### 2022 PA Super 19

LIBERTY MUTUAL GROUP, INC., LIBERTY MUTUAL INSURANCE COMPANY, AMERICAN STATES INSURANCE COMPANY, COLORADO CASUALTY COMPANY, EMPLOYERS INSURANCE COMPANY OF WAUSAU, EXCELSIOR INSURANCE COMPANY, LIBERTY INSURANCE CORPORATION, LIBERTY MUTUAL FIRE INSURANCE COMPANY, LIBERTY MUTUAL **INSURANCE** COMPANY/CONSOLIDATED INSURANCE COMPANY, LIBERTY NORTHWEST INSURANCE CORPORATION, LM INSURANCE CORPORATION, PEERLESS INDEMNITY INSURANCE COMPANY, PEERLESS INSURANCE COMPANY, AND SAFECO INSURANCE COMPANY OF ILLINOIS

IN THE SUPERIOR COURT OF PENNSYLVANIA

No. 3357 EDA 2019

Appellants

٧.

700 PHARMACY, LLC, INSIGHT PHARMACEUTICAL SOLUTIONS, LLC, D/B/A INSIGHT PHARMACY, UNITED PHARMACY SERVICES, LLC, D/B/A UNITED PHARMACY, ARMOUR PHARMACEUTICAL SOLUTIONS, LLC, D/B/A ARMOUR PHARMACY, OMNI PHARMACY SERVICES, LLC, D/B/A OMNI PHARMACY, EMPIRE PHARMACY SERVICES, LLC, D/B/A EMPIRE PHARMACY, MEDARBOR, LLC, D/B/A MEDARBOR PHARMACY, 1ST CHOICE PHARMACY, LLC, MEDICINE WORX, LLC, PHILLIP SHIN, MIROSLAV KESIC, MANDEEP GILL, RISHIN A. PATEL, N.D., JASON CHONG, MINA NAKHLA,

eliants

STEVEN KATSARAKES, YOUNG HOON GIM, NINA LUU, GRACJA OSINSKA, CHRISTINE VU, HAJIRA EBADY, JULIETTA LEUNG, MITESH K. PATEL, M.D., MITESWAR PUREWAL, M.D., SHAILEN JALALI, M.D., MARK AVART, D.O., LAURA SECZECH, PA-C, THERESA DIJOSEPH, PA-C, AVNER R. GRIVER, M.D., DENNIS W. IVILL, M.D., JONAS JOAGUIN GOPEZ, M.D., JOSEPH DAVID PAZ, D.O., RONALD LUBER, D.O., THOMAS SKEEHAN, M.D., UPLEKH PUREWAL, M.D., SCOTT EPSTEIN, M.D., MARK ESKANDER, M.D., CORY HAWLEY, D.P.M., RONALD B. LINCOW, D.O., GERALD E. SWORKIN, D.O., STEVEN VALENTINO, D.O.

Appeal from the Order Entered September 13, 2019 In the Court of Common Pleas of Philadelphia County Civil Division at No(s): No. 170901541

BEFORE: STABILE, J., NICHOLS, J., and COLINS, J.\*

OPINION BY NICHOLS, J.:

#### FILED FEBRUARY 1, 2022

Appellants, Liberty Mutual Group, Inc., and its related companies, underwriters, and subsidiaries, appeal from the order granting the motion for summary judgment filed by Appellees, a group of pharmacies, pharmacists, physicians, physician assistants, and lay investors, and entering judgment in favor of Appellees on all claims. We affirm.

We adopt the trial court's thorough summary of the facts underlying this matter. **See** Trial Ct. Order & Op., 9/13/19, at 2-9. By way of brief background, we note that Appellants filed a complaint against Appellees

- 2 -

<sup>\*</sup> Retired Senior Judge assigned to the Superior Court.

alleging fraud, insurance fraud, aiding and abetting, and unjust enrichment.<sup>1</sup> Therein, Appellants claimed that Appellees had created an unlawful business structure under which doctors prescribed topical compound pain creams to patients who had been injured at work or in automobile accidents. The patients then filled the prescriptions at pharmacies in which the doctors had a financial interest. Appellees alleged that the compound pain creams were formulated by pharmacies for the sole purpose of generating a profit and that Appellee doctors were receiving unlawful kickbacks.

Specifically, Appellants claimed:

[Appellees] engaged in illegal compounding by producing and dispensing vast quantities of the fraudulent compounded creams in set formulations, in violation of federal and Pennsylvania state regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities, rendering them ineligible to receive reimbursement for their services;

The fraudulent compounded creams were provided pursuant to predetermined fraudulent treatment protocols designed solely to financially enrich [Appellees], rather than to treat or otherwise benefit the patients who purportedly received them;

[Appellees] participated in illegal, collusive relationships in which licensed physicians prescribed fraudulent compounded creams in exchange for unlawful kickbacks paid by the Pharmacy [Appellees];

[Appellees] made false and fraudulent statements and/or representations to [Appellants] by submitting, or causing to be submitted for payment, invoices for fraudulent compounded

\_

<sup>&</sup>lt;sup>1</sup> Appellants also alleged that Appellees committed insurance fraud under the Pennsylvania Workers' Compensation Act, 77 P.S. § 1039.3(b), and that Appellees violated the disclosure provision for self-referrals under 35 P.S. § 449.22. However, the trial court dismissed these counts after Appellees filed preliminary objections.

creams. These invoices were provided pursuant to invalid, duplicitous, and formulaic prescriptions; and

[Appellees] made false and fraudulent misrepresentations to [Appellants] concerning the maximum permissible charges for the fraudulent compounded creams allegedly provided to the patients in order to induce [Appellants] to reimburse [Appellees] for benefits to which they were not entitled.

Am. Compl., 11/6/17, at ¶ 33(i)-(v) (formatting altered).

