin T. Shelton
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/s/ R. Joseph Kramer (*Pro Hac Vice* Pending)
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2019 SC BAR CONVENTION

Health Care Law Section

Friday, January 18

Healthcare Litigation Issues

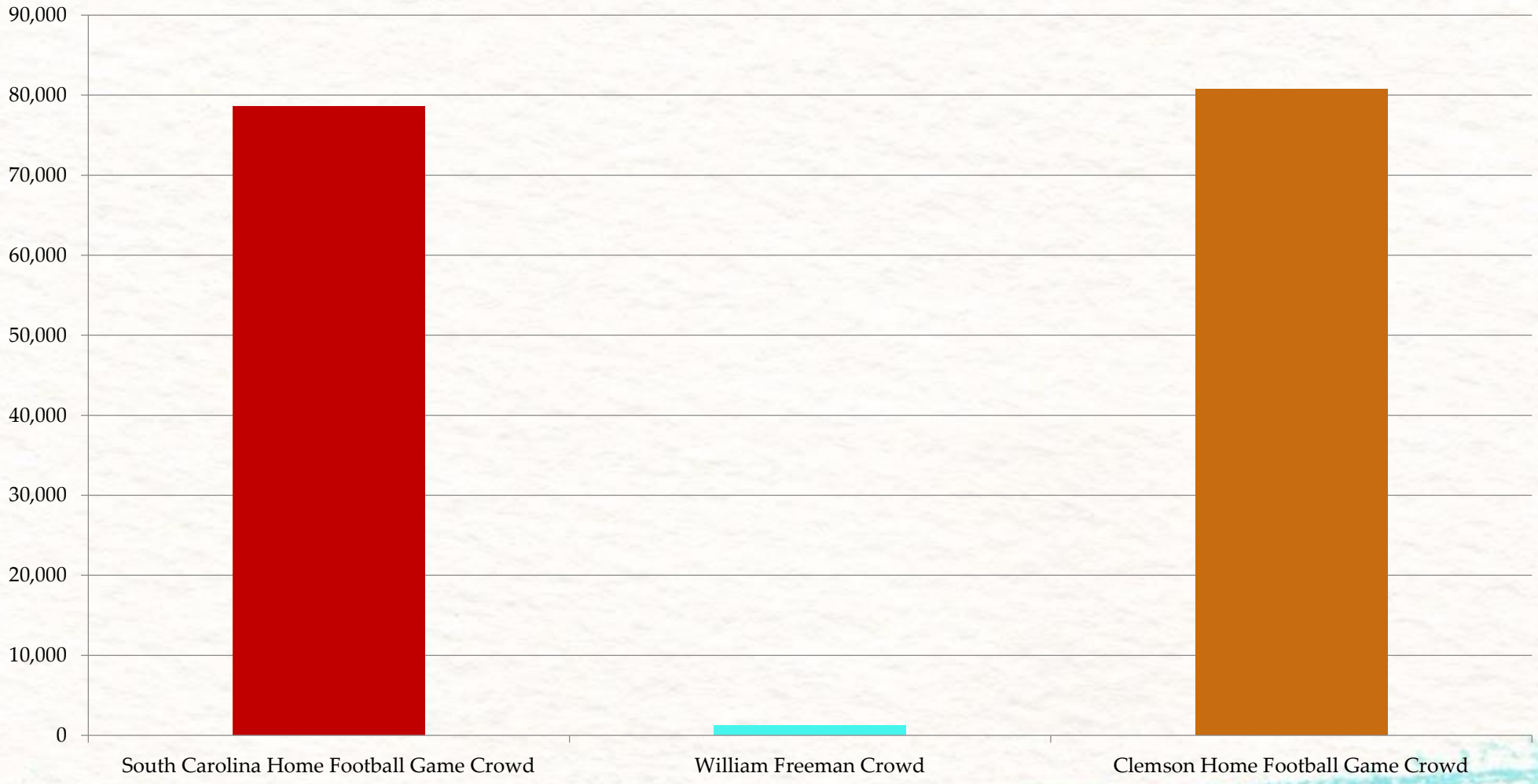
William S.F. Freeman

HEALTHCARE LITIGATION ISSUES

William S. F. Freeman


GAMECOCKS

AVERAGE ATTENDANCE



COMPLIANCE LAWS

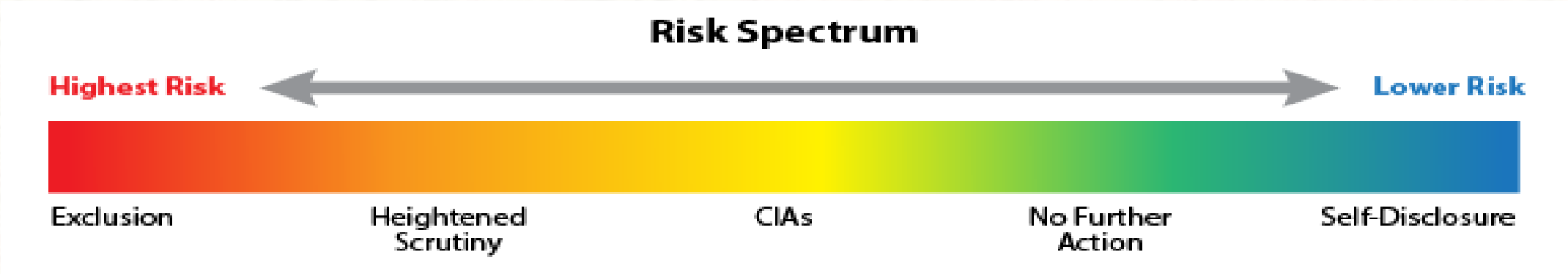
- Stark Law
  42 U.S.C. § 1395nn
- Anti-Kickback Statute
  42 U.S.C. § 1320a-7b(b)
- False Claims Act
  31 U.S.C. §§ 3729-3733
- Exclusion Authorities
  42 U.S.C. §§ 1320a-7, 1320c-5
- Civil Monetary Penalties Law
  42 U.S.C. §1320a-7a
- Criminal Health Care Fraud Statute
  18 U.S.C. §§ 1347, 1349

STARK LAW

- Prohibits a physician from referring patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies
- Prohibits designated health services entity from submitting claims for those services resulting from a prohibited referral

Representative Fortney Hillman "Pete" Stark, Jr.

- Overpayment/refund obligation
- False Claims Act liability
- Civil monetary penalties and program exclusion for knowing violations
- Civil assessment of up to three times the amount claimed



ANTI-KICKBACK STATUTE

- The Anti-Kickback Statute has been interpreted to cover any arrangement where *one* purpose of the remuneration was to obtain money for the referral of services or to induce further referrals.

United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

- Fines up to $100,000 per violation
- Up to a 10 year prison term per violation
- False Claims Act liability
- Civil monetary penalties and program exclusion
- Potential $20,000, $30,000 or $100,000 CMP per violation
- Civil assessment of up to three times amount of kickback

STARK COMPLIANCE IS NOT DISPOSITIVE

- "Neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (*i.e.*, inducing Federal health care program business.)"

- *United States ex rel Armfield v. Gills*, 2012 WL 12918277 (M.D. Fla, 2012)

