RENDERED: AUGUST 10, 2018; 10:00 A.M.
TO BE PUBLISHED

Commonwealth of Kentucky

Court of Appeals

NO. 2016-CA-001919-MR

CATHOLIC HEALTH INITIATIVES, INC.;
and SAINT JOSEPH HEALTH
SYSTEM, INC. APPELLANTS

APPEAL FROM LAUREL CIRCUIT COURT
v. HONORABLE GREGORY A. LAY, JUDGE
ACTION NO. 12-CI-00090

KEVIN RAY WELLS, SR. APPELLEE

AND NO. 2017-CA-000081-MR

KEVIN RAY WELLS, SR. CROSS-APPELLANT

CROSS-APPEAL FROM LAUREL CIRCUIT COURT
v. HONORABLE GREGORY A. LAY, JUDGE
ACTION NO. 12-CI-00090

CATHOLIC HEALTH INITIATIVES, INC.;
SAINT JOSEPH HEALTH SYSTEM, INC.;
SAINT JOSEPH LONDON; PREMIER HEART
AND VASCULAR CENTER assumed name

Corporation of SAINT JOSEPH HEALTH SYSTEM, INC. CROSS-APPELLEES

OPINION
REVERSING AND REMANDING AS TO APPEAL NO. 2016-CA-001919-MR;
AFFIRMING IN PART AND VACATING IN PART AS TO CROSS-APPEAL NO. 2017-CA-000081-MR

** ** ** ** **

BEFORE: ACREE, KRAMER, AND TAYLOR, JUDGES.

KRAMER, JUDGE: Kevin Wells, Sr., asserted various civil claims in Laurel Circuit Court against Catholic Health Initiatives, Inc., and its subsidiary, Saint Joseph Health System, Inc., (collectively, the "Hospital Defendants") stemming from what he alleged was the wrongful implantation of a pacemaker device in his chest. In the first of the two appeals before this Court (Appeal No. 2016-CA-001919-MR), the Hospital Defendants contest the judgment that was ultimately entered in conformity with a jury verdict in Wells's favor regarding his claims. Specifically, they argue two of Wells's claims -- respectively based upon theories of conspiracy and joint venture -- should have been dismissed at the directed verdict phase; and, that the trial court abused its discretion and substantially prejudiced their defense of this matter by allowing Wells to utilize two documents (a "Clinical Necessity Report" and "OIG Report") as substantive evidence. Upon review, we reverse and remand for a new trial.

In the second of these two appeals (Cross-Appeal No. 2017-CA-000081-MR), Wells argues the trial court erred by reducing his award of punitive damages to conform with a pre-trial itemization of damages he filed in this matter pursuant to Kentucky Rule of Civil Procedure (CR) 8.01(2). To the extent that the trial court held that any amount of punitive damages Wells could have been awarded was required to conform with his pre-trial itemization of damages, we affirm. However, considering our disposition of the Hospital Defendants' appeal and our conclusion that a new trial is warranted, we vacate the remainder of the trial court's judgment to the extent that it awarded Wells any amount.

With that said, the overarching history of this litigation is as follows. On September 22, 2010, at Saint Joseph London Hospital, Dr. Anis Chalhoub implanted a pacemaker in Wells. Thereafter, Wells filed suit in Laurel Circuit Court against Dr. Chalhoub, arguing the pacemaker implantation had been medically unnecessary; it had become a detriment to his health; and that Dr. Chalhoub, prior to implanting the pacemaker, had failed to secure his informed consent to do so.

Wells also filed suit against the Hospital Defendants, arguing Dr. Chalhoub never would have had the opportunity to implant the pacemaker absent the Hospital Defendants' failure to properly supervise physicians at their facility. As to why Wells believed the Hospital Defendants had failed to properly supervise

their physicians, he based his claim upon a series of the Hospital Defendants' contractual arrangements that were in effect at the time of his pacemaker implantation -- contractual arrangements through which, in his view (and as he repeated throughout trial), the Hospital Defendants had "allowed the foxes to guard the henhouse." In his brief, he explains in relevant part as follows:

> While this case involves the unnecessary implantation of a pacemaker by settling defendant Dr. Anis Chalhoub, the facts and claims are rooted in the Hospital Defendants' pattern and practice of incentivizing and profiting from such conduct. Wells's injury was caused by the Hospital Defendants' failure to implement any mechanism to monitor the performance of these cardiac procedures. Instead, the Hospital Defendants worked with local cardiologists to develop a joint venture affiliation model that improperly incentivized physicians to perform large volumes of unnecessary cardiac procedures.
> . . .
>
> [O]n August 1, 2008, the Hospital Defendants along with Dr. Satyabrata Chatterjee, Dr. Ashwini Anand, and Cumberland Clinic, the practice group co-owned by Chatterjee and Anand, executed an Affiliation Agreement to effectuate this co-management model.[1] The complicated Affiliation Agreement involved several contracts and entities with overlapping ownership and interests.
> . . .
> Under this arrangement, affiliated physicians were compensated based on the number of work relative value units ("WRVUs") performed. The more WRVUs they performed, the more each WRVU was worth -- it was an

[1] Dr. Chalhoub joined the Affiliation Agreement in March of 2010.

> accelerated and graduated compensation system. As another source of income, ICS contracted with Cumberland Clinic physicians to pay them as medical directors. As part of the medical director duties, the Hospital Defendants tasked the physicians with developing their own well-defined criteria for cardiovascular services. Essentially, through these medical director contracts, the Hospital Defendants put the physicians in charge of supervising the quality, safety, and appropriateness of the very procedures that they had a financial incentive to perform.

In short, Wells pointed out that hospitals have a duty to maintain procedures appropriate and adequate to determine whether the physicians on the staff of the hospital are carrying out their duties in a manner consistent with good medical practices. *See, e.g., Rogers v. Kasdan*, 612 S.W.2d 133, 135-36 (Ky. 1981) (observing this constitutes one facet of a hospital's duty of ordinary care relative to claims of negligence). But, he argued, the Hospital Defendants had breached their duty by (1) providing cardiologists with financial incentives to perform high volumes of surgical procedures, and then (2) allowing those same cardiologists to function as medical directors, effectively trusting them to objectively assess whether the surgical procedures they were being paid to perform on a volume basis were consistent with good medical practices.

Following extensive litigation and a trial, Wells submitted a total of six claims for the jury to consider. The first three of those claims are, for the most part, implied by what is set forth above: First, negligence (relating to whether Dr.

Chalhoub violated medical standards of care by implanting Wells's pacemaker). Second, informed consent (also relating to Dr. Chalhoub). And third, negligent supervision (relating to the Hospital Defendants).

Wells's final three claims were more abstract. In Wells's fourth claim, he asked the jury to assess whether the Hospital Defendants had engaged in a "conspiracy." Fifth, he asked for a determination of whether the Hospital Defendants had participated in a "joint venture." And sixth, he tasked the jury with deciding whether the Hospital Defendants had violated the Kentucky Consumer Protection Act (KCPA), codified in Kentucky Revised Statutes (KRS) 367.110 *et seq*. Ultimately, the jury found in Wells's favor with respect to all six of Wells's claims.

I. DIRECTED VERDICTS (Appeal No. 2016-CA-001919-MR)

This leads to the first category of arguments raised by the Hospital Defendants on appeal. The Hospital Defendants assert the trial court erred in denying their motions for directed verdicts with respect to Wells's "conspiracy" and "joint venture" claims. We address each of these points in turn. As to the standard for reviewing a trial court's decision to grant or deny a directed verdict,

> [it] consists of two prongs. The prongs are: "a trial judge cannot enter a directed verdict unless there is a complete absence of proof on a material issue or if no disputed issues of fact exist upon which reasonable minds could differ." *Bierman v. Klapheke*, 967 S.W.2d 16, 18–19 (Ky. 1998). "A motion for directed verdict admits the

> truth of all evidence which is favorable to the party against whom the motion is made." *National Collegiate Athletic Ass'n By and Through Bellarmine College v. Hornung*, 754 S.W.2d 855, 860 (Ky. 1988), citing *Kentucky & Indiana Terminal R. Co. v. Cantrell*, 298 Ky. 743, 184 S.W.2d 111 (1944).
>
> Clearly, if there is conflicting evidence, it is the responsibility of the jury, the trier of fact, to resolve such conflicts. Therefore, when a directed verdict motion is made, the court may not consider the credibility or weight of the proffered evidence because this function is reserved for the trier of fact. *National*, 754 S.W.2d at 860 (citing *Cochran v. Downing*, 247 S.W.2d 228 (Ky. 1952)).