Appellees subsequently moved for summary judgment, arguing that Appellants had neither "presented nor produced any evidence to support the allegations in the [c]omplaint." **See** 700 Pharmacy Defendants' Mot. for Summary Judgment, 5/9/19, at 1.<sup>2</sup> Specifically, Appellees explained:

Rather than produce witnesses and other evidence to support their claims, [Appellants] have instead failed to produce any fact witnesses, or any other evidence, to support the assumptions underlying their complaint and their experts' reports.

[T]he universe of testimony and documents exchanged during discovery establishes that [Appellee] pharmacies (1) dispense a wide range of medications, including compound medications, (2) are licensed and operate within the boundaries of state and federal law, (3) have physicians with minority ownership consistent with state and federal law, (4) paid each owner (whether or not a physician) profits based solely upon their percentage of ownership, *i.e.*, there were no kickbacks, (5) did not require physician owners to prescribe any medications through the pharmacies, and (6) operated legally even according to William Welch, who has overseen [Appellants'] investigation since 2014.

In filing their motions for summary judgment, individual defendants incorporated and fully adopted the arguments raised by other defendants in this case. **See** Pa.R.Civ.P. 1019(g) (stating that "[a]ny part of a pleading may be incorporated by reference in another part of the same pleading or in another pleading in the same action"). Therefore, for purposes of brevity, we

cite only one of Appellees' motions.

*Id.* at 2. Further, Appellees claimed that the trial court lacked subject matter jurisdiction because Appellants failed to join indispensable parties, including at least two doctors who had received dividends from the pharmacies after prescribing compound pain creams in 2016. *Id.* at 31-32.

In response, Appellants argued:

The majority of the key evidence in this case comes not from [Appellants,] but from discovery obtained from [Appellees] in the form of written documents, including tax documentation, and deposition testimony, which has revealed a complex scheme perpetrated by [Appellees] whereby multiple pharmacies were created to facilitate and promote submission to [Appellees] of fraudulent claims for compounded medications using pre-printed, non-individualized prescriptions and letters of medical necessity. This generated huge profits for [Appellee pharmacies] and insiders as [Appellee doctors] received huge kickbacks disguised as dividends and other payouts based on volume of prescribing or filling of fraudulent scripts for topical pain cream, all to the detriment of [Appellants] and the public at large by [Appellees'] billing the insurers thousands of dollars per tube of cream and raking in millions of dollars in profit as a result.

Appellees' Opposition to 700 Pharmacy's Mot. for Summary Judgment, 6/20/19, at 48. Further, Appellees asserted that there was "[e]vidence of [the] fraudulent scheme" in (1) Appellees' letters of medical necessity, which misrepresented that the prescriptions were specifically tailored to the needs of each patient; (2) the characterization of the prescription pain creams as compound drugs under Section 503A of the Food, Drug and Cosmetic Act (FDCA),<sup>3</sup> and (3) the illegal structure of Appellees' business. *Id.* at 49-53.

<sup>&</sup>lt;sup>3</sup> 21 U.S.C. § 353a.

Ultimately, the trial court granted summary judgment in favor of Appellees and dismissed Appellant's amended complaint. **See** Trial Ct. Order & Op., 9/13/19, at 1. The trial court noted that Appellants "failed to produce evidence to show that [Appellees] made material misrepresentations" to support their claim of fraud. **Id.** at 18. With respect to the letters of medical necessity, the trial court found that it did not have jurisdiction to consider whether those letters contained misrepresentations about the necessity of each patient's medical treatment outside of the Workers' Compensation Act. **Id.** at 11-12. Further, the court concluded that the prescription pain creams met the definition of a "compound drug" under Section 503A of the FDCA and that Appellees' business structure was legal. **Id.** at 12-18. Finally, the trial court concluded that there was no evidence to support a claim for unjust enrichment and that, because Appellants failed to prove an underlying tort by Appellees, their aiding and abetting claim must also fail. **Id.** at 18-19.

Appellants filed a timely notice of appeal and a court-ordered Pa.R.A.P. 1925(b) statement. The trial court issued a Rule 1925(a) adopting the legal analysis set forth in its order and opinion granting summary judgment.<sup>4</sup>

On appeal, Appellants raise multiple issues, which we have reordered as follows:

<sup>&</sup>lt;sup>4</sup> On September 23, 2019, the trial court issued a revised opinion which included an additional footnote citing to an exhibit. However, for purposes of clarity, and because that modification does not affect the court's ruling or our analysis, we will refer to the trial court's original opinion in this Court's opinion.

- 1. Whether the [trial] court had subject matter jurisdiction when [Appellants] did not sue all of the owners of the limited liability companies operating the pharmacies?
- 2. Whether the [trial court] had jurisdiction to determine whether there were any misrepresentations contained in the letters of medical necessity?
- 3. Whether there was sufficient evidence of misrepresentations contained in the letters of medical necessity, regarding the compound pain creams prescribed, and concerning the legality of the business structure of the pharmacies, to raise genuine issues of material fact and preclude the entry of summary judgment on the common law and statutory insurance fraud claims?
- 4. Whether there was sufficient evidence presented to support a claim for unjust enrichment and to preclude the entry of summary judgment on that claim?
- 5. Whether the claim for aiding and abetting would survive a motion for summary judgment without the predicate common law and statutory insurance fraud?

Appellant's Brief at 2-4.

# **Subject Matter Jurisdiction**

Appellants argue that the trial court erred in concluding that it lacked subject matter jurisdiction based on Appellants' failure to join indispensable parties. Specifically, Appellants contend:

[T]here is no subject matter jurisdiction issue presented here. The pharmacies were limited liability companies that had the capacity to sue and be sued as entities. Further, the members or managers had no personal liability except to the extent of their personal participation in some misconduct. The remaining members or managers are not indispensable parties. The courts can fashion appropriate relief without the necessity of dragging every member of each limited liability company into the case.

Appellants' Brief at 21.

