

COMMONWEALTH OF KENTUCKY
McCRACKEN CIRCUIT COURT
DIVISION NO. II
CASE NO. 18-CI-00313

ENTERED
NEW NOV 20 2018
McCRACKEN CIRCUIT COURT
PADUCAH, KENTUCKY

COMMONWEALTH OF KENTUCKY, *ex rel.*,
ANDY BESHEAR, ATTORNEY GENERAL

PLAINTIFF

VS.

JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS,
INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS,
INC. n/k/a JANSSEN PHARMASEUTICA, INC. n/k/a
JANSSEN PHARMACEUTICALS, INC.

DEFENDANTS

ORDER DENYING MOTION TO DISMISS

This matter is before the Court on motion by Defendant, Janssen Pharmaceuticals, to dismiss the complaint against it. The Court, after having reviewed the motion and conducted a hearing on the matter, hereby **DENIES** the motion.

PROCEDURAL HISTORY

Kentucky Attorney General Andy Beshear filed this Complaint alleging that Johnson & Johnson and Janssen, acting as Johnson & Johnson's agent, engaged in deceitful marketing tactics that: 1) violated the KY Consumer Protection Act, 2) committed Medicaid fraud, 3) committed assistance program fraud, 4) committed fraud at common law, 5) created a public nuisance, 6) unjustly enriched the defendants, and 7) warranted punitive damages.

In response, Janssen filed its Motion to Dismiss arguing: 1) a lack of causation, 2) failure of the Commonwealth to adequately particularize allegations of the Complaint,

and 3) federal preemption. Janssen also makes individualized arguments for counts I-V, VII-VIII.

STANDARD TO DISMISS COMPLAINT

A motion to dismiss will be granted when the plaintiff fails to adequately state facts supporting the complaint. *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544, 546 (2007). “[A] claim must be dismissed” where: 1) the complaint lacks allegations as to an essential element of the claim, or 2) the legal conclusions are “inconsistent” with the facts presented to the court. *Wood v. Wyeth-Ayerst Labs.*, 82 S.W.3d 849, 851-52 (Ky. 2002). In this case, the Complaint does provide facts supporting each allegation it has made and survives scrutiny under *Wood*.

CAUSATION

First, Janssen argues that the Commonwealth cannot recover due to the “derivative-injury” rule. This rule is applicable where plaintiffs seek recovery from defendants for harms done to third parties and is designed to prevent recovery when the harm is too remote from the original injury. For example, in *Kentucky Laborers v. Hill & Knowlton, Inc.*, the court found that nonprofit union multi-employer health and welfare plans could not recover costs from either cigarette manufacturers or tobacco-affiliated companies for allegedly misrepresenting the negative effects of tobacco to plan participants. 24 F. Supp. 2d 755 (W.D. Ky. 1998). While it is true that, in that instance, Plaintiffs were barred from recovery under the derivative injury rule, the Commonwealth sues Janssen as *parens patriae* and not as an insurance provider. *Id.* Consequently, the cited case is not dispositive of the issue. Additionally, the derivative-injury rule is

inapplicable here as the Commonwealth seeks recovery for economic losses suffered by *the Commonwealth* and not a third party.

Second, Janssen argues that the Commonwealth's knowledge of the risks of opioids generally creates a break in the chain of causation of injury. Janssen cites *Sandoz, Inc. v. Commonwealth* where the Court of Appeals ruled the Commonwealth could not recover under a theory of inflated pricing by a pharmaceutical manufacturer because it had knowledge of the prices at the time it paid for the prescriptions and therefore consented to the costs. 405 S.W.3d 506 (Ky. App. 2012). However, at the time the Commonwealth paid for prescriptions manufactured by Janssen, it was unaware of Janssen's "fraudulent marketing" for opioids. Therefore, the Commonwealth was unable to consent to the actions of Janssen at that time it paid for the drugs.