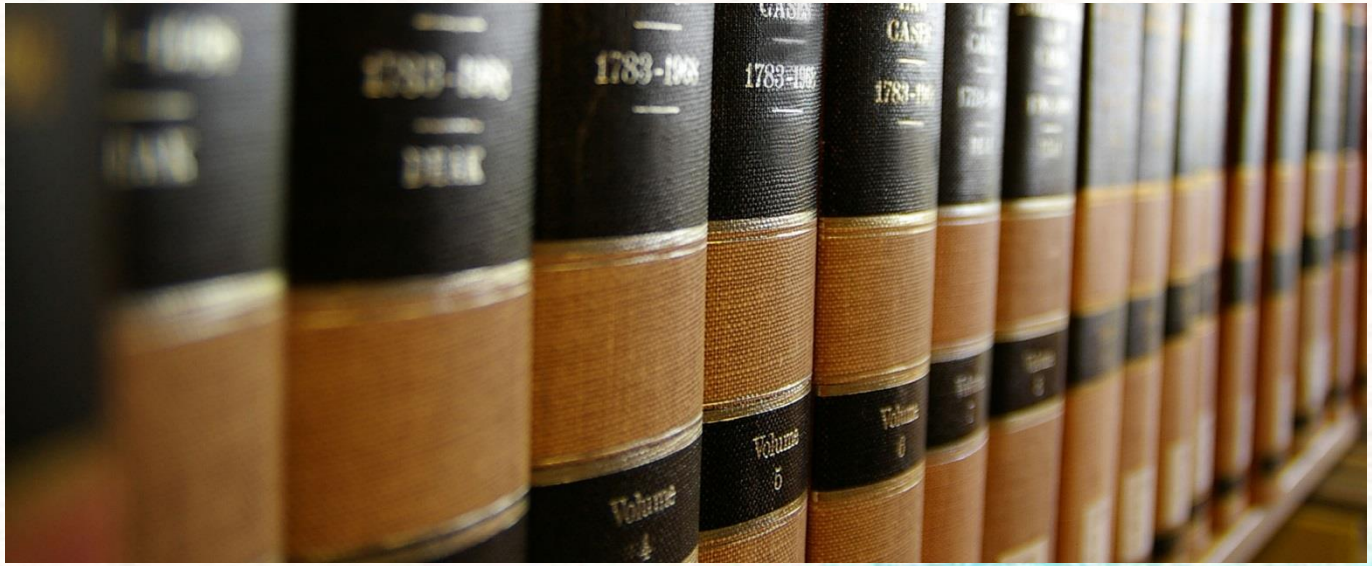
FALSE CLAIMS ACT

- Civil False Claims Act 31 U.S.C. §§3729 - 3733
  - False claims
  - Overcharging
  - Substandard services or goods

- "Knowing" standard
  - Actual knowledge
  - Deliberate ignorance
  - Reckless disregard of the true or falsity of the information related to the claim
  - No proof of specific intent to defraud
- Criminal False Claims Act 18 U.S.C. §287