Appellees respond that Appellants failed to join indispensable parties, including "physicians and owners who were part of the allegedly fraudulent plot." Appellees' Brief at 62. In support, Appellees argue that "Appellants alleged a broad conspiracy in the prescription and dispensing of medication, and in the creation of the pharmacies. Consequently, Appellants' failure to name these parties was a fatal defect warranting summary judgment." *Id.* at 62-63.

Whether a court has subject matter jurisdiction presents a question of law, for which our standard of review is *de novo* and the scope of our review plenary. *Mazur v. Trinity Area Sch. Dist.*, 961 A.2d 96, 101 (Pa. 2008). Notably, "lack of subject-matter jurisdiction is a non-waivable issue, which may be raised by the parties at any stage of the proceedings and can be raised by the appellate courts *sua sponte*." *Weir v. Weir*, 631 A.2d 650, 653 (Pa. Super. 1993) (citations omitted and formatting altered).

"[A] party is indispensable 'when his or her rights are so connected with the claims of the litigants that no decree can be made without impairing those rights." *City of Phila. v. Commonwealth*, 838 A.2d 566, 581 (Pa. 2003) (citation omitted). "If no redress is sought against a party, and its rights would not be prejudiced by any decision in the case, it is not indispensable with respect to the litigation." *Grimme Combustion, Inc. v. Mergantime Corp.*, 595 A.2d 77, 81 (Pa. Super. 1991) (citation omitted).

This Court has held that trial courts must weigh the following considerations in determining if a party is indispensable to a particular

litigation: (1) whether absent parties have a right or an interest related to the claim; (2) if so, the nature of that right or interest, (3) whether that right or interest is essential to the merits of the issue, and (4) whether justice can be afforded without violating the due process rights of absent parties. *Martin v. Rite Aid of Pa., Inc.*, 80 A.3d 813, 814 (Pa. Super. 2013). "In determining whether a party is indispensable, the basic inquiry remains 'whether justice can be done in the absence of a third party." *Pa. State Educ. Ass'n v. Commonwealth*, 50 A.3d 1263, 1277 (Pa. 2012) (*PSEA*) (citation omitted).

Here, the trial court did not identify the parties that were indispensable to the instant matter, nor did the court explain why those individuals were necessary to resolve Appellants' claims against Appellees. However, as noted previously, Appellees' motion for summary judgment claimed that Dr. Bruce Levin and Dr. Thomas Whalen were indispensable parties because both were doctors that prescribed pain creams and held an ownership interest in Appellee 1st Choice Pharmacy, LLC, in 2016.

Appellants seek money damages and attorneys' fees from Appellees for their alleged involvement in a fraudulent scheme. With respect to the individual doctors named in this case, Appellants have maintained that Appellee doctors received "kickbacks" from the pharmacies based on the quantity of pain creams that they prescribed. **See** Appellant's Brief at 31-32 (arguing that "the members received kickbacks for their self-referrals of patients to the pharmacies that they owned"). If Appellants successfully prove their claim against Appellee doctors named in this suit, those individuals may

be personally liable for money damages awarded to Appellants. Such a remedy generally would not affect the interests of the doctors who were not named in the suit.<sup>5</sup>

Moreover, the fact that Dr. Bruce Levin and Dr. Thomas Whalen may have a pecuniary interest in the financial performance of the companies named in this suit does not necessarily make them indispensable parties under the unique facts and circumstances of this case. Typically, individual members of an LLC are not personally liable for judgments against the company. **See** 15 Pa.C.S. § 8834(a) (stating that a "debt, obligation or other liability of a limited liability company is solely the debt, obligation or other liability of the company" and that a "member or manager is not personally liable, directly or indirectly, by way of contribution or otherwise, for a debt, obligation or other liability of the company solely by reason of being or acting as a member or manager"). Therefore, absent an appropriate claim and identifiable issues of material fact concerning misconduct by the unnamed defendants, this record does not establish that they were indispensable parties. See PSEA, 50 A.3d at 1277; *Martin*, 80 A.3d at 814. For these reasons, we respectfully disagree with the trial court's reasoning that it lacked subject matter jurisdiction. However, although we conclude that the trial court was incorrect in this

<sup>&</sup>lt;sup>5</sup> Additionally, no party has cited authority mandating that every investor or dividend recipient must be individually joined in a fraud case where the allegations are limited to selected individual actors. Indeed, Appellees acknowledge that there is no Pennsylvania case law requiring joinder in a fraud case. **See** Appellees' Brief at 63.

determination, for reasons that are set forth below, Appellant is entitled to no relief on this basis.

## **Jurisdiction to Review Letters of Medical Necessity**

Appellants also challenge the trial court's conclusion that it lacked jurisdiction to review the letters of medical necessity outside of the procedures established by the Pennsylvania Workers' Compensation Act. Appellants' Brief at 21.

By way of background to this issue, the trial court explained:

[Appellants] allege that the [letters of medical necessity] contained material misrepresentations because they were form letters submitted and signed by the physicians without individually considering the specific patient for whom the combination of the medications was being prescribed and without explaining the specific reason why the particular combination was more appropriate for that particular patient.

As it pertains to these letters, this court is not the proper forum to evaluate whether the [letters of medical necessity] set forth a proper explanation as to why the compound medication was reasonable and necessary for the patient. Disputes regarding the reasonableness or necessity of treatment must be resolved through the procedures set forth in the Workers' Compensation The administrative process established in the workers' compensation realm is the appropriate forum to make the determination of efficacy. The record contains evidence that some claims submitted by [Appellees] were subject to utilization reviews. The utilization reviewers, based on the reasonable and necessary standard, made the decision to pay or not pay the claims. This court will not second guess decisions made in that process and will not decide reasonableness and necessity on those claims which were not submitted for a utilization review but could have been. Since this court is not the forum to review the [letters of medical necessity] for efficacy, [Appellants] may not rely upon the [letters of medical necessity] as a material misrepresentation for fraud and [Appellants'] claim for fraud based on the [letters of medical necessity] is dismissed.