Despite Janssen's assertion to the contrary, Janssen can be held liable for the alleged fraudulent marketing of opioids to doctors in spite of the "learned intermediary doctrine." Under this doctrine, it is the doctor's obligation to be fully informed of medications they prescribe to patients. *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 762 (Ky. 2004). Janssen argues that it fulfilled all obligations it owed by acting in compliance with Food and Drug Administration (FDA) labeling laws. However, in 2008, the Kentucky Supreme Court made clear that the learned intermediary doctrine was not a valid defense where "other evidence undermined the effectiveness of these warnings." *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93 (Ky. 2008). The Commonwealth has successfully pled the existence of other evidence that would undermine Janssen's warning labels.

Like the derivative injury rule and the learned intermediary doctrine, illegal activity of others related to opioids does not constitute an intervening act and does not create a break the chain of causation. Janssen draws parallels with federal case law exemplifying cases where gun manufacturers could not be held liable for resulting gun violence and cold medicine manufacturers could not be held liable for the crimes associated with methamphetamine. See *Camden County Board of Chosen Freeholders v. Beretta, U.S.A. Corp.*, 273 F.3d 536 (3d Cir. 2001) and *Ashley County v. Pfizer, Inc.*, 552 F.3d 659 (8th Cir. 2009). Under Kentucky law, however, an intervening act will only break the chain of causation when it can be considered a superseding cause. *Bruck v. Thompson*, 131 S.W.3d 764, 767 (Ky. Ct. App. 2004). To be a superseding cause, "the intervening act or event must be of independent origin, unassociated with the original act." *Id.* at 768 citing *NKC Hosp., Inc. v. Anthony*, 849 S.W.2d 564, 568 (Ky. Ct. App. 1993). The Commonwealth sufficiently draws the causal chain by alleging an increased addiction of opioids because Janssen's marketing tactics led to opioid-related crimes. Consequently, those illegal acts are neither independent nor unassociated with Janssen's alleged fraudulent marketing tactics.

Additionally, it is well established under Kentucky common law that illegal criminal acts do not relieve tort liability where the criminal act is a foreseeable result. *Waldon v. Hous. Auth. of Paducah*, 854 S.W.2d 777, 778-79 (Ky. Ct. App. 1991) citing *Wheeler v. Andrew Jergens Company, Ky.*, 696 S.W.2d 326 (Ky. Ct. App. 1985). Whether those criminal acts were a foreseeable consequence of Janssen's alleged actions is a question for the trier of fact and not pertinent in a motion to dismiss. *Bailey v. N. Am. Refractories Co.*, 95 S.W.3d 868, 872-73 (Ky. Ct. App. 2001).

PARTICULARITY OF THE COMPLAINT

There are two standards governing how specific a complaint must be pleaded. Counts III-VI and VI of the Complaint alleges fraud and are therefore governed by CR 9.02. This requires all allegations of fraud or mistake “shall be stated with particularity.” All other counts are governed by the lower requirements of CR 8.01 as they do not allege fraud. Even under the more stringent standard of CR 9.02, a complaint is not required to include the exact identities of the doctors to whom the fraudulent statements were made. A well-pleaded complaint must include the “the time, place, and substance” of the allegations, but that language does not require the explicit identities of persons referenced in the Complaint. *Keeton v. Lexington Truck Sales, Inc.*, 275 S.W.3d 723 (Ky. Ct. App. 2008). Thus, the Complaint must allege the “*when, where, and what*” but is not required to provide “*who.*” *Id.*

In addition to Janssen’s argument that the Complaint was not particularly pleaded, Janssen alleges that the Complaint fails to adequately state the existence of an agency relationship between Janssen and third-party actors referred to in the Complaint, namely the element of control. In an agency relationship, “the principle has the power or responsibility to *control* the method, manner, and details of the agent’s work.” *Nazar v. Branham*, 291 S.W.3d 599, 606 (Ky. 2009) (emphasis added). The Complaint specifically alleges that Janssen operated, edited, approved, and contracted with these various third parties. Therefore, the Commonwealth has offered facts that would support a finding that the control element of an agency relationship exists between Janssen and the third-party actors.

With respect to the individual statements Janssen argues are not fraudulent or misleading, the Commonwealth has alleged that they are fraudulent, and Janssen argues that they are not. Factual disputes are not reviewed on a motion to dismiss.