"REVERSE" FALSE CLAIMS ACT

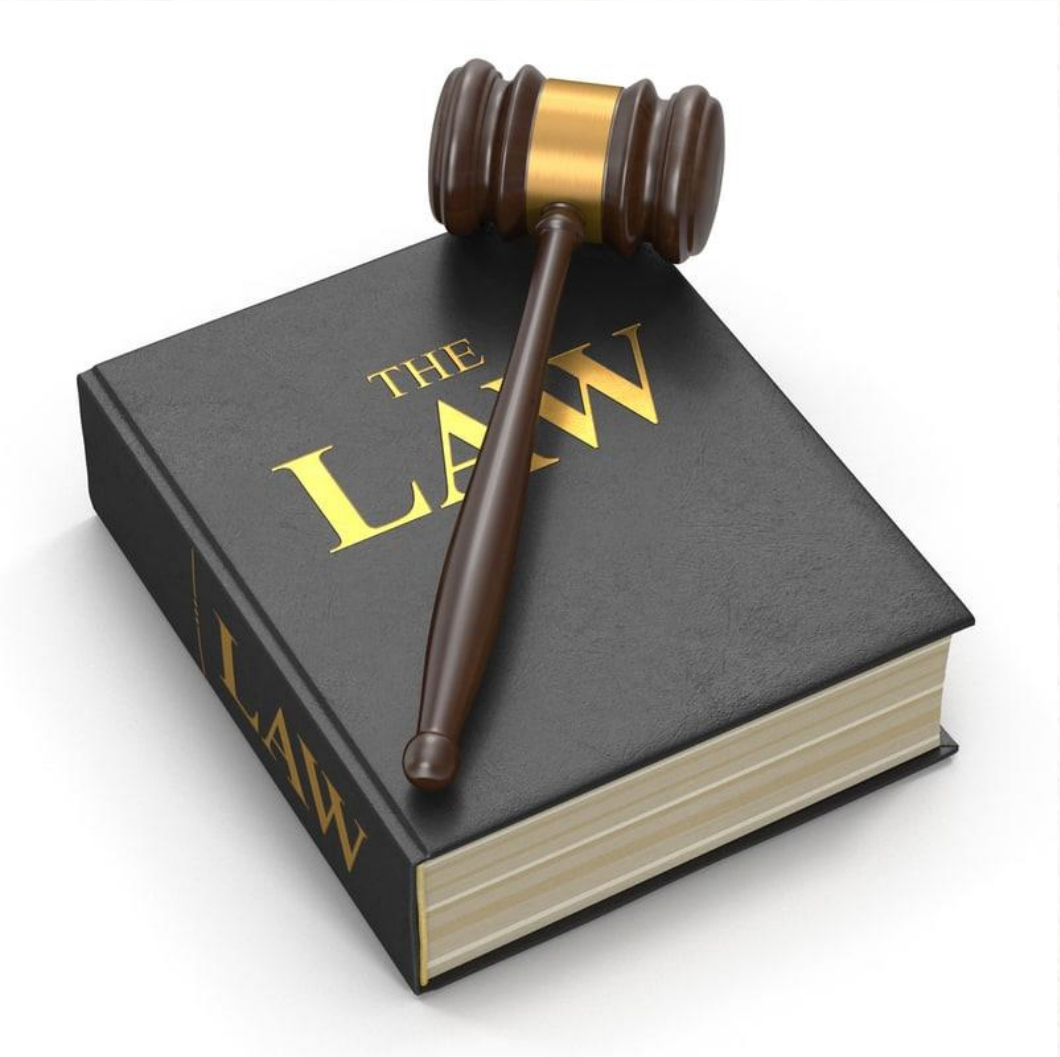
- False Claims Act liability for anyone who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."
- 31 U.S.C. §3729(a)(1)(G)



AFFORDABLE CARE ACT

- Any person who has "received an overpayment …. shall report and return the overpayment …. by the date which is 60 days after the date on which the overpayment was identified."
- Any payment retained after the deadline is an "obligation" under the False Claims Act.
- 42 U.S.C. § 1320a-7k(d)

- "Overpayment means any funds that a person receives or retains [from Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled…"
- 42 U.S.C. § 1320a-7k
- No de minimis exception



FALSE CLAIMS ACT PENALTIES

- Treble damages
- Penalties
  - *c.* $11,000 to $22,000 per claim
- *Qui tam* cases brought by whistleblowers
  - For fiscal year 2018, *qui tam* settlements and judgments accounted for 73.36% of the total amount

- If a claim is paid as a result of a kickback or for a period of time when an arrangement violated Stark, it is a false claim
- An "overpayment" therefore includes the entire amount received for claims submitted during the period of time when an arrangement violated Stark or Anti-Kickback
- This can quickly become a substantial amount

- "It seems as if, even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act."

United States ex rel. Drakeford v. Tuomey, 792 F.3d 364, 395 (4th Cir. 2015) (concurrence)

TUOMEY
HEALTHCARE SYSTEM

FALSE CLAIMS ACT STATISTICS FROM FISCAL YEAR 2018

- Ninth consecutive year that the Department of Justice's civil health care fraud settlements and judgments have exceeded $2,000,000,000.
- More than 2.5 billion in settlements and judgments related to health care
- $2,113,405,258 arose from lawsuits filed under the *qui tam* provisions of the False Claims Act
- $301,728,654 paid out to relators

THE UNITED STATES DEPARTMENT of JUSTICE

HOW CAN A STARK ISSUE ARISE INNOCENTLY?