Daniels v. CDB Bell, LLC, 300 S.W.3d 204, 215 (Ky. App. 2009). When reviewing the propriety of either a summary judgment or a directed verdict, however, questions of law are always reviewed *de novo* by this Court. *Hardin Cty. Schools v. Foster*, 40 S.W.3d 865, 868 (Ky. 2001).

1. ***Conspiracy***

The concept of civil conspiracy was explained in *Peoples Bank of N. Ky., Inc. v. Crowe Chizek and Co. LLC*, 277 S.W.3d 255, 260-61 (Ky. App. 2008):

> [C]ivil conspiracy ... has been defined as "a corrupt or unlawful combination or agreement between two or more persons to do by concert of action an unlawful act, or to do a lawful act by unlawful means." *Smith v. Board of Education of Ludlow*, 264 Ky. 150, 94 S.W.2d 321, 325 (1936). In order to prevail on a claim of civil conspiracy, the proponent must show an unlawful/corrupt combination or agreement between the alleged conspirators to do by some concerted action an unlawful

act. *Montgomery v. Milam*, 910 S.W.2d 237, 239 (Ky. 1995).

Importantly, civil conspiracy is not a free-standing claim; rather, it merely provides a theory under which a plaintiff may recover on an apportioned basis from multiple defendants for an underlying tort. *See Davenport's Adm'x v. Crummies Creek Coal Co.*, 299 Ky. 79, 184 S.W.2d 887, 888 (1945); *see also Insight Ky. Partners II, L.P. v. Preferred Automotive Serv., Inc.*, 514 S.W.3d 537, 556-57 (Ky. App. 2016) (explaining the tort of "aiding and abetting a breach of fiduciary duty," a claim that is effectively one of civil conspiracy, warrants apportionment pursuant to KRS 411.182.).[2,3]

As to the nature of Wells's conspiracy claim, the manner in which Wells describes it in his brief is somewhat nebulous, but the jury instructions at

[2] In *Steelvest, Inc. v. Scansteel Serv. Ctr., Inc.*, 807 S.W.2d 476, 485 (Ky. 1991), a claim that an entity "aided, abetted, and conspired" with another to breach a fiduciary duty was recognized by the Kentucky Supreme Court as a claim of aiding and abetting a breach of fiduciary duty, a viable civil claim in Kentucky.

[3] That claims of civil conspiracy warrant *apportionment* was a point that was missed by the trial court; due to the success of Wells's civil conspiracy claim, the trial court erroneously determined the Hospital Defendants were *jointly and severally liable* for all of Wells's claims, including the amount of fault that the jury apportioned to Dr. Chalhoub (*i.e.*, 50%). As an aside, the *Steelvest* Court indicated that under the common law civil conspiracy-type claims result in joint and several liability. *Id*. at 485. But, as the *Insight* Court later recognized, that is no longer the rule in Kentucky. Specifically, KRS 411.182 alters the common law, applies to "all tort actions," and thus precludes joint tortfeasors (including those who aided and abetted a breach of fiduciary duty or otherwise engaged in a civil conspiracy) from being held jointly and severally liable. The *Steelvest* Court did not have the opportunity to address the effect of KRS 411.182 on the common law because that issue was not before it and *Steelvest* commenced before the statute went into effect.

least describe who Wells believed participated in it, and what he believed the act in furtherance of the conspiracy was. After the first two instructions provided some preliminary directions, instructions "3" and "3A" collectively asked the jury to determine whether Dr. Chalhoub was negligent (*i.e.*, whether his treatment of Wells amounted to a breach of the applicable medical standard of care and was a substantial factor in causing Wells to suffer an injury). Instructions "4" and "4A" collectively asked the jury to determine whether Dr. Chalhoub had breached his duty to secure Wells's informed consent prior to implanting the pacemaker in Wells and, if so, whether that breach was also a substantial factor in causing Wells to suffer an injury. After that, the jury instructions explained:

> If you answered "NO" to either Instruction No. 3 or No. 3A, and you answered "NO" to either Instruction No. 4 or 4A, then you have found in favor of the Defendants and you shall return to the Courtroom. Otherwise, please proceed to Instruction No. 5.

In other words, the instructions defined the alleged *act* that was committed in furtherance of the conspiracy. Namely, the instructions prohibited the jury from finding the Hospital Defendants liable under Wells's conspiracy theory, or under any of his other theories, *unless* the jury determined that when Dr. Chalhoub implanted a pacemaker in Wells: (1) Dr. Chalhoub had breached the applicable medical standard of care, and his negligence was a substantial factor in causing Wells an injury; and/or (2) Dr. Chalhoub had failed to secure Wells's

informed consent beforehand, and his failure to do so was a substantial factor in causing Wells an injury.[4]

Moreover, the alleged players in the conspiracy are clearly defined as Dr. Chalhoub and the Hospital Defendants. Indeed, they were explicitly identified as the *only* players: Further on in instruction "9," the jury was asked to apportion

---

[4] During oral arguments in this matter, and for what appears to be the first time during this litigation, Wells represented that the act committed in furtherance of the asserted conspiracy was *not* Chalhoub's negligence or failure to secure Wells's informed consent, but was rather what he believes qualified as "false advertising" on the part of the hospital defendants regarding whether Chalhoub or various other doctors were its employees – the same "false advertising" he alleged was the crux of his KCPA claim. That said, Wells's representation in this vein cannot be accepted for at least three reasons.

First, and as discussed, the jury instructions do not permit any such inference.

Second, any such inference runs contrary to what Wells represented to the trial court prior to judgment in this matter. When pressed on this issue during the hearing on the hospital defendants' directed verdict motion relative to this claim, Wells represented to the trial court, by and through his counsel, "We believe that the, the unlawful act was the implantation of an unnecessary pacemaker, which would be a battery, among other things."

Third, and as Wells conceded at trial (in response to directed verdict arguments and a specific question from the trial court), no evidence supported that Wells relied upon any advertising from the hospital defendants:

> COURT: Even if you assume that the hospital [falsely advertised], how did that cause or substantially contribute to Kevin Wells's injury? I can understand your causation on all the other elements, but where's the causation here?
>
> WELLS'S COUNSEL: Well, I think the causation is that Kevin and Ruth believed they were getting care by a St. Joseph's London physician. And, to the extent that they went to him and trusted him as a result of that, and to find out later that he's not a St. Joseph's London physician, is false and misleading.
>
> COURT: Is there any testimony that they would have, but for that advertising or whatever that they would have went elsewhere?
>
> WELLS COUNSEL: No, your honor.

fault for Wells's injury; the jury was only provided the option of apportioning fault between the Hospital Defendants and Dr. Chalhoub; and, between these parties, the instructions required the percentages of apportionment "must total 100%."

However, what is missing from the jury instructions, Wells's arguments, and Wells's evidence is any indication of the "unlawful act" or "unlawful means" that Dr. Chalhoub and the Hospital Defendants allegedly agreed upon. This was one of the several reasons why the Hospital Defendants moved for a directed verdict in this respect. Below, Wells conceded Dr. Chalhoub and the Hospital defendants never *agreed* to implant him, or anyone else, with an unnecessary pacemaker. Wells produced nothing indicating Dr. Chalhoub and the Hospital defendants *agreed* to mislead him, or anyone else, about the necessity of having a pacemaker. Moreover, if the crux of Wells's theory was that the hospital's use of incentives and quality of oversight fostered an environment that allowed Dr. Chalhoub the *opportunity* to misinform or act negligently toward Wells, that, too, was insufficient; conspiracies require specific intent,[5] and are not formed through negligence or recklessness. *See James v. Wilson*, 95 S.W.3d 875, 897-98 (Ky. App. 2002) (recognizing that while "civil conspiracy" is recognized in

[5] As discussed, civil conspiracy requires "concerted action," a term this Court has previously defined by relying upon the RESTATEMENT (Second) of Torts § 876. *See Farmer v. City of Newport*, 748 S.W.2d 162, 164 (Ky. App. 1988). In turn, Comment a of that section of the Restatement explains that "Parties are acting in concert when they act in accordance with an agreement to cooperate in a particular line of conduct or to accomplish a particular result. . . ."

Kentucky, claims for "negligent encouragement" are not). For that reason, the trial court erred by denying the Hospital Defendants a directed verdict on this claim, and we reverse in this respect.

2. ***Joint venture***

A "joint venture" (or "joint enterprise") is a form of partnership and a means of imputing *vicarious liability*. *See, e.g., Huff v. Rosenberg*, 496 S.W.2d 352, 355 (Ky. 1973), explaining:

> A 'joint enterprise' rests upon an analogy to the law of partnership. It is something like a partnership for a more limited period of time and a more limited purpose. It is an undertaking to carry out a small number of acts or objectives which are entered into by association under such circumstances that all have an equal voice in directing the conduct of the enterprise. The law then considers that each is the agent or servant of the others and that the act of any within the scope of the enterprise is to be charged vicariously against the rest.