Trial Ct. Op. at 11-12 (footnotes omitted).

On appeal, Appellants reiterate their claim that the trial court incorrectly "deferred to the administrative process laid out in the workers' compensation law" and by declining to "decide reasonableness and necessity on those claims which were not submitted for a utilization review [(UR)]." Appellant's Brief at 22 (citation omitted). Appellants contend that, even if the trial court "were correct in its deference to the fee review and/or utilization review provisions of the workers' compensation act, the argument does not oust the common pleas court of jurisdiction to decide allegations of fraud." *Id.* at 24. Further, Appellants note that "the automobile accident cases and the New Jersey workers' compensation cases would never be subject to the review procedures" set forth in the Pennsylvania workers' compensation statutes. *Id.* at 18. Therefore, Appellants request that we "engage in *de novo* review of the misrepresentation claims based on the letters of medical necessity or . . . vacate and remand for further proceedings." *Id.* at 25.

Section 306(f.1)(6) of the Workers' Compensation Act provides, in relevant part, as follows:

[D]isputes as to reasonableness or necessity of treatment by a health care provider shall be resolved in accordance with the following provisions:

(i) The reasonableness or necessity of all treatment provided by a health care provider under this [A]ct may be subject to prospective, concurrent or retrospective [UR] at the request of an [employee], employer or insurer. The [D]epartment shall authorize utilization review organizations [(UROs)] to perform [UR] under this [A]ct. [UR] of all treatment rendered by a health care provider

shall be performed by a provider licensed in the same profession and having the same or similar specialty as that of the provider of the treatment under review. Organizations not authorized by the [D]epartment may not engage in such [UR].

- (ii) The [URO] shall issue a written report of its findings and conclusions within thirty (30) days of a request.
- (iii) The employer or the insurer shall pay the cost of the [UR].
- (iv) If the provider, employer, [employee] or insurer disagrees with the finding of the [URO], a petition for review by the [D]epartment must be filed within thirty (30) days after receipt of the report. The [D]epartment shall assign the petition to a workers' compensation judge [(WCJ)] for a hearing or for an informal conference under [S]ection 402.1 [of the Act, 77 P.S. § 711.15]. The [UR] report shall be part of the record before the [WCJ]. The [WCJ] shall consider the [UR] report as evidence but shall not be bound by the report.

77 P.S. § 531(6).

Further, the Commonwealth Court has explained:

The . . . [UR] process is the exclusive way to challenge medical bills. Neither a WCJ nor the Board has jurisdiction to determine the reasonableness of medical treatment unless and until a report is issued and the URO issues a determination. Parties may not, even by stipulation, agree to bypass [UR] and proceed directly to a hearing before a WCJ. If the health care provider, employer, employee or insurer disagrees with the determination of the URO, he may, within 30 days of the URO's determination, seek review by a WCJ. This hearing before the WCJ is a *de novo* proceeding; the WCJ is required to consider the reviewer's report as evidence, but he is not bound by it.

Cty. of Allegheny v. Workers' Comp. Appeal Bd. (Geisler), 875 A.2d 1222, 1226-27 (Pa. Cmwlth. 2005) (emphasis added; citations and footnote omitted).

In a "WCJ review of a UR determination[,] . . . 'either party is free to offer evidence beyond that considered in the UR process in meeting their [sic] burden of proof.'" Importantly, "[t]he [WCJ] has jurisdiction over all [UR] petitions and any alleged technical deficiency or irregularity in the [UR] process; the *de novo* hearing before the [WCJ] provides for a fair review in which both parties [are] free to offer other evidence." *Carter v. Workers' Comp. Appeal Bd. (Hertz Corp.)*, 790 A.2d 1105, 1109 (Pa. Cmwlth. 2002) . . . .

## Notwithstanding,

[UR] is not an alternative to a review by a WCJ, but a mandatory first step in determining whether a provider's treatment is reasonable and necessary. This Court has consistently held that a WCJ lacks subject matter jurisdiction to determine the reasonableness and necessity of medical treatment if the matter has not first gone to [UR].

Burgess v. Workers' Compensation Appeal Board (Patterson-UTI Drilling Company LLC), 231 A.3d 42, 46-47 (Pa. Cmwlth. 2020) (some citations omitted and formatting altered), appeal denied, 240 A.3d 112 (Pa. 2020).

Here, to the extent Appellants challenge the reasonableness or necessity of the treatment provided to patients who suffered work-related injuries, the trial court correctly concluded that it did not have jurisdiction to revisit that issue. **See id.** at 46-47. However, as noted previously, many of the claims submitted to Appellants were for patients who were injured in automobile accidents or in work-related injuries that occurred in New Jersey, which do not fall under the Pennsylvania Workers' Compensation Act. Therefore, we agree with Appellants that the trial court erred in resolving this issue solely based on the Pennsylvania workers' compensation statutes. In any event, for

reasons discussed in greater detail below, our determination on this discrete claim does not entitle Appellants to appellate relief.

#### **Fraud Claim**

Appellants next argue that the trial court erred in granting summary judgment with respect to fraud because there was "ample evidence" that Appellees made material misrepresentations in the claims submitted to Appellants. Appellants' Brief at 26. Specifically, Appellants refer to (1) the letters of medical necessity; (2) the characterization of the pain creams as a compound drug; and (3) the legality of Appellees' ownership and operation of the pharmacies. We will address each allegation separately.