- Failure to make a required payment (*e.g.* rent; promissory note)
- Breach of an agreement that gives rise to a claim for damages (*e.g.* recruiting agreement; lease; employment agreement)

- Inadvertent payment (*e.g.* mathematical error in quarterly reconciliation or physician compensation; FMV changes)

RESPONSES TO POTENTIAL VIOLATIONS

- For Medicare Parts A & B, a person must use reasonable diligence to timely investigate, in good faith, credible information (*See* 81 Fed.Reg. 7654, 7662)
- Document the investigation and conclusions
  - *e.g.* no intent under AKS

- Investigate whether there is a potential violation that could be addressed
  - *e.g.* holdover provision; late-signed contract; use of disparate documents as a signed contract; repayment
  - six year lookback period (42 C.F.R. § 401.305(f))

- Would a return be more cost efficient or viable?

"IDENTIFICATION"

- case law from 2015: An overpayment is identified when a provider is first put on notice of the possibility an overpayment existed. *U.S. ex rel. Kane v. Healthfirst, Inc.*, 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015)

- Subsequent regulations from 2016: An overpayment is "identified" when a person has (1) determined that the person received an overpayment and (2) quantified the amount of the overpayment. 42 C.F.R. 401.305(a)(2)

"IDENTIFICATION" TIMEFRAME

- Good-faith investigations should be "at most 6 months from receipt of the credible information, except in extraordinary circumstances." 81 Fed.Reg. 7654, 7662
- This is essentially an eight month maximum standard: six months for investigating and two months for reporting 81 Fed.Reg. 7654, 7662

EXTRAORDINARY CIRCUMSTANCES

- Extraordinary circumstances may include
  - "natural disasters"
  - "a state of emergency" and
  - "unusually complex investigations"
    - including certain Stark violation investigations that are referred for disclosure
- 81 Fed.Reg. 7654, 7662

LITIGATION AND COMPLIANCE

- Quantify the funds owed
  - litigation or arbitration award as valuation
  - outside counsel opinion on the commercially reasonable value of an issue
- Extraordinary circumstances
  - Litigation or arbitration often take more than six months
  - outside counsel can document the complex nature of the investigation
- Apply the isolated transactions exception

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South Carolina Bar
Continuing Legal Education Division

2019 SC BAR CONVENTION

Health Care Law Section

Friday, January 18

Overview of Prescription Drug Distribution, Manufacturing, and Delivery

Jon A. Wallace

Prescription Drug Distribution and Delivery

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MUSC College of Pharmacy

Clinical Associate Professor
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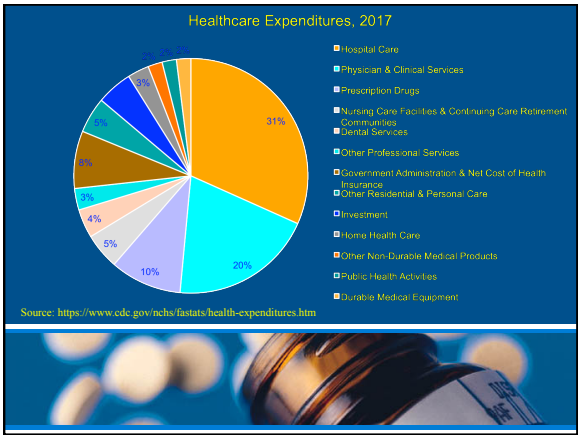


Simple Branded Rx Example Gross-to-Net

- $100 Wholesale Acquisition Price (Gross Sale)
- ($20) Rebate to PBM
- ($20) Co-Pay Assistance
- ($8) Wholesaler Distribution Fees
- ($4) Returns
- ($2) Cash Discounts
- $46 Net Sales to Manufacturer

*Does not include Cost of Goods Sold

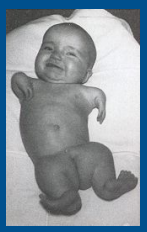
Government Agencies

THE FOOD AND DRUG ADMINISTRATION (FDA)

HISTORY

- VACCINE ACT OF 1813
- IMPORT DRUG ACT OF 1848
- 1906 PURE FOOD AND DRUG ACT
- 1938 FOOD DRUG AND COSMETIC ACT (FDCA)
- 1951 DURHAM-HUMPHREY
- 1962 KEFAUVER-HARRIS (DRUG EFFICACY AMENDMENT)

Thalidomide Defects



Drug Amendments of 1962 (Kefauver Harris), 76 Stat. 780, 788 (1962).