(Citation omitted.)

Here, Wells's joint enterprise theory largely duplicated his conspiracy theory: The jury instructions identified Dr. Chaloub and the Hospital Defendants as members of the alleged joint enterprise, and provided that the offending acts perpetrated within the scope of the joint enterprise were Dr. Chalhoub's alleged negligence and failure to secure Wells's informed consent. Likewise, Wells asserted this theory as a means of holding the Hospital Defendants vicariously liable for Dr. Chalhoub's conduct. And because of the jury's finding that Dr.

Chalhoub and the Hospital Defendants had been engaged in a joint enterprise at all relevant times, the Hospital Defendants *were* held vicariously liable for Dr. Chalhoub's conduct. Specifically, the jury apportioned "50%" of the fault for Wells's injuries to Dr. Chalhoub; and, pursuant to the jury's finding that a joint enterprise had existed between the parties, the trial court entered judgment holding the Hospital Defendants vicariously liable for Dr. Chalhoub's apportioned 50%.

The Hospital Defendants claim the circuit court erred in failing to direct a verdict in their favor regarding Wells's theory of vicarious liability based upon joint enterprise because Wells entered into a settlement with Dr. Chalhoub prior to trial. We agree.

To explain, vicarious liability is a rule of public policy that holds an individual who is personally innocent[6,7] responsible for the negligent acts of *others* committed in the course and scope of the individual's business. *See American General Life & Acc. Ins. Co. v. Hall*, 74 S.W.3d 688, 692 (Ky. 2002). Thus, in the

[6] For purposes of Wells's joint venture theory, the Hospital Defendants must be considered "innocent" parties because this theory was an attempt to hold them secondarily liable and, under the doctrine of vicarious liability, secondarily liable parties are not considered tortfeasors. Rather, vicarious liability is only concerned with fault attributable to the primarily liable party.

[7] This discussion, of course, has no bearing upon Wells's claims against the Hospital Defendants for negligent supervision. *See, e.g., Lake Cumberland Regional Hospital, LLC v. Adams*, 536 S.W.3d 683, 694 (explaining that a claim of negligent supervision against a hospital, while derivative of a physician's negligence, "is not a case where the dismissal of an agent also relieves the master of liability" because the "claim against the hospital arises from the hospital's own alleged negligence.").

employer-employee context, such liability is wholly "vicarious" in that it rests not on the fault of the employer, but on that of the employee, making the employee's responsibility primary and the employer's secondary. *See id*. The same holds true in the context of partnerships. *See Roethke v. Sanger*, 68 S.W.3d 352, 361 (Ky. 2001) (explaining the doctrine of vicarious liability applies "whether the agency relationship is one of partnership, principal/agent, or master/servant.").

In other words, the doctrine is founded upon the notion that there is a singular unit of liability for a singular cause of action. For example, because the secondarily responsible party's liability is *dependent* upon a third person's right of recovery from the primarily responsible party, a verdict in favor of the primarily responsible party necessarily operates to *exonerate* the secondarily responsible party. *See Overstreet v. Thomas*, 239 S.W.2d 939, 941 (Ky. 1951). Because "a party can have but one satisfaction for an injury resulting from a tort,"[8] the doctrine prohibits a plaintiff from recovering full satisfaction for his injury *twice* (*i.e.*, *once* from the secondarily responsible party, and *again* from the primarily responsible party). And if the plaintiff recovers from the secondarily liable party, the secondarily liable party, in turn, is subrogated to plaintiff's rights against the primarily responsible party and is entitled to indemnity. *See Eichberger v. Reid*, 728 S.W.2d 533 (Ky. 1987) (explaining this rule in the context of partnerships).

[8] *See Daniel v. Turner*, 320 S.W.2d 135, 138 (Ky. 1959).

Moreover, where a plaintiff settles with or covenants not to sue the primarily liable party, the secondarily liable party is likewise released from any claim that depends upon vicarious liability. *See Waddle v. Galen of Ky., Inc.*, 131 S.W.3d 361, 366 (Ky. App. 2004) (explaining this principle).

This was the crux of why the Hospital Defendants moved for a directed verdict with respect to Wells's joint enterprise theory: Wells dismissed every claim he asserted against Dr. Chalhoub after he and Dr. Chalhoub entered into a confidential settlement agreement, and the Hospital Defendants argued that the release effectuated by the confidential settlement agreement operated to release them from liability with respect to Wells's vicarious liability claims. As discussed, the Hospital Defendants were correct. The trial court erred by denying their motion for a directed verdict in this respect, and we accordingly reverse.

As a caveat, we emphasize that Wells's settlement with Dr. Chalhoub did not effectuate a release of any other claim Wells asserted against the Hospital Defendants. *See, e.g.*, *Adams*, 536 S.W.3d at 694 (explaining that a claim of negligent supervision against a hospital, while derivative of a physician's negligence, "is not a case where the dismissal of an agent also relieves the master of liability" because the "claim against the hospital arises from the hospital's own alleged negligence"); *see also* KRS 411.182(4) (addressing the procedure when one defendant settles in a tort case.)

II. EVIDENTIARY ISSUES (Appeal No. 2016-CA-001919-MR)

The remaining issues raised by the Hospital Defendants relate to evidence Wells was permitted to introduce at trial in support of his claims against them for negligent supervision and KCPA violations. Their arguments involve two documents which the parties have dubbed the "Clinical Necessity Report" and the "OIG Report." We review a trial court's evidentiary rulings under the abuse of discretion standard. *Goodyear Tire and Rubber Co. v. Thompson*, 11 S.W.3d 575, 578 (Ky. 2000).

1. *The Clinical Necessity Report*

In 2012, the Hospital Defendants submitted a random sampling of their medical procedure case files from 2009 and 2010 to an outside entity that examines documentation to conduct external peer reviews. This ultimately led to the creation of what the parties describe as the "Clinical Necessity Report." Perhaps the clearest explanation of the Clinical Necessity Report's purpose was provided by Daniel W. Varga, M.D., the doctor who, while employed by the Hospital Defendants, pushed for the investigation that led to the report's creation. By deposition, he testified:

> DR. VARGA: So my rationale for pushing for an external peer review, not of Saint Joe London, but of all of Saint Joseph Health System, so just to be specific, in 2010 was related to two fundamental principles. One

was we had received notice, not personal health system notice, but notice that CMS and the RAC auditors[9] were doing essentially external audits of high-volume procedures. The specific notice here -- and this came from some -- one of your all's societies, one of the -- some lawyerly society that said if you're a health care lawyer, you should be aware of the fact that CMS in this situation was specifically through their RACs looking at implantable cardioverters and defibrillators and specifically evaluating whether the clinical documentation in the chart supported the procedure that was billed for.

And it became clear, from the advisory that had -- that we became aware of, that they were specifically looking at health care systems that did high volumes of ICDs, and it wasn't just limited to cardiovascular, but that there were other high-volume sorts of procedures, like the ordering of MRIs and other things, where they were looking to see does the clinical documentation available support the intervention done.

I made -- I initiated a discussion with Gene Woods, the CEO, and with Jackie Kingsolver and said, you know, we are the highest volume cardiac program in the state of Kentucky. Saint Joseph Hospital, Saint Joseph London added together were the biggest heart surgery program in the state of Kentucky. Add up all of our programs together, our interventional program was the biggest program in the state of Kentucky.

I said if it's true around just kind of trolling ICD doers to find out if they comply with national payment determination criteria, then the likelihood is they'll be

[9] CMS is a reference to "Centers for Medicare and Medicaid Services." "RAC" is a reference to "Recovery Audit Contractor." The purpose of the RAC program is to identify and recover improper Medicare payments paid to healthcare providers under fee-for-service Medicare plans. *See generally* 42 United States Code (U.S.C.) 1395ddd.

> looking at high-volume surgery programs, high-volume interventional cardiology programs, even though we don't have objective quality information that says there's any problem, and we didn't. I know that's a double negative, and I apologize. But our quality data said we performed well. If you looked at our ACC data, if you looked at our core measure data, et cetera, we performed at or above national average in almost every one of those indicators.
>
> So even though we don't have a clinical performance indicator, it's in our best interest, particularly from a regulatory standpoint, but -- from a regulatory exposure standpoint, *but also from the standpoint of making sure that patient care is actually -- is actually meeting the standards we look for*, we should do an external peer review of our interventional program.
>
> Q: So this was not prompted by any particular investigation into your facility --
>
> DR. VARGA: Not at all.
>
> Q: -- or any particular doctor.
>
> DR. VARGA: Not at all.