In reviewing an order granting summary judgment, we are guided by the following principles:

Our standard of review is *de novo* and our scope of review is plenary. *Eclipse Liquidity, Inc. v. Geden Holdings, Ltd.*, 200 A.3d 507, 509-10 (Pa. Super. 2018). Summary judgment is appropriate where there is no genuine issue of material fact as to a necessary element of a cause of action that can be established by discovery or expert report. Pa.R.C.P. No. 1035.2(1). "In reviewing an order granting a motion for summary judgment, an appellate court must examine the entire record in the light most favorable to the non-moving party and resolve all doubts against the moving party." *Donegal Mut. Ins. Co. v. Fackler*, 835 A.2d 712, 715 (Pa. Super. 2003).

**Marion v. Bryn Mawr Trust Company**, 253 A.3d 682, 688 (Pa. Super. 2021).

To establish a claim for common law fraud, the plaintiff must demonstrate:

(1) A representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and, (6) the resulting injury was proximately caused by the reliance.

Weston v. Northampton Pers. Care, Inc., 62 A.3d 947, 960 (Pa. Super. 2013) (citation omitted).

This Court has explained:

[A] fraudulent misrepresentation can take many forms: fraud consists in anything calculated to deceive, whether by single act or combination, or by suppression of truth, or a suggestion of what is false, whether it be direct falsehood or by innuendo, by speech or silence, word or mouth, of look or gesture. It is any artifice by which a person is deceived to his disadvantage. Where a plaintiff asserts fraudulent misrepresentation without showing that the defendant intended to mislead the plaintiff into reliance on the misrepresentation, the defendant is entitled to judgment as a matter of law.

Kostryckyj v. Pentron Lab. Techs., LLC, 52 A.3d 333, 339 (Pa. Super. 2012) (citations omitted and formatting altered). "Unsupported assertions and conclusory accusations cannot create genuine issues of material fact as to the existence of fraud." Hart v. Arnold, 884 A.2d 316, 339 n.7 (Pa. Super. 2005) (citation omitted).

The insurance fraud statute provides, in part, that an individual commits an offense if he:

(2) Knowingly and with the intent to defraud any insurer or self-insured, presents or causes to be presented to any insurer or self-insured any statement forming a part of, or in support of, a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim.

(3) Knowingly and with the intent to defraud any insurer or self-insured, assists, abets, solicits or conspires with another to prepare or make any statement that is intended to be presented to any insurer or self-insured in connection with, or in support of, a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim, including information which documents or supports an amount claimed in excess of the actual loss sustained by the claimant.

18 Pa.C.S. § 4117(a)(2)-(3).

## **Letters of Medical Necessity**

In their amended complaint, Appellants argued:

In furtherance of their fraudulent scheme, [Appellee] pharmacies supplied [Appellee] doctors with preprinted prescription forms from which to select the fraudulent compounded creams. Such forms thwart the independent medical decision making process on behalf of a prescribing medical provider. [Appellee] pharmacies also provided "letters of medical necessity" to submit to insurance companies like [Appellants] with reasons why the fraudulent compounded creams were supplied. [Appellee] pharmacies also provided references and purported supportive medical literature concerning compounded medications. [Appellees] knew or should have known the cited medical literature in the letters of medical necessity were not literature from widely accepted medical or peer review journals, but rather were untested, non-peer reviewed, self-serving opinions unrelated to [Appellees'] fraudulent compounded creams.

Am. Compl. at ¶ 28 (some formatting altered).

On appeal, Appellants reiterate that "[t]here was ample evidence of misrepresentations" in the letters of medical necessity. Appellants' Brief at 18. Specifically, Appellants assert that (1) "[t]he letters contained general information and cited to uncontrolled, non-peer reviewed studies" but that some "doctors testified that they did not read all of the studies that were cited in the form letters," (2) several of the letters stated that topical pain creams

were required because those patients were suffering from gastrointestinal upset from oral medication, although gastrointestinal issues were not reflected in every patient's medical records, and (3) the topical pain creams did not reduce opioid levels. *Id.* 

Appellees respond that although the pharmacies provided sample letters of medical necessity to doctors in order to "assist in explaining the pharmaceutical science behind the compound cream prescription when requested by an insurer," the doctors were also free to draft their own letters. Appellees' Brief at 22. Further, Appellees argue that there was "no evidence that [Appellees] misrepresented or made any inaccurate claims about the efficacy of the medications prescribed and dispensed." *Id.* at 40. Appellees assert that "[e]ach prescription was compounded for a specific patient and tailored to the needs of that patient based upon the prescribing physician's independent medical judgment." *Id.* at 31. Therefore, Appellees argue that the trial court properly rejected Appellant's claims.

As noted previously, the trial court did not address whether the letters of medical necessity contained material misrepresentations. However, based on our review of the record, we conclude that Appellants have failed to identify any evidence, let alone material issues of fact, to support this claim. Specifically, Appellants have failed to establish how the inclusion of uncontrolled, non-peer reviewed studies, is a fact, or even presents a material issue of fact, amounting to a material misrepresentation by the medical providers who submitted the letters of medical necessity as a template for

their insurance claims. Further, even accepting Appellants' assertions that "gastrointestinal issues were not reflected in every patient's medical records" or that the creams did not appear to reduce opioid levels, those facts do not establish that the providers misrepresented their patients' need for topical pain creams. Therefore, Appellants are not entitled to relief.

## <u>Description of Pain Creams as Compound Drugs</u>

Appellants also argue that Appellees misrepresented that the pain creams were "compound drugs," as defined by Section 503A of the FDCA. Appellants' Brief at 28-29. In support, Appellants contend that "[a]Ithough the theory behind the compounded medications is that they are formulated individually for specific patients having unique needs, the evidence showed that the creams were prefabricated and predetermined by the pharmacists without input from the medical providers." *Id.* at 32. Relying on an opinion by Appellants' expert, Jackelyn Rodriguez, Appellants argue that "the pharmacies did not operate as compounding pharmacies in compliance with section 503A, but, instead, functioned as outsource facilities under section 503B, thus triggering federal registration and oversight." *Id.* at 30.