- Changed Section 505 from premarketing notification to premarket approval
- Added the requirement of proof of effectiveness to 1938 requirement of proof of safety
- Adequate and well controlled clinical investigations
- IND, GMPs, etc.

Problem: drugs in the marketplace prior to 1962.

Section 107(c) (4) provides, "In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the amendments . . . shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling . . . .

2011 Compliance Policy Guide (CPG)

Under the 1962 grandfather clause, the FD&C Act exempts a drug from the effectiveness requirements if its composition and labeling has not changed since 1962 and if, on the day before the 1962 Amendments became effective, it was (a) used or sold commercially in the United States, (b) not a new drug as defined by the FD&C Act at that time, and (c) not covered by an effective application."

Drug Efficacy Study Implementation (DESI) Program and the Prescription Drug Wrap-Up

- FDA contacted with National Academy of Sciences/National Research Council (NAS/NRC)
- Evaluate the effectiveness of drugs approved between 1938 and 1962
- For drugs not approved between 1938 and 1962, but were commercially available, as stated in Section 107, are generally known as "Prescription Drug Wrap-Up"
  - Not Subject to DESI Review
  - "GRASE"

FDA 2011 Compliance Policy Guideline

- Risk-based
- Drugs that present "health fraud"
- Drugs that present direct challenges to the new drug approval and OTC monograph systems
- Violative of FD&C in other ways i.e.. CGMP, etc.

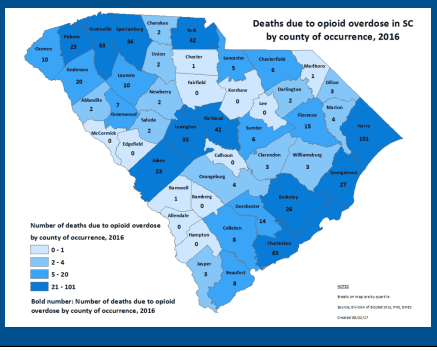
Rx vs. OTC vs. Dietary Supplement

- 1951 Durham Humphrey Amendment
- OTC pursuant to a monograph
  - Advertising subject to FTC
- Dietary Supplement Health Education Act

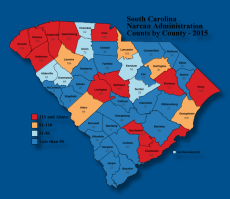
Controlled Substances: Primary Sources of Authority and Enforcement

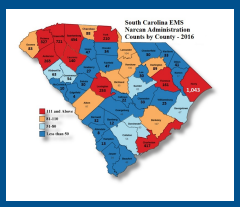
- Drug Enforcement Administration
  - Controlled Substances Act (21 U.S.C. §§ 801-970)
- DHEC
  - Controlled Substances Act (S.C. Code Ann. §44-53-10 *et seq.*

Opioid "Epidemic"



Naloxone Administration





DEA

- Increased scrutiny
  - Prescription Drugs are number one drug of abuse
- DEA Method of Detection/Screening
- Tactical Diversion Squads

Ryan Haight Online Consumer Protection Act of 2008

- Amends the Controlled Substances Act to prohibit the delivery, distribution, or dispensing of controlled substances over the Internet without a valid prescription. Exempts telemedicine practitioners.
- Defines "valid prescription" as a prescription that is issued for a legitimate purpose by a practitioner who has conducted at least one in-person medical evaluation of the patient.
- Adds definitions to the Controlled Substances Act relating to online pharmacies and the issuance of prescriptions over the Internet. Imposes registration and reporting requirements on online pharmacies.
- Authorizes the Attorney General to issue a special registration under this Act for telemedicine practitioners.
- Increases criminal penalties involving controlled substances in Schedules II, IV, and V of the Controlled Substances Act.
- Authorizes states to apply for injunctions or obtain damages and other civil remedies against online pharmacies that are deemed a threat to state residents.