PREEMPTION

Although Janssen argues otherwise, alleged violations of state law are not preempted by the Supremacy Clause merely because the FDA has approved the labeling Janssen uses for their pharmaceuticals. The Commonwealth does not challenge the warning labels on Janssen's products. Instead, the Commonwealth challenges the marketing tactics by Janssen in advertising their opioid pharmaceuticals. Janssen may still be held liable for any malpresentation of opioid risks despite compliance with FDA labeling requirements. Otherwise, companies would be allowed to market their products using any form of misrepresentation and shield themselves from repercussion by relying on their FDA-labels. Such an absurd result, coupled with the strong presumption against preemption arguments by Kentucky courts, render this argument unavailing. See *Wyeth v. Levine*, 555 U.S. 555 (2009); *Niehoff v. Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997).

JANSSEN AS AN AGENT OF JOHNSON & JOHNSON

The Commonwealth has adequately alleged facts supporting an agency relationship between Janssen and Johnson & Johnson. In its complaint, the Commonwealth is required to allege more than a mere statement of agency between Janssen and its parent company, Johnson & Johnson. *Nazar v. Branham*, 291 S.W.3d 599, 606 (Ky. 2009). Among the several elements of agency, the most important is whether one entity exercises "control" over another. *CSX Transp., Inc. v. First Nat'l*

Bank of Grayson, 14 S.W.3d 563, 567 (Ky. Ct. App. 1999). The Complaint alleges Johnson & Johnson controlled the development and sales of Janssen's drugs and communicated with the FDA concerning those products. This allegation is sufficient to find an agency relationship.

THE KENTUCKY CONSUMER PROTECTION ACT

The Commonwealth may be entitled to restitution under the Consumer Protection Act even though Janssen never received payment from Medicaid directly. Restitution is the return of "a benefit [that] has been conferred on the defendant and unjustly retained by [them]." *Kentucky Laborers v. Hill & Knowlton, Inc.*, 24 F. Supp. 2d 755, 755 (W.D. Ky. 1998). Medicaid paid for prescriptions to pharmacies, and those pharmacies paid Janssen for the drugs Duragesic, Nucynta ER, and Nucynta. Therefore, the Commonwealth has conferred a benefit to Janssen (through Medicaid) and that benefit has allegedly been unjustly retained.

As assessed elsewhere in this order, the Commonwealth has also adequately alleged "unfair" acts or practices by Janssen as "false, misleading, and deceptive."

KENTUCKY MEDICAID FRAUD

Janssen may still be held liable for Medicaid fraud despite being a manufacturer. Janssen's argument is that pharmaceutical manufacturers are excluded under KRS Chapter 205, as they are neither a "provider" nor "recipient" as required for a claim under this chapter. See KRS § 205.8451(2). While "fraud" is defined as a being committed by either a recipient or provider under KRS Chapter 205, KRS § 205.8463 states that "any person" may violate that statute, making clear that the legislature's intent was not to limit possible violators of this form of Medicaid fraud.

The Complaint also adequately alleges the commission of Medicaid fraud by Janssen. Janssen argues that the Commonwealth failed to allege Janssen ever created a claim for payment or other matter under the Cabinet's jurisdiction that contains allegedly false information. Janssen admits, however, that Kentucky courts have not litigated the level of specificity required to plead a violation of this statute.

The Kentucky Medicaid fraud statute provides:

(2) No person shall intentionally, knowingly, or wantonly make, present, or *cause to be made or presented* to an employee or officer of the Cabinet for Health and Family Services any *false, fictitious, or fraudulent statement, representation, or entry* in any application, claim, report, or document used in determining rights to any benefit or payment; [...]

(4) No person shall, in any matter within the jurisdiction of the Cabinet for Health and Family Services under this chapter, knowingly falsify, *conceal, or cover up by any trick, scheme, or device a material fact*, or make any false, fictitious, or fraudulent statement or representation, or make or use any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry.

KRS § 205.8463(2), (4), *emphasis added*. The Medicaid fraud statute covers more than just false statements, and it does not require first person action to satisfy the elements of Medicaid fraud. Indirect misrepresentation and actions in furtherance of a scheme to defraud would each be sufficient to commit Medicaid fraud—both of which the Commonwealth has sufficiently pled in the Complaint.