\_

<sup>&</sup>lt;sup>6</sup> In her report, Rodriguez stated that there was "no variation in the formulas being prescribed by the doctors," and that "the list of drug ingredients listed were the same and the compounding pharmacies followed the same formulas." **See** Ex. 38 at 11. Rodriguez concluded that "[t]his clearly shows that these compounding pharmacies are not true compounding under the requirements of [Section 503A] and have been compounding formulas, not per individual patient requirements, but instead, they are clearly operating as manufacturing outsource facilities under [Section 503B] of the [FDCA]." **Id.** at 12.

Therefore, Appellants argue that "[w]hile [Appellees] claimed to engage in allowable anticipatory compounding, [Appellants'] experts contradicted that, creating issues of fact requiring a trial," and the trial court should have denied summary judgment. *Id.* at 19.

Appellees respond that "Appellants presented no evidence and no legal argument to support this theory." Appellees' Brief at 39. Appellees assert that anticipatory compounding is permissible in limited quantities under Section 503A when done based on "a history of the licensed pharmacist receiving valid prescription orders for the compound AND the order having been generated solely within an established relationship." *Id.* at 55 (emphasis in original).

Appellees assert that the prescription requirement of Section 503A "ensures that non-FDA approved compounded drugs are dispensed based upon an individual's specific needs. However, this does not mandate that the compound be prepared only after receipt of the prescription." Appellees' Brief at 54. Instead, Appellees note that anticipatory compounding is permissible in limited quantities, which has been defined as "(1) no more than a 30-day supply to fill valid prescriptions not yet received, and (2) the 30-day inventory

\_

<sup>&</sup>lt;sup>7</sup> Appellees note that "each doctor and pharmacist explained that every medication was prepared for an individual patient or in a small batch based upon prior refill orders[,]" that the "largest' of these batches was for no more than three patients" and that "no Appellee [p]harmacy had the capability to make more than 750 grams of compound pain relief cream at any given time." Appellees' Brief at 39 (citing deposition testimony from several doctors and pharmacists at R.R.1294a-1295a, R.R.1402a, R.R.1485a, R.R.1547a, R.R.1548a-1549a, R.R.1550a, R.R.1555a-1556a, R.R.1698a-1699a).

supply must be based on the actual number of valid prescriptions that the compounder received for actual patients in a 30-day period over the past year." *Id.* at 55. Appellees contend that Appellants presented no evidence that Appellees failed to comply with these limitations and that, therefore, their claim must fail. *Id.* 

The trial court addressed Appellants' claim as follows:

[T]he compound pain creams prescribed by [Appellee] physicians fit the definition of a compound drug under Section 503A. The pain creams were ordered by licensed physicians for their specific individual patients. The prescriptions for the pain creams were "valid prescriptions" as required by Section 503A since the prescriptions identify the name of the patient for whom the drug was prescribed. The use of pre-printed prescriptions or rubber stamps is not precluded by Section 503A and does not affect the prescription's status as a "valid prescription" since the prescriptions identify the name of the individual patient for whom the drug is prescribed. Moreover, no evidence has been produced that the compound drug formulas prescribed by physicians are commercially available. Prescribing a similar formula for a compound pain cream to more than one patient does not remove the pain cream formula from the compound drug designation. The pain cream formula need only be prescribed for an individual patient, not solely for one patient. The pain cream formulas prescribed for one patient may also be beneficial for other patients who for instance may have an allergy to a dye or may be unable to swallow pills.

Additionally, Section 503A permits pharmacies to produce compound drugs in small batches. 21 U.S.C. § [353a](a)(2)[(A)] of the [FDCA] permits compounding by a licensed pharmacist or licensed physician in "limited quantities before the receipt of a valid prescription order for such individual patient." This is known as anticipatory compounding. In this situation, compounding may occur before the receipt of a valid prescription based on the history of the pharmacy receiving prescriptions for a particular drug product for an identified individual patient. The compounding occurs in the context of the relationship between the physician and the patient. The pharmacist will then compound a batch of

drugs in anticipation of receiving a valid prescription for the drug. There is no evidence that any anticipatory compounding occurred outside these parameters. Since this court finds that the pain creams prescribed here satisfy the definition of compound drug, [Appellants'] arguments to the contrary may not form the basis for a fraud claim.

Trial Ct. Op. at 13-15 (some formatting altered, footnotes omitted).

Based on our review of the record, we find no error in the trial court's conclusion that Appellants failed to present evidence to establish that Appellees failed to comply with Section 503A. Section 503A limits the quantity of drug product that pharmacies may compound before receiving a prescription. However, there is nothing in the record to establish that any of the pharmacies exceeded those limitations. Further, as noted by the trial court, "[t]he pain cream formula need only be prescribed for an individual patient, not solely for one patient." See id. at 15. Therefore, to the extent Appellants' expert opined that the pharmacies were operating as "outsource" facilities" because they filled more than one prescription for the same compound pain cream, that does not present an issue of material fact that would defeat summary judgment. See Hart, 884 A.2d at 339 n.7 (stating that "[u]nsupported assertions and conclusory accusations cannot create genuine issues of material fact as to the existence of fraud"). Therefore, Appellants are not entitled to relief on this claim.

# Appellees' Business Ownership Structure

Appellants also claim that Appellees made "misrepresentations regarding the ownership and operation of the pharmacies." Appellants' Brief at 19. Specifically, Appellants argue:

The medical practitioners supposedly owned minority interests in But, the ownership was masked in some the pharmacies. instances, and several of the doctors owned shares in multiple pharmacies. Moreover, the doctors were the engines that drove the financial success of the pharmacies. The physicians referred the patients to the pharmacies they owned so the prescriptions would be filled. The constant stream of self-referrals for the highpriced products ensured that the revenue would continue to flow through the pharmacies and back to the owners in the form of profit distributions. The outlandish size of these distributions, together with inconsistencies in the amounts distributed to seemingly similar ownership interests, and the fluctuating percentages of ownership create questions of fact regarding the legitimacy and proportionality of the distributions. The jury should have been allowed to decide whether the payments were kickbacks.