(Emphasis added.)

Some of the case files that the Hospital Defendants submitted to this external peer review process related to cardiovascular procedures performed in their facilities in 2010, some of which were performed by Dr. Chalhoub. The total number of Dr. Chalhoub's procedures submitted for review remains unknown, but during discovery the Hospital Defendants produced a report, dated May 7, 2013, that summarized the external peer reviewer's findings relative to twelve of Dr.

Chalhoub's pacemaker implantation procedures (*e.g.*, the "Clinical Necessity Report").

Each of the twelve summaries within the Clinical Necessity Report included information under the following headings: (1) "Procedure performed"; (2) "Brief clinical summary leading to the procedure," (3) "NCD indications for single chamber pacemaker (indications met/indications not met)"; (4) "NCD indications for dual chamber pacemaker (indications met/indications not met)"; and (5) "Clinical indication for the pacemaker and support by clinical guidelines." In the Clinical Necessity Report, the external reviewer noted that all twelve of the procedures reviewed had resulted in no surgical or post-operative complications. But the external reviewer further determined, according to what was documented in each of the twelve case files, that "NCD indications" had not been met and pacemakers had not been clinically indicated. For the sake of illustration and brevity, we will only set forth the external reviewer's statements to that effect with respect to three of the pacemakers Dr. Chalhoub implanted:

- [Procedure 1] NOT SUPPORTED: The clinical indication for the pacemaker was "symptomatic bradyarrhythmia with underlying atrial fibrillation"; however, the clinical notes up to the day prior to admission specifically noted the absence of symptoms referable to arrhythmia.

Furthermore, there was no evidence of significant pause or sustained bradyarrhytmia on 24-hour ambulatory electrocardiography.

- [Procedure 2] NOT SUPPORTED: The clinical indication for the pacemaker was "sick sinus syndrome with symptomatic tachy-brady arrhythmias"; however, the provided clinical notes failed to demonstrate any causal relationship with arrhythmia. The electrocardiograms all demonstrated sinus rhythm and no evidence of pathologic bradyarrhythmia. The only report of any bradycardia was a reported minimum heart rate of 50 BPM on a 24-hour Holter monitor and there were no symptoms reported. Because there was no clear association with symptoms and no bradycardia reported as ever less than 50 BPM (and uncertain if this was when sleeping), there were no acceptable criteria for device implantation identified.
- [Procedure 3] NOT SUPPORTED: The clinical indication for the pacemaker was "sick sinus syndrome"; however, the provided clinical notes failed to demonstrate any causal relationship with the arrhythmia. The electrocardiograms all demonstrated sinus rhythm and no evidence of pathologic bradyarrhythmia. The only report of any bradycardia was a reported minimum heart rate of 52 BPM on a 24-hour Holter monitor and this was at 04:47 and without symptoms reported. Because there was no clear association with symptoms and no bradycardia reported as ever less

than 52 BPM and this was while sleeping, there were no acceptable criteria for device implantation identified.

The identity of the individual who performed the external peer reviews of Dr. Chalhoub's twelve procedures is unknown. The case files referenced by the external reviewer were never introduced into evidence. The names of the twelve patients in question were redacted from the report. But, it is undisputed that Dr. Chalhoub's treatment of Wells was *not* reviewed in the Clinical Necessity Report.

As an aside, the Hospital Defendants moved to bifurcate these proceedings between Wells's underlying malpractice claim against Dr. Chalhoub and Wells's derivative claims against the Hospital Defendants of negligent supervision, vicarious liability, and KCPA violations. *See* CR 42.02. The trial court denied their motion.

Thereafter, Wells sought to introduce the Clinical Necessity Report at trial as substantive evidence of his claims. The trial court expressed reservations about allowing him to do so, particularly when Wells sought to use it as a means of impeaching Dr. Dale Wirthem, an expert witness the Hospital Defendants presented to provide an opinion that Dr. Chalhoub had met the standard of care applicable to physicians. At an ensuing bench conference, the trial court had the following exchange with Wells's counsel:

> WELLS'S COUNSEL: Your honor, may I add one other thing? He [Dr. Wirthem] said it [Dr. Chalhoub's decision to implant Wells's pacemaker] was a "judgment call." Those things [the twelve summaries set forth in the Clinical Necessity Report] go to prove that this was not a "judgment call" for Dr. Chalhoub, it was a pattern in practice.
>
> COURT: If your intent in introducing the evidence of the, uh, I forget what it was. Twelve or twenty --
>
> WELLS'S COUNSEL: Twelve.
>
> COURT: Twelve, um, incidences of whatever you want to call them, unnecessary procedures or improper documentation. If your reason for introducing that evidence is to prove that on September 22, Doctor Chalhoub acted in conformity with that, then this case is going to get reversed if you get a verdict. So that's not --
>
> WELLS'S COUNSEL: That's not the purpose of the, introducing the report, judge --
>
> COURT: That's right. That's not the purpose you introduced that, that testimony. So, in the court's view, this witness spoke to the issue of whether or not Dr. Chalhoub violated the standard of care leading up to and on September 22, 2010. And if I permit you to go into these other, uh, things, it will confuse the jury on that issue. It will serve to confuse the jury on why that evidence was introduced, and for that reason I'm not going to permit you to get into that with this witness.

But as this exchange indicates, the trial court *did* permit Wells, over the Hospital Defendants' objection, to introduce the Clinical Necessity Report as substantive evidence; specifically, as evidence supporting Wells's claim that the standard of care applicable to *hospitals* had required the Hospital Defendants to

regularly perform this type of external peer review process as early as 2007, and that their failure to do so until 2013 had *enabled* Dr. Chalhoub's *negligence*. This, in turn, led to the following discussion about the Clinical Necessity Report at trial between Wells's counsel and Wells's *hospital* standard of care expert, Dr. Fred Hyde:

> WELLS'S COUNSEL: So, they, they were looking at, and that is the same for all twelve of these, they went through and they looked at, do any of these meet the national coverage determination, and they looked at the records to see if there were any clinical indications to support the implantation of a pacemaker?
>
> HYDE: Right. This is what I meant by a hospital sort of getting this process in place. It's a good process. Coming back to a different, in 2012, 2013, a different place they had been in 2009 and 2010.
>
> WELLS'S COUNSEL: And they went through, in these twelve procedures, and one after the other they stated "not supported clinically," "not supported clinically," "not supported clinically," "not supported clinically," "not supported clinically," "not supported clinically," "not supported clinically," "not supported clinically," "not supported clinically," "not supported clinically," and "not supported clinically."
>
> HYDE: You showed me a dozen of these. And, I think I was aware they had got a dozen reports.
>
> WELLS'S COUNSEL: *And, so this isn't just a, "does Dr. Chalhoub keep good records." This is, "does Dr. Chalhoub put in pacemakers that are unnecessary."*
>
> HYDE: *That's what the twelve cases show.*

(Emphasis added.)

Wells then continued to characterize and reference the Clinical Necessity Report in roughly the same manner during his examination and cross-examination of several other witnesses.

The Hospital Defendants argue the Clinical Necessity Report should have been excluded because whatever probative value it may have had was substantially outweighed by its danger of undue prejudice. *See* Kentucky Rule of Evidence (KRE) 403. To an extent, we agree.

As discussed, Wells asserted two overarching claims of negligence in this matter. The first claim was medical negligence (*i.e.*, malpractice) against Dr. Chalhoub. Wells's second claim, which he asserted against the Hospital Defendants, was dependent upon and derivative of the malpractice claim, and approximated what has been dubbed "negligent credentialing" -- something other states have recognized as a standalone tort, but Kentucky has recognized as another iteration of negligent supervision. *See Lake Cumberland Regional Hospital, LLC v. Adams*, 536 S.W.3d 683 (Ky. 2017).

The Kentucky Supreme Court has emphasized that when both types of claims are presented in the same lawsuit, they should not be presented to a jury at the same time but should instead be presented in bifurcated proceedings. *Id*. at 697. This is not simply for reasons of judicial economy (although if the underlying malpractice action is dismissed, it would usually necessitate the dismissal of the

negligent supervision claim). It is also to avoid undue prejudice and juror confusion. *Id*. at 692, n.3. This is because proving a hospital was negligent in supervising a doctor often requires proof that a hospital failed to notice several of the doctor's *past misdeeds*; whereas, introducing proof of the doctor's *past misdeeds* can unduly prejudice any defense of the underlying claim of malpractice. *See* Kyle Deskus, *Health Law—Band-Aid Jurisprudence: Why the Recognition of Negligent Credentialing Threatens Patient Care in Massachusetts*, 37 W. New Eng. L. Rev. 27, 36 (2015) (citing *Schelling v. Humphrey*, 123 Ohio St.3d 387, 916 N.E.2d 1029, 1035-36 (2009)).