Schedules

- Schedule I - no accepted medical use, high abuse potential, lack info on safety of their use, even under med supervision
- Opiates & Opium derivatives
  - Hallucinogenic
  - Depressants
  - Stimulants

Schedule II

Accepted med use, high abuse potential, severe physical & psychological dependence

- Opium & Opiates, opium poppy, coca leave
- Stimulants
- Depressants
- Hallucinogenic

(codeine, hydrocodone, oxycodone, morphine, meperidine, barbiturates & amphetamines)

Schedule III

Current med use, less abuse than I & II, Moderate or low physical depend, high psycho depend

- Stimulants
- Depressants (sch II barbiturates combo & supp)
- Nalorphine
- Anabolic steroids
  - Anabolic Steroids Control Act of 1990
  - Anabolic Steroids Act of 2004
- Buprenorphine

Schedule IV

- Accepted med use, lower abuse potential, physical & psycho depend
  - Narcotic drugs (difenoxin w/Atro Sulf, dextropropoxyphene)
  - Depressants (benzos- “azolam” & “azepam”)
  - Sleep aids (Lunestra®, Sonata®, Ambien®)
  - Fenfluramine
  - Stimulants
  - Tramadol (Ultram®) (effective 8/2014)

Controlled Substance Prescription

- Person entitled to prescribe
  - Practitioner authorized to prescribe CS by the jurisdiction in which licensed
  - Either registered or exempt from registration
- Purpose of CS Rx
  - To be valid
    - Legitimate medical purpose
    - Practitioner in course of professional practice
    - Rx not meeting criteria is not a Rx
    - Not issued for detox treatment or maintenance treat

Schedule II Rx

- Written
  - Dispense pursuant to written Rx properly executed
- Oral
  - Emergency
    - Quantity prescribed & dispensed
    - Immediate reduce to writing
    - Reasonable effort legitimate
    - SC law receive in **72 hrs.**; Fed Law 7 days
    - Designate on Rx- Emergency Dispensing
    - Pharmacist must notify DEA if Rx not rec’ d
    - ***What is an emergency?***

Corresponding Liability Doctrine

21 CFR 1306.04 Purpose of Issuance of Prescription

- "A prescription . . . Must be issued for a legitimate medical purpose . . . in the usual course of his professional practice."
- SC Code Ann. §44-53-360
- Take: There is a distinction between identifying "bad medicine" and identifying "non-medicine."

South Carolina Board of Pharmacy

- South Carolina Pharmacy Practice Act, SC Code Ann. 40-43-10 et seq.
- Licenses pharmacists
- Permits pharmacies (resident and non-resident), wholesalers, and manufacturers

Pharmaceutical Manufacturers

New Drugs to Market

- Investigational New Drug Application ("IND") – Preclinical
- Clinical Trials
  - Phase I- detect adverse affects, kinetics, etc.
  - Phase II- limited safety and efficacy
  - *Phase III- full safety and efficacy
  - Phase IV- post-marketing data/surveillance

New Drug Application (NDA)

- Submit all data/summaries
  - Substantial Evidence
- Advisory Committee
- Labeling negotiation
- Post-approval mandates
- Fast Track Products
- ANDA- Abbreviated NDA
- SNDA- Supplemental NDA

Good Manufacturing Practices (cGMP)

- Must be registered with FDA
- Regularly inspected
  - Generally two years
  - Prior history of deficiencies may require more inspections
- Confirm production
- ACTIVELY control production

PROMOTION INCLUDING OFF-LABEL USES

- FDA Office of Prescription Drug Promotion ("OPDP")
- FDA'S Bad Ad Program (any violations)
- Physician Sunshine Act
- Off Label Promotion
  - FDA 2014 Compliance Guidance
  - U.S. v. Caronia Decision

Direct-to-Consumer Advertising

- Subject to FDA scrutiny
- Accurate
- Comply with approved labeling
- "Fair balance," which is an explanation of risks and effectiveness of the drug
- "Adequate provision"

Wholesaler

Wholesaler

- Role
- Compensation
- Future Model
- Drug Quality and Security Act
  - Track and Trace

Drug Supply Chain Security Overview: 3 parts

1. **Traceability**: Establishes a two phased national system for tracing pharmaceutical products through the supply chain
2. **Licensing**: Establishes uniform national licensing standards for wholesale distributors and 3rd party logistics providers
3. **Preemption**: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e. pedigree requirements) AND state laws regarding wholesalers

Traceability

Establishes a two phased national system for tracing pharmaceutical products through the supply chain

Phase 1 Product tracing – supply chain partners pass transactional data to subsequent purchasers (data exchange occurs with change of ownership only).