#### **Id.** at 19-20.

In response, Appellees argue:

The basis for [Appellants'] claims was that the Appellee physicians owned small (in most cases 1 to 2 percent) non-voting interests in the Appellee pharmacies to whom the patients were referred, and the ownership structure amounted to an illegal kickback scheme. There is nothing improper, however, about Appellees' business model. Physician ownership of the non-controlling minority interests in the pharmacies is expressly permitted under the Pennsylvania Pharmacy Act [35 P.S. § 449.22]. Pennsylvania law also expressly recognizes the propriety of referrals by the physicians to these pharmacies, provided proper disclosure is made.

Appellees' Brief at 32-33.

The trial court addressed this claim as follows:

The last category of misrepresentation relates to the illegality of [Appellees'] ownership structure. Particularly, [Appellants] take issue with [Appellee] physicians' minority ownership in [Appellee] pharmacies. [Appellants] argue that the ownership structure provides a means for defendant physicians to be paid alleged kickbacks for the prescriptions written. The Pharmacy Act governs the practice of pharmacies by its rules and regulations and its establishment of the State Board of Pharmacy, which is charged with regulating the practice of pharmacies, licensing pharmacists, investigating all violations of the Pharmacy Act, and prosecuting violations where appropriate. The Pharmacy Act clearly indicates legislature's intention specifically define 'grossly to unprofessional conduct' by means of the thirteen enumerated grounds provided in the statute in order to provide in advance clear notice of what is prohibited conduct and thus avoid vagueness defects. Physician ownership is not prohibited by the Pharmacy Act as long as the medical practitioners holding a proprietary or beneficial interest in the pharmacy does not exercise supervision or control over the pharmacist in his professional responsibilities and duties. [Appellees] admit that they are investors/owners in the pharmacies. The evidence shows that the interest owned by the physicians is not more than 49%, a percentage which has been approved by the Pharmacy Board. Hence, physician ownership in [Appellee] pharmacies is lawful. The evidence further shows that the interest held by [Appellee] physicians is non-voting, non-controlling and non-supervisory.

[Appellants] further argue that the pharmacies business structure is illegal because defendant physicians engaged in self-referrals and received "kickbacks" for the number of prescriptions written for pain creams. According to [Appellants], the "kickbacks" were in the form of dividends; the more prescriptions written for pain creams, the larger the dividend. In an effort to support this claim, [Appellants] attached as exhibits tax returns for the pharmacies as well as included charts within their response to the motions for summary judgment for each pharmacy anonymously identifying the investor by number, the percentage ownership and the dividend received. However, there is no evidence correlating the amount of the dividend received by the investor to the number of prescriptions written and that physician [Appellees] were paid more dividends based on the number of prescriptions for pain cream they wrote. Owners were paid dividends based on the pharmacies' profits, which included compounded drugs as well as pills and other medications the pharmacies were authorized to

dispense and the percentage of ownership in the pharmacy. The fact that the investors were paid large dividends does not correlate to illegal kickbacks. The large dividends were in part due to the fee schedule used by [Appellants] to reimburse the claims. The evidence shows that the pain creams were billed at the average wholesale price (AWP), a price which is standard within the industry and paid based on [Appellants'] use of the standard fee schedules. As such, while the dollar amount of the dividends paid to the investors is great, the court does not find the dividend payment to be a "kickback."

[Appellants] also rely on the alleged illegality of self-referrals to support their fraud claim. [H]owever, there is no evidence that any self-referrals were contrary to the law.

Title 35 P.S. § 449.22 (a) provides as follows: "any practitioner of the healing arts shall, prior to referral of a patient to any facility or entity engaged in providing health-related service[s], tests, pharmaceuticals, appliances or devices, disclose to the patient any financial interest of the practitioner or ownership by the practitioner in the facility or entity. In making any referral, the practitioner of the healing arts may render any recommendations he considers appropriate, but shall advise the patient of his freedom of choice in the selection of a facility or entity."

This statutory provision does not make self-referrals automatically illegal. On the contrary, a physician may refer a patient to a pharmacy if the physician disclosed his/her financial interest in the pharmacy. The record evidence shows that in fact such disclosures were made. There is no evidence of illegal self-referrals. Based on the foregoing, the court finds that [Appellants] have failed to produce evidence to show that [Appellees] made material misrepresentations.

Trial Ct. Op. at 15-18 (footnotes omitted).

Based on our review of the record, we discern no error of law in the trial court's ruling. The trial court thoroughly addressed Appellants' claim regarding the legality of Appellees' business structure and concluded that there was no evidence of a misrepresentation by Appellees. **See id.** Although Appellants disagree with the trial court's legal analysis, they failed to identify

reversible error. **See Marion**, 253 A.3d at 688; **see also** Pa.R.C.P. 1035.2(2). Therefore, we affirm on the basis of the trial court's analysis of this issue. **See** Trial Ct. Op. at 15-18.

### **Unjust Enrichment**

Appellants next argue that the trial court erred in granting summary judgment on their unjust enrichment claim. Appellants' Brief at 36-37. In support, Appellants assert that Appellees realized benefits that "were unjust[,] given that they were paid out on claims which were submitted and paid for medications that were not legitimate compound medications for specific individuals based upon their unique and documented medical needs." Id. at Appellants argue that "the prefabricated medicines were supposedly 37. justified on the basis of false letters of medical necessity which—like the medicines themselves— were developed by the pharmacies without regard to the particulars of any patient's case." Id. at 38. Further, Appellants claim that "the presentation of these prescriptions for reimbursement were fraudulent under the common law and the insurance fraud statute" and that "[i]t would be unconscionable to allow [Appellees] to retain the entirety of this huge windfall when all of the other circumstances warrant disgorgement of the ill-gotten gains." **Id.** at 38.