With that said, there are at least two reasons why the trial court's decision to allow Wells to introduce the Clinical Necessity Report into evidence in these non-bifurcated proceedings posed a substantial danger of causing undue prejudice and juror confusion. First, and as the trial court itself understood, even if Wells had another reason for introducing the Clinical Necessity Report, it nevertheless posed a substantial danger of impermissibly leading the jurors to believe that *because* Dr. Chalhoub unnecessarily implanted pacemakers in *twelve other* individuals, he must have implanted an unnecessary pacemaker in *Wells*. *See* KRE 404(b)(1). It is well-recognized that triers of fact are apt to give proof of other crimes, wrongs, or bad acts more weight than it deserves; and, it always carries with it a substantial risk of distracting a jury, and of leading jurors to

believe that because a person has acted badly on other occasions, that person acted badly on the occasion at issue in the case. *Trover v. Estate of Burton*, 423 S.W.3d 165, 172 (Ky. 2014); *see also Pauly v. Chang*, 498 S.W.3d 394, 411 (Ky. App. 2015) (explaining it is not the jury's responsibility to compare the treatment that a plaintiff received to the treatment someone else received from the same physician; rather, the jury's responsibility is to determine whether the plaintiff received substandard care.).

Second, the Clinical Necessity Report could strongly suggest to a lay juror that Dr. Chalhoub violated a standard of care applicable to the law of medical negligence. But, any such inference would have been impermissible. In medical negligence cases, the plaintiff is required to provide *expert testimony* to prove the treatment at issue fell below the standard of care expected of reasonably competent providers, and that such negligent care proximately caused the plaintiff's injuries. *Reams v. Stutler*, 642 S.W.2d 586, 588 (Ky. 1982). And here, despite the sweeping statements Wells made throughout trial, and yet another statement he has made in his appellate brief that the Clinical Necessity Report "showed [Dr. Chalhoub] had been implanting pacemakers unnecessarily, identifying twelve unnecessary procedures," Wells makes no pretense of arguing the Clinical Necessity Report *qualified* as standard of care evidence. Its author remains

unknown and, undisputedly, the Clinical Necessity Report never reviewed Wells's procedure.

Indeed, to the extent that Wells argues the Clinical Necessity Report was probative at all, his arguments are directed solely at the dependent or derivative claims he asserted against the Hospital Defendants. In his brief, Wells argues in relevant part as follows:

> [T]his case involved multiple claims, and evidence that might be inadmissible for one purpose does not exclude it for all purposes. *See* KRE 105(a). Indeed, Rule 407 by its very text "does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures." The Report showed that the Hospital Defendants controlled -- or had the ability to control -- oversight of cardiac procedures at SJL.
>
> Moreover, as the jury heard, the Hospital Defendants had their own, independent duty to review the necessity of cardiac procedures being performed at its facilities. As Dr. Hyde testified, conducting reviews of "clinical necessity was a hospital's job" by 2007. Yet, the Hospital Defendants neglected that duty for years, not conducting such reviews until 2012. The Report showed that the Hospital Defendants could have been performing reviews of cardiac procedures much earlier.
>
> . . .
>
> The Report was also relevant for Wells's claim that the Hospital Defendants violated the KCPA. Medical care only comes within the purview of the KCPA if it involves the "business aspect of the practice of medicine." *Barnett v. Mercy Health Partners-Lourdes*,

> *Inc.*, 233 S.W.3d 723, 730 (Ky. App. 2007). The Report shows the Hospital Defendants were involved in the "business aspect" of the pacemaker procedures.
>
> . . .
>
> As the Kentucky Supreme Court has stated, the "'means of protection' against the 'multiple admissibility dilemma,' *i.e.*, the possibility the jury might consider evidence for an improper purpose," is to request "a jury admonition limiting the scope of the evidence to its proper purpose." *St. Clair v. Commonwealth*, 140 S.W.3d 510, 559 (Ky. 2004) (citing KRE 105(a)). The Hospital Defendants never requested an admonition.

As Wells indicates, where evidence is relevant for one purpose, but not for another, a party may request an admonition from the trial court to that effect to cure any potential prejudice that might arise from its introduction. However, admonitions are only warranted if the evidence *should* be introduced; and the threshold for determining whether any evidence should be introduced is, as discussed, whether the probative value of the evidence "is substantially outweighed by the danger of undue prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, or needless presentation of cumulative evidence." KRE 403. Here, if the Clinical Necessity Report was relevant for any of the reasons urged by Wells, it was only relevant to his derivative or dependent claims against the Hospital Defendants. It was not relevant and could only have caused undue prejudice and confused the jury with respect to his medical malpractice claims against Dr. Chalhoub. This was undue prejudice and confusion

that an admonition could not have cured. *See Greene v. Commonwealth*, 244 S.W.3d 128, 138 (Ky. App. 2008) (explaining a circumstance in which the presumptive efficacy of an admonition falters is "when there is an overwhelming probability that the jury will be unable to follow the court's admonition and there is a strong likelihood that the effect of the inadmissible evidence would be devastating to the defendant[.]" (Citation omitted.))

If, as here, an allegedly negligent doctor settles all claims without an admission of fault, the plaintiff nevertheless remains obligated to prove the doctor was negligent to proceed against the hospital under any dependent or derivative tort theory, and the hospital, for the sake of its own dependent or derivative liability, remains obligated to defend the doctor. *See Adams*, 536 S.W.3d at 693-94.[10] If the offending doctor is entitled to a fair trial, the hospital placed in the position of defending that doctor is, too. The trial court abused its discretion by refusing to bifurcate these proceedings and then admitting the Clinical Necessity Report into evidence. Because this error substantially prejudiced the Hospital Defendants' right to a fair trial, a new trial is warranted on that ground.

[10] Considering this substantive point made by the Kentucky Supreme Court, we disagree with what we regard as *dicta* in the conclusion of its opinion in *Adams* (*i.e.*, *Adams*, 536 S.W.3d at 697); namely, its suggestion that bifurcation might not be necessary where, as here, the doctor accused of committing the predicate malpractice ultimately settles with the plaintiff and is dismissed from the suit.

The Hospital Defendants further argue that the Clinical Necessity Report should have been completely excluded. We disagree.

To be sure, many of the reasons Wells offers, above, regarding the probative value of the Clinical Necessity Report indicate that this evidence was mostly cumulative. For example, Wells argues it was relevant because (1) it demonstrated it would have been *feasible* for the Hospital to have performed randomized retrospective clinical reviews in the years prior to when Wells was treated in 2010; and (2) it "showed that the Hospital Defendants controlled -- or had the ability to control -- oversight of cardiac procedures at SJL." But, these were points the Hospital Defendants never contested and indeed admitted through the several witnesses they presented at trial.

Next, Wells points out that "the Hospital Defendants had their own, independent duty to review the necessity of cardiac procedures being performed at its [sic] facilities." Wells's statement is consistent with Kentucky precedent. *See, e.g., Adams*, 536 S.W.3d at 690 ("Hospitals have a duty to make sure patients receive a medically acceptable standard of care, and this duty extends to making sure qualified staff are providing the appropriate medical care"); *see also Rogers v. Kasdan*, 612 S.W.2d 133, 135 (Ky. 1981) (noting that one criteria a jury might use to decide the question of ordinary care is whether a hospital maintained "procedures appropriate and adequate to determine whether the physicians on the

staff of the hospital were carrying out their duties in a manner consistent with good medical practices.").

However, the dispute in this litigation was not *whether* the hospital owed Wells a duty of ordinary care, but the *extent* of that duty. Both sides in this dispute produced experts who provided opposing opinions about whether, *prior to when Wells received treatment in 2010,* the extent of that duty (*i.e.*, standard of care) *required* the Hospital Defendants to perform randomized prospective and retrospective clinical reviews of its physicians' procedures. The fact that the Hospital Defendants conducted a randomized, retrospective clinical review *years afterward* had no bearing upon that issue. Similarly, the feasibility of providing a level of care that would have *exceeded* the applicable standard of care does not affect what the applicable standard of care *was* at any given time. *See Adams*, 536 S.W.3d at 695 (explaining that a hospital's decision to maintain standards higher than that required by ordinary care does not "create a higher standard of care or otherwise alter its liability.").

Wells also argues the Report was relevant to his "claim that the Hospital Defendants violated the KCPA" because it "shows the Hospital Defendants were involved in the 'business aspect' of the pacemaker procedures." Wells does not elaborate further upon this statement, and it is not our prerogative to decipher his meaning. Suffice it to say that the Hospital Defendants never

contested that implanting pacemakers was a recurring procedure performed at their facility.