Phase 2 Product identifier – supply chain partners trace product identifiers through the supply chain

Pharmacy Benefit Manager

PBM

- History and Current Role
- Compensation
  - Rebates (Brand)
    - Formulary leverage
  - Spread (Generic)
- Pharmacy Networks
  - DIR Fees
- Future Model?

Pharmacy

Pharmacy

- Types
  - Retail
  - Mail Order
  - Specialty
  - Compounding
    - NECC
    - Drug Quality and Security Act
      - Non-Sterile
      - Sterile
        - » 503B Outsourcing Facility

New England Compounding Center ("NECC")

- Fungal Meningitis (*Exserohilum rostratum*) allegedly associated with injectable steroids
- NECC ceased operations, surrendered pharmacy permit and recalled products from facility

Drug Quality and Security Act

- DQSA signed into law November 27, 2013
- DQSA legislation consists of two Titles:
  1. Compounding Quality Act
  2. Drug Supply Chain Security

Compounding Quality Act

- Two Basic Regulatory Schemes
  1. Traditional state licensed pharmacies
  2. Outsourcing Facilities

Basically, if a pharmacy does not fall under one of these categories, FDA will send a warning letter

Sterile Compounders can get a license (known as an "outsourcing facility"), but is voluntary—would have to comply with GMP, AE reporting, etc.

Compounding Quality Act

- Traditional State Licensed Pharmacies are not subject to 503a (cGMP, etc.) and continue to be regulated by state pharmacy boards if compounder complies with 10 conditions
  - Drugs must be compounded for identified, individual patient pursuant to a prescription (no office use preparations)
  - Drugs must be compounded pursuant to an Rx or before is history or receiving past orders (must be reasonable)
  - Compounding in compliance with USP (bulk substances must be components of FDA-approved drugs or subject to USP or NF monograph
  - Cannot compound drugs withdrawn or removed from market (FDA publishes list 21 CFR 216.24)
  - Cannot copy "inordinate" amounts of drugs that are essentially commercial copies
  - Compounder is generally prohibited from distributing more than 5% of its Rxs out of state—Will not be enforced until finalizing MOUs with states

Compounding Quality Act

- Outsourcing Facilities
  - Sterile Compounding
  - Facilities register with FDA
  - Voluntary
  - Compounded drugs prohibited from wholesale
  - cGMP Requirements and labeling requirements
  - Allows for "office use" compounding, which is not allowed otherwise
  - Drugs compounded for "office use" are compounded in bulk without a specific prescription

Prescriber

Prescriber

- Controlled Substances
  - Manslaughter conviction for reckless prescribing opioids
    - People vs. Stan XuHui Li, 2017 N.Y. Slip Op 08438 (Nov. 30, 2017)
  - Suboxone Clinics
    - What are they?
- Physician Dispensing Model

Patient

Patient

- Payment
  - Part D
  - Medicaid
  - Other Government
  - 3rd Party Commercial
  - Cash
- Pricing Issues
  - Cost sharing
  - Co-Pay Assistance Cards
- Pharmacogenetics

Questions

South Carolina Bar
Continuing Legal Education Division

2019 SC BAR CONVENTION

Health Care Law Section

Friday, January 18

Panel Discussion: Developments in Healthcare Enforcement

Moderator: Matthew "Matt" R. Hubbell
Beattie B. Ashmore
Deborah B. Barbier
E. Bart Daniel
Joseph P. Griffith, Jr.
James C. Leventis, Jr.

No Materials Available