Appellees respond that the unjust enrichment claim was premised on Appellants' "belief that Appellees 'were paid out on claims which were submitted and paid for medications that were not legitimate compound medications for specific individuals based upon their unique and documented

medical needs." Appellees' Brief at 60-61. However, Appellees reiterate that Appellants paid claims "for specific medications for specific individuals based upon their unique and documented medical needs." *Id.* at 61. Therefore, Appellees conclude that "because Appellees were paid the amounts to which they were entitled, there was no basis for an unjust enrichment claim." *Id.* at 58 (some formatting altered).

To succeed on an unjust enrichment claim, the plaintiff must prove: "(1) benefits [were] conferred on [the] defendant by [the] plaintiff; (2) appreciation of such benefits by [the] defendant; and (3) acceptance and retention of such benefits under such circumstances that it would be inequitable for [the] defendant to retain the benefit without payment of value." *Wilson v. Parker*, 227 A.3d 343, 353 (Pa. Super. 2020) (citation omitted). "In determining if the doctrine applies, our focus is not on the intention of the parties, but rather on whether the defendant has been unjustly enriched." *Id.* (citation and emphasis omitted).

Here, the trial court addressed Appellants' unjust enrichment claim as follows:

[Appellants'] claim for unjust enrichment fails as a matter of law. First, while [Appellee] pharmacists, lay investors, physicians and physician assistants did realize a benefit in the form of dividends distributed by the defendant pharmacies to them, the dividends may not be the basis for the unjust enrichment since any dividends paid arise from the [Appellants'] ownership interest in the pharmacies. To the extent [Appellee] pharmacists, lay investors, physicians and physician assistants benefitted, the benefit was a result of their ownership in the pharmacies and not from [Appellants]. As for the remaining group of [Appellees], the

pharmacies, while the claim reimbursements were made directly to them, there is no evidence that the reimbursements were unjust. The evidence shows that the pharmacies were paid pursuant to the workers['] compensation and [Motor Vehicle Responsibility Law] fee schedules. There is no evidence that the pharmacies were paid more than the average wholesale price. Since there is no evidence of overpayment, the claim for unjust enrichment fails.

Trial Ct. Op. at 18-19.

Based on our review of the record, we agree with the trial court that Appellants failed to present evidence, let alone identify any issues of material fact, to support their unjust enrichment claim. Further, Appellants failed to establish legal error in the trial court's legal conclusions. Instead, Appellants reiterate their assertion that Appellees were unjustly enriched through their participation in a fraudulent scheme. However, because Appellants have failed to produce evidence to prove fraud, their unjust enrichment claim must also fail. Therefore, Appellants are not entitled to relief.

## **Aiding and Abetting**

Finally, Appellants argue that the trial court erred in dismissing the claim for aiding and abetting. Appellants' Brief at 50. In support, Appellants claim:

The facts of this case demonstrate without question that [Appellees] worked together in a common design to form a network of pharmacies and cross-investors for the sole purpose of enriching themselves and each other to the tune of thousands, even millions of dollars at [Appellants'] expense. [Appellants'] have clearly identified the wrong--the fraudulent prescribe for profit scam based on compounded drugs that were not in actuality compounded at all, use of which was justified by letters of medical necessity which were not individual to patient prescriptions, just as the drugs were not individually formulated for the specific patients, as the Food, Drug and Cosmetic Act sets forth in section

503A. The pharmacy ownership was illegal under the Pharmacy Act and Anti-Kickback Laws, yet [Appellees] went merrily along prescribing millions of dollars' worth of these creams. It was no coincidence that claims dropped off precipitously when it became clear to the players that the insurers were on to the scheme and ready to take on [Appellees].

Accordingly, if this Court were to reverse on the common law or statutory fraud counts, then it must also reinstate the aiding and abetting claim as well.

Appellants' Brief at 52.

Appellees respond that an aiding and abetting claim requires "tortious conduct, which did not occur here." Appellees' Brief at 62. Further, Appellees contend that "Appellants offer their own legal conclusions that are neither supported by the record nor consistent with [the trial court's] detailed analysis of the facts of record. Consequently, the trial court properly dismissed the claim of aiding and abetting." *Id.* 

"Section 876 of the Restatement (Second) of Torts addresses the tort of civil aiding and abetting, which is also known as concerted tortious conduct[.]" **Sovereign Bank v. Valentino**, 914 A.2d 415, 421 (Pa. Super. 2006).

Section 876 of the Restatement (Second) of Torts provides:

For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he

- (a) does a tortious act in concert with the other or pursuant to a common design with him, or
- (b) knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself, or
- (c) gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered, constitutes a breach of duty to the third person.

Restatement (Second) of Torts § 876.

Here, the trial court concluded that "[s]ince the claims for fraud and insurance fraud fail, the underlying unlawful act required to state a claim for aiding and abetting is nonexistent and therefore the claim is dismissed." Trial Ct. Op. at 19.

Appellants failed to establish a cause of action for an underlying tort, the aiding and abetting claim must also fail. **See** Restatement (Second) of Torts § 876 (requiring plaintiffs to prove "tortious" act or conduct); **see also Valentino**, 914 A.2d at 421. Therefore, Appellants are not entitled to relief on this issue.

In sum, although we conclude that the trial court erred in its resolution of the jurisdictional issues, *i.e.* Appellants' failure to join indispensable parties and the applicability of the Workers' Compensation Act, those errors do not affect our disposition.

Therefore, for the reasons set forth above, we conclude the trial court correctly granted summary judgment in favor of Appellees based on Appellants' failure to present evidence to support their claims of fraud, unjust enrichment, and aiding and abetting. Accordingly, we affirm.

Order affirmed.

Judgment Entered.

Joseph D. Seletyn, Eso.

Prothonotary

Date: <u>2/1/2022</u>