Additionally, to the extent that the Clinical Necessity Report assessed whether the documentation in each of the twelve case files satisfied "NCD indications," it was irrelevant. This related to the Hospital Defendants' compliance with reimbursement guidelines applicable to Medicare and Medicaid regulations; an "NCD" (short for "national coverage determinations") is a determination of whether an item or service is covered nationally under Medicare. *See* 42 Code of Federal Regulations (C.F.R.) § 405.1060(a)(1). Congress has explicitly rejected the notion that such regulations establish any duty or standard of care owed to a patient in negligence or medical malpractice actions.[11]

Nevertheless, the Clinical Necessity Report was at least relevant to the extent of its commentary regarding the clinical indications of Dr. Chalhoub's twelve referenced procedures. *See Adams*, 536 S.W.3d at 690 (noting that theories

[11] *See, e.g.*, 42 United States Code (U.S.C.) § 18122(1), providing in relevant part: "[T]he development, recognition, or implementation of any guideline or other standard under any Federal health care provision shall not be construed to establish the standard of care or duty of care owed by a health care provider to a patient in any medical malpractice . . . action or claim." This broad construction of Federal law applies to Medicare and Medicaid regulations and guidelines, and thus includes "NCD indications," which are reimbursement guidelines promulgated under the authority of 42 U.S.C. 1395 *et seq*. *See* 42 U.S.C. § 18122(2)(A), providing in relevant part that in the context of subsection (1), "The term "Federal health care provision" means any provision of . . . title XVIII or XIX of the Social Security Act (42 U.S.C. 1395 *et seq.*, 42 U.S.C. 1396 *et seq*.)."

based upon negligent credentialing "*apply peer review statutes*[12] and find that hospitals have a direct duty to grant and continue staff privileges only to competent doctors while also having a duty to remove incompetent doctors." (Emphasis added.)) When Dr. Varga discussed the purpose of the Clinical Necessity Report, he testified that *apart* from ensuring regulatory compliance to avoid a Medicaid or Medicare reimbursement action, the purpose of the external peer review was "making sure that patient care is actually -- is actually meeting the standards we look for[.]"

Here, the jury was entitled to believe Wells's expert, Dr. Hyde, who testified that as part of their supervisory duties the Hospital Defendants were required to regularly perform this type of external peer review process as early as 2007. If the jury believed Dr. Hyde, they were likewise entitled to infer from the Clinical Necessity Report that, had the Hospital Defendants been performing this type of external peer review process as early as 2007, they would more likely than

[12] As indicated, the Clinical Necessity Report was generated by and resulted from the process of *peer review*. Such reports have long been recognized as discoverable in these types of proceedings. *See, e.g., Pauly v. Chang*, 498 S.W.3d 394, 408 (Ky. App. 2016). That aside, during the pendency of these appeals, the General Assembly prospectively amended KRS 311.377, the statute applicable to the peer review process, to severely restrict the discovery and use of such reports as evidence in these types of proceedings. *See* KRS 311.377(2).

not have been alerted to concerns with the level of care Dr. Chalhoub provided to his patients *before* he treated Wells.[13]

In short, the Hospital Defendants are entitled to a new trial. The new trial must be bifurcated. Wells's claims against Dr. Chalhoub must be tried first. If a jury finds in Wells's favor on those claims, Wells's claims against the Hospital Defendants shall be tried second; then, and only then, may Wells utilize the Clinical Necessity Report consistently with what is set forth above.

2. ***The OIG report***

On March 4, 2011, the Cabinet for Health and Family Services, Office of Inspector General ("OIG"), completed a week-long audit of medical records at Saint Joseph Hospital's London facility to assess the facility's compliance with federal certification requirements and reimbursement guidelines relating to participation in Medicaid and Medicare. Afterward, by way of a March 18, 2011 report, the OIG notified the Hospital Defendants of the result of its investigation. On the first page of the report, the OIG explained in relevant part:

> It was determined that the hospital was in substantial compliance with federal certification requirements; however, standard level deficiencies were identified.

[13] The Hospital Defendants assert the Clinical Necessity Report constituted inadmissible evidence of a "subsequent remedial measure" because they themselves relied upon it as a basis for *firing* Dr. Chalhoub. We disagree. The trial court prohibited any mention at trial of Dr. Chalhoub's termination. Moreover, Wells produced expert testimony supporting that the Clinical Necessity Report demonstrated not remediation, but the Hospital Defendants' compliance with a pre-existing supervisory duty.

> Enclosed is the Statement of Deficiencies (CMS-2567) identified during the complaint investigation. A plan of correction is not required to be submitted to our office.
>
> As to the "deficiencies" indicated in the report, the accompanying

CMS-2567 described them in relevant part as follows:

> A000 INITIAL COMMENTS
>
> A complaint investigation (KY15678) was initiated on February 23, 2011 and concluded on March 4, 2011. The allegation was substantiated with standard level deficient practice identified.
>
> A 658 482.30(f) REVIEW OF PROFESSIONAL SERVICES
>
> The committee must review professional services provided to determine medical necessity and to promote the most efficient use of available health facilities and services.
>
> This STANDARD is not met as evidenced by:
> Based on interview, policy review, and record review, it was determined the facility failed to review professional services provided to determine medical necessity and to promote the most efficient use of available health facilities and services.
>
> The findings include:
>
> A review of the procedure for Cardiac Catheterizations revealed the pre-cardiac catheterization orders and the pre-cardiac catheterization history and physical were the only documents the hospital used to ensure medical necessity for a cardiac catheterization. However, there was no evidence of utilization review for the medical necessity for those professional services.

> A review of the policy and procedure for Utilization Review revealed the policy/procedure did not include a review of medical necessity for outpatient professional services.
>
> Record review revealed that between January 1, 2010 and December 31, 2010, the facility conducted 3,667 cardiac catheterizations to include both inpatient and outpatient. There was no evidence the facility reviewed these professional services for the medical necessity of outpatient services.

Despite the OIG's admonition that the Hospital Defendants were not required to submit a plan of correction, the Hospital Defendants responded to the OIG Report by providing one. In their plan, they stated:

> (1) Corrective action: The Utilization Review Plan will be reviewed and revised as needed to ensure a description of the process for review of professional services, including medical necessity, for care provided to both inpatient and outpatients at Saint Joseph-London.
> Complete By: The plan will be updated by April 30th, 2011 and presented for Committee approval in May 2011.
> Responsible Party: Director of Quality and Risk Management
> Monitoring: The UR plan will be reviewed at least annually and updated as needed.
>
> (2) Corrective Action: The Utilization Review (UR) Committee will be re-educated on the 482.30 Conditions of Participation requirements and committee responsibilities which include review of professional services.
> Complete By: Education will be completed by May 30, 2011

Responsible Party: Chair of the UR Committee and the Director of Quality and Risk Mgmt.
Monitoring: Education will be provided to new members during the committee orientation process and to the entire committee when changes occur. A review of committee responsibilities will be completed when the plan is reviewed.

(3) Corrective Action: Ensure that professional services, including but not limited to cardiac catheterizations, are reviewed quarterly by the UR Committee. Improve data flow as appropriate.
Completed By: Review will be completed by May 30, 2011
Responsible Party: Chair of the MSQIC/UR Committee and the Director of Quality.
Monitoring: Quarterly committee minutes will demonstrate review of professional services.

(4) Corrective Action: Validation of the pre-procedure medical necessity screening will be performed on a random number of cardiac diagnostics, including cardiac catheterizations. This will be conducted through the medical staff quality review process and outcomes reported to the UR Committee. The current practice of committee review for any concern brought forward, including medical necessity, will continue.
Completed By: The process of validation will be in place by May 30th, 2011
Responsible Party: Cardiovascular Service Line.
Monitoring: Quarterly committee minutes will demonstrate review of professional services.

(5) Corrective Action: An evaluation of the process of staff validation of medical necessity documentation pre-catheterization will be conducted. The facility will also evaluate process of MD notification and issuance of an ABN if necessary.
Completed By: The evaluation will be completed by April 30th, 2011

> Responsible Party: The Director of the Cardiac Catheterization Lab
> Monitoring: The manager/director will collect data on compliance of with process of staff validation and will be reported through the Performance Improvement Steering Committee quarterly.
>
> Clarification
> UR Committee reviews medical necessity and utilization of cardiac procedures.
>
> Clarification
> Hospital's patient access department performs verification/review of procedures in the outpatient setting for medical necessity.
>
> The Hospital Defendants produced the OIG Report during discovery.

Thereafter, Wells sought to introduce it as substantive proof in support of his negligence claims. In his brief, Wells summarizes the arguments he offered below regarding why he believed the OIG Report was relevant, contending in pertinent part:

> [A]s with the Clinical Necessity Report, the OIG Report shows the Hospital Defendants knew prior to Wells's procedure they had an obligation to review for medical necessity and if reviews had taken place, they would have discovered cardiologists were performing unnecessary cardiac procedures. The OIG Report was directly relevant to the Hospital Defendants' independent duty of oversight and to its involvement in the "business aspect of the practice of medicine" for purposes of the KCPA claim.[14] *Barnett v. Mercy Health Partners-*

[14] As with the Clinical Necessity Report, Wells does not elaborate further upon how the OIG Report demonstrated the Hospital Defendants were involved in the "business aspect of the

> *Lourdes, Inc.*, 233 S.W.3d 723, 730 (Ky. App. 2007). The OIG Report showed that cardiologists at SJL had the *opportunity* to perform unnecessary cardiac procedures because of a lack of oversight. *See* KRE 404(b)(1). The Hospital Defendants also argue the OIG Report is unduly prejudicial. But "even relevant evidence has the capacity to be prejudicial." [Thorpe v. Commonwealth, 295 S.W.3d 458, 462 (Ky. App. 2009) citing] *Ford Motor Co. v. Fulkerson*, 812 S.W.2d 119, 127 (Ky. 1991).

The Hospital Defendants objected, arguing the OIG Report had no bearing upon whether they had violated any standard of care applicable to common law negligence in general or to Wells in particular; the OIG Report was otherwise irrelevant because it only addressed heart catheterizations (a procedure Wells never underwent); and because the OIG Report did not address Wells's pacemaker procedure, or even refer to Dr. Chalhoub. The trial court overruled their objection and, thereafter, permitted Wells to introduce the OIG Report into evidence and to use it throughout trial for the purposes Wells set forth in his argument, above. The Hospital Defendants argue the trial court erred in doing so. We agree.

The fundamental error of Wells's argument and the trial court's determination that the OIG Report qualified as relevant evidence concerns the phrase "medical necessity" -- a term Wells and the trial court appear to have equated with a negligence *per se* standard. Namely, Wells contended that the

---

practice of medicine" for the purpose of his KCPA claim. As noted, however, the Hospital Defendants have never contested that implanting pacemakers was a recurring procedure performed at their facility.

Hospital Defendants had an obligation to "review professional services provided to determine medical necessity and to promote the most efficient use of available health facilities and services" (as indicated in the OIG report) as part of their "independent duty of oversight," and that had they done so in a non-negligent fashion "they would have discovered cardiologists were performing unnecessary cardiac procedures."

The term "medical necessity," as used in the context of the OIG Report, does not mean what Wells assumes it means. As used in that context, it was an administrative term of art applicable only to the federal regulatory scheme of Medicaid. Subject to federal law, Medicaid regulations authorize state governments to define what qualifies as "medical necessity,"[15] and the term is utilized in conjunction with assessing whether Medicaid must reimburse a medical provider for the cost of a given health care service or item. *See* 907 Kentucky Administrative Regulation (KAR) 3:130 § 2.[16] Thus, "medical necessity" is not a

[15] *See* 42 C.F.R. 440.230(d) (expressly permitting participating states to "place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.")

[16] 907 KAR 3:130 § 2 provides:

> Medical Necessity Determination.
> (1) The determination of whether a covered benefit or service is medically necessary shall:
>
> > (a) Be based on an individualized assessment of the recipient's medical needs; and

standard created by the Federal Government to ensure adequate care of patients or adequate supervision of physicians. Instead, the term relates to meeting administrative criteria for the sole purpose of obtaining financial reimbursement for care provided to patients under the Medicare and Medicaid statutes.

> (b) Comply with the requirements established in this paragraph. To be medically necessary or a medical necessity, a covered benefit shall be:
>
> > 1. Reasonable and required to identify, diagnose, treat, correct, cure, palliate, or prevent a disease, illness, injury, disability, or other medical condition, including pregnancy;
> > 2. Appropriate in terms of the service, amount, scope, and duration based on generally-accepted standards of good medical practice;
> > 3. Provided for medical reasons rather than primarily for the convenience of the individual, the individual's caregiver, or the health care provider, or for cosmetic reasons;
> > 4. Provided in the most appropriate location, with regard to generally-accepted standards of good medical practice, where the service may, for practical purposes, be safely and effectively provided;
> > 5. Needed, if used in reference to an emergency medical service, to exist using the prudent layperson standard;
> > 6. Provided in accordance with early and periodic screening, diagnosis, and treatment (EPSDT) requirements established in 42 U.S.C. 1396d(r) and 42 C.F.R. Part 441 Subpart B for individuals under twenty-one (21) years of age; and
> > 7. Provided in accordance with 42 C.F.R. 440.230.
>
> (2) The department shall have the final authority to determine the medical necessity and clinical appropriateness of a covered benefit or service and shall ensure the right of a recipient to appeal a negative action in accordance with 907 KAR 1:563.

In other words, when the OIG used the phrase "medical necessity" in the context of its report, it was *not* citing a violation of any standard applicable or relevant to common law negligence or malpractice in Kentucky. *See infra*, note 10 (explaining Medicare and Medicaid regulations and guidelines are not relevant to common law negligence and malpractice actions); *see also Young v. Carran*, 289 S.W.3d 586, 589 (Ky. App. 2008) (explaining claims of negligence in Kentucky cannot be based upon violations of federal statutory or regulatory law).

Taken out of context as it was, however, the OIG Report lent the appearance of governmental support to Wells's theory that the Hospital Defendants *violated* the standard of care applicable to his negligence claims. Whether the Hospital Defendants violated the standard of care applicable to Wells's negligence claims was a primary point of dispute throughout trial; both sides produced expert witnesses who gave opposing testimony on that subject; and Wells's use of the OIG Report improperly bolstered the credibility of his evidence and undermined the credibility of any evidence to the contrary.

In short, the trial court erred by allowing Wells to introduce the OIG Report into evidence. Because this error substantially prejudiced the Hospital Defendants' defense of this matter, a new trial is also warranted on this basis.

As discussed, the jury found in Wells's favor regarding what he alleged were the Hospital Defendants' KCPA violations. The record is unclear

regarding the specifics of Wells's KCPA claim, or what portion (if any) of his damages represented a recovery relating to this claim.[17] However, the Hospital Defendants argue that the erroneous admission of those documents warrants a new trial of every claim not properly disposed of by directed verdict; and Wells indicates throughout his brief that the "Clinical Necessity Report" and "OIG Report" were instrumental in proving his KCPA claim. Accordingly, Wells's KCPA claim must also be retried.

III. PUNITIVE DAMAGES (Cross-Appeal No. 2017-CA-000081-MR)

The issue presented in Wells's cross-appeal turns upon the interpretation of CR 8.01(2), which provides:

> In any action for unliquidated damages the prayer for damages in any pleading shall not recite any sum as alleged damages other than an allegation that damages are in excess of any minimum dollar amount necessary to establish the jurisdiction of the court; provided, however,

[17] As discussed, the circuit court ultimately entered judgment in favor of Wells for amounts representing: (1) medical expenses; (2) pain and suffering; and (3) punitive damages. The KCPA, however, is not a vehicle for recovering medical expenses, pain and suffering, or punitive damages in contexts, such as this, where those types of damages would otherwise be the subject of a common law action for medical malpractice. *See, e.g., Barnett v. Mercy Health Partners-Lourdes, Inc.*, 233 S.W.3d 723, 730 (Ky. App. 2007) (explaining "[n]egligently performing surgery or providing treatment that is below the standard of care and failing to inform a patient of such actions are not included in the business aspect of the practice of medicine. Therefore, they are not covered under the [KCPA].); *see also Ford Motor Company v. Mayes*, 575 S.W.2d 480, 487 (Ky. App. 1978) (explaining the KCPA does not expand the right to claim punitive damages but does not limit the right to punitive damages where one previously existed.) Wells also argued he was entitled to attorney's fees due to the KCPA, but the circuit court denied his request. Given that Wells offered no evidence that he relied upon any advertising from the hospital defendants in his decision to seek treatment at their facility, it is unclear what his KCPA claim was actually based upon.

> that all parties shall have the right to advise the trier of fact as to what amounts are fair and reasonable as shown by the evidence. *When a claim is made against a party for unliquidated damages, that party may obtain information as to the amount claimed by interrogatories. If this is done, the amount claimed shall not exceed the last amount stated in answer to interrogatories; provided, however, that the trial court has discretion to allow a supplement to the answer to interrogatories at any time where there has been no prejudice to the defendant*.

(Emphasis added).

As this Court has noted previously,

> The Supreme Court has consistently held that the purpose of CR 8.01(2) is to put the defendant on notice of the amount of damages at stake and that the "shall not exceed" language of the rule is mandatory. *Thompson v. Sherwin Williams Co., Inc.*, 113 S.W.3d 140, 143 (Ky. 2003); *see also LaFleur v. Shoney's, Inc.*, 83 S.W.3d 474, 480 (Ky. 2002); *Fratzke v. Murphy*, 12 S.W.3d 269, 271 (Ky. 1999); *Burns v. Level*, 957 S.W.2d 218, 221 (Ky. 1997); *Nat'l Fire Ins. Co. v. Spain*, 774 S.W.2d 449, 451 (Ky. App. 1989). If the plaintiff responds to a CR 8.01(2) interrogatory and does not supplement the response, the plaintiff's recovery is limited to the amount stated in the last response; if the plaintiff does not respond to the interrogatory, the plaintiff is not entitled to an instruction on unliquidated damages. *Id*.

Greer v. Hook, 378 S.W.3d 316, 319 (Ky. App. 2012).

Here, by way of background, Wells responded to a CR 8.01(2) request from the Hospital Defendants by submitting a statement regarding the total amount of damages he was seeking in his action. He requested $22,876.94 for claimed

medical expenses; $500,000 for past pain and suffering; $750,000 for future pain and suffering; $5,000,000 for, in his words, "Punitive Damages (if the Court requires a cap);" and he then listed his "total" as $6,272,876.94.

After the close of the evidence and outside the presence of the jury, the parties discussed the specifics of the jury instructions. At that time, Wells informed the trial court that he believed punitive damages do not qualify as "unliquidated damages" within the meaning of CR 8.01(2); thus, notwithstanding his response to the Hospital Defendants' CR 8.01(2) request, Wells argued the jury should be permitted to award him an amount of punitive damages in excess of $5 million. The Hospital Defendants objected. Ultimately, the trial court decided to reserve judgment on this dispute until after the jury returned its verdict. Doing so, it explained, would allow the parties to avoid briefing an issue that could possibly become moot. In the interim, the trial court determined the instructions it would submit for the jury's consideration would not confine the jury to any specific cap associated with a potential award of punitive damages.[18]

[18] The entire substance of this discussion between the trial court and opposing parties was as follows:

> DEFENSE COUNSEL: Plaintiff filed an amended itemization of damages, um, stating that they were requesting $5,000,000 in punitive damages. I'm okay with, with no parenthetical under the monetary line as long as we're clear as I think the law provides that they're limited by their *Fratzke* compliance.
>
> COURT: Mr. Poppe?

Ultimately, the jury awarded Wells a total of $24,785.94 for his claimed medical expenses; $500,000 for past pain and suffering; $750,000 for future pain and suffering; and $20,000,000 representing punitive damages, for a total of $21,274,785.94. The parties then briefed and argued the issue of whether punitive damages qualified as unliquidated damages within the meaning of CR 8.01(2). The trial court determined it did; it accordingly reduced Wells's total

---

> WELLS'S COUNSEL: Yes, your honor. We did that out of an abundance of caution. We don't think that the "not to exceed" number applied to punitive damages. We've never addressed that issue with the court, so we always, until we find out how a court feels about it, we always list a "not to exceed" number, but we think that we should be permitted to argue that it's up to the discretion of the jury, the amount to award.
>
> COURT: Alright. Um --
>
> DEFENSE COUNSEL: There's, there's nothing under the law that exempts the punitive damages. They're required to state what the damages are that they're seeking. That would apply to punitives just as surely as it would apply to compensatories.
>
> WELLS'S COUNSEL: I think that CR 8.01 and *Fratzke* apply to compensatory damages and by their nature punitive damages are not compensatory.
>
> COURT: Well, I understand your argument Mr. Hume. I'm inclined to agree with you. But, you know, if we get here, I think this is a matter that sounds like it probably needs to be briefed and argued post-verdict.
>
> DEFENSE COUNSEL: Um, I'm not sure. Let me see if I'm understanding the court's ruling. Um, are you deferring a ruling as to whether they are bound by their itemization of damages with respect to punitives?
>
> COURT: What I'm going to is, I'm not going to put a "not to exceed" figure in the instructions. But if there is a verdict, if there is a punitive damages award, and if it exceeds what you've indicated, I'll hear you both out on whether or not it's limited thusly, okay?

award to $6,274,785.94; and this cross-appeal followed. Wells now raises three arguments regarding why, in his view, the trial court erred in reducing his award.

First, Wells argues that if punitive damages qualify as unliquidated damages within the meaning of CR 8.01(2), his discussion with the trial court, wherein he stated he wished for unliquidated damages in excess of $5 million, qualified as a timely supplement to his prior disclosure within the meaning of the rule and, accordingly, should have entitled him to keep his initial award.

In making this argument, however, Wells misreads the plain language of CR 8.01(2). Issues of timeliness aside, the rule requires the disclosure of a specific number to serve as a maximum amount of unliquidated damages (*i.e.*, an "amount claimed"). Wells's statement to the trial court, which was effectively that he wished for *whatever amount the jury was willing to award him*, does not comply with the rule; thus, it could not have qualified as a supplement to his prior disclosure.

Second, Wells argues the Hospital Defendants waived any right to have his award conform to his CR 8.01(2) disclosure because they allowed the jury to consider instructions that did not state that punitive damages could only be, at most, $5 million.

Wells is incorrect. A "waiver" requires proof of a knowing and voluntary surrender or relinquishment of a known right. *Pangallo v. Kentucky Law*

Enforcement Council, 106 S.W.3d 474, 479 (Ky. App. 2003). Here, nothing of the sort occurred. The Hospital Defendants only permitted the jury to be instructed in the manner stated above upon assurance from the trial court that it would have no bearing upon whether Wells was bound by this CR 8.01(2) disclosure.

Lastly, Wells argues punitive damages do not qualify as unliquidated damages within the meaning of CR 8.01(2). We disagree. The Kentucky Supreme Court explained in *Osborne v. Keeney*, 399 S.W.3d 1, 23, n. 92 (Ky. 2012), that "the amount of punitive damages sought by Osborne on any subsequent retrial is limited to the amount claimed in any pretrial itemization required under CR 8.01(2)."[19]

Accordingly, while our disposition of the Hospital Defendants' appeal (2016-CA-001919-MR) necessitates vacating the trial court's award in favor of Wells in its entirety, we affirm the trial court to the extent that it determined Wells's request for punitive damages was subject to and must conform with his CR

[19] This Court has on several occasions likewise declared that punitive damages are unliquidated damages. *See Chesapeake Appalachia, LLC v. Collins*, 2011–CA–002069–MR, 2013 WL 645913 at *7 (Ky. App. February 22, 2013); *Pickett v. Shields*, 2003–CA–000744–MR, 2005 WL 3246838 at *1 (December 2, 2005) ("We believe that punitive damages are by their very nature unliquidated and, thus, constitute unliquidated damages within the meaning of CR 8.01(2)."); *Village Campground v. Liberty Bank*, 2007–CA–001454–MR, 2008 WL 4998478 at *5, n.3 (November 26, 2008) ("While we found no published Kentucky case defining 'unliquidated damages,' we note that they are defined in Black's Law Dictionary as '[d]amages that cannot be determined by a fixed formula and must be established by a judge or jury.' Black's Law Dictionary (8th Ed. 2004). Punitive damages would seem to fit squarely within that definition."). We cite these unpublished cases pursuant to CR 76.28(4)(c).

8.01(2) disclosure. Thus, on any subsequent retrial, his unliquidated damages are likewise limited. *See Osborne*, 399 S.W.3d at 23, n. 92.

CONCLUSION

With respect to Appeal No. 2016-CA-001919-MR, we REVERSE and REMAND for further proceedings not inconsistent with this opinion.

With respect to Cross-Appeal No. 2017-CA-000081-MR, we AFFIRM IN PART and VACATE IN PART as discussed.

ALL CONCUR.

BRIEF FOR APPELLANTS/CROSS-APPELLEES:

Bradley R. Hume
Chad O. Propst
B. Todd Thompson
Joey A. Wright
Louisville, Kentucky

BRIEF FOR APPELLEE/CROSS-APPELLANT:

Hans G. Poppe
Scarlette R. Burton
Kirk A. Laughlin
Kathleen Coffey
Kevin C. Burke
Jamie K. Neal
Louisville, Kentucky

ORAL ARGUMENT FOR APPELLANTS/CROSS-APPEELLEES:

Bradley R. Hume
Louisville, Kentucky

ORAL ARGUMENT FOR APPELLEE/CROSS-APPELLANT:

Hans G. Poppe
Louisville, Kentucky