The Commonwealth may also recover under KRS § 446.070 for instances of Medicaid fraud by Janssen. KRS § 446.070 states: “[a] person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation.” In *Kicky v. General Electric Company*, the Kentucky Supreme Court ‘carefully limited’ § 446.070 to

apply only where statute allegedly violated provides no remedy for aggrieved party. 593 S.W.3d 19, 24 (Ky. 2018). The penalties available under the KY Medicaid fraud statute do not offer a remedy for the Commonwealth's economic recovery for losses sustained due to Janssen's alleged actions. As this is the exact circumstance described by KRS § 446.070, the Commonwealth may recover.

KENTUCKY ASSISTANCE PROGRAM FRAUD

Janssen may still be liable for assistance program fraud even though the precise statements made by Janssen to doctors were not submitted to Medicaid. The assistance program fraud statute, KRS § 194A.505(6), states: "no person shall, with intent to defraud or deceive, devise a scheme or plan a scheme... by means of false or fraudulent representations or intentionally engage in conduct that advances the scheme or artifice." There is no indication that the verbatim language used by Janssen must be included in a claim for Janssen to be held liable, as furthering a scheme which defrauds or deceives Medicaid would be enough. Therefore, the Commonwealth has sufficiently alleged that Janssen violated the Kentucky assistance program fraud statute to avoid dismissal.

Although Janssen argues that the Commonwealth lacks a civil remedy available to them under KRS § 194A.505, there is no language indicating the Commonwealth would be barred from obtaining a civil judgement.

PUBLIC NUISANCE

Kentucky has adopted the Restatement (Second) of Torts, which identifies three circumstances that may "sustain a holding that an interference with a public right is unreasonable":

- a) If the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or
- b) If the conduct is proscribed by a statute, ordinance or administrative regulation, or
- c) If the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the action knows or has reason to know, has a significant effect upon the public right.

Restatement (Second) of Torts § 821B; *see also Nichols v. Com.*, 226 S.W.2d 796, 798 (Ky. App. 1950). The Commonwealth has sufficiently alleged that Janssen's actions negatively affected public health and safety, were in violation of Kentucky's Consumer Protection Act and various fraud statutes, and have produced long-lasting and significant effects within Kentucky. These allegations are sufficient to suggest a violation of public rights by Janssen.

UNJUST ENRICHMENT

The Commonwealth has adequately pleaded that Janssen was unjustly enriched. The elements of unjust enrichment are: 1) a benefit conferred upon the defendant at the plaintiff's expense, 2) a resulting appreciation of the benefit by the defendant, and 3) inequitable retention of the benefit without payment for its value. *Furlong Dev. Co. v. Georgetown-Scott Cty Planning and Zoning Comm'n*, 504 S.W.3d 34, 39-40 (Ky. 2016). The Complaint alleges that: 1) Janssen profited and benefited from opioid purchases made by the Commonwealth as an expected and intended result of its conscious wrongdoing, 2) that due to and as intended by its deceptive acts, Janssen has made millions of dollars at the expense of the Commonwealth, and 3) that it would be inequitable for

Janssen to retain profits and benefits reaped from deception, misrepresentation and unlawful activity.

The Court rejects Janssen's argument that the Commonwealth is unable to recover under a theory of unjust enrichment where it has claimed remedies at law elsewhere in its complaint. This is an incorrect statement of law. As found in *Furlong Denver Company*, an unjust enrichment claim does not require a finding that the party has no remedy at all. 504 S.W.3d 34, 39-40 (Ky. 2016).

PUNITIVE DAMAGES

The Commonwealth has made allegations against Janssen which would warrant punitive damages. KRS § 411.184 states: "[a] plaintiff shall recover punitive damages only upon proving, by clear and convincing evidence, that the defendant from whom such damages are sought acted toward the plaintiff with oppression, fraud or malice." Fraud, defined by Chapter 411, is "an intentional misrepresentation, deceit, or concealment of material fact known to the defendant and made with the intention of causing injury to the plaintiff." KRS § 411.184.

The Complaint states that Janssen acted purposefully and deceptively to create false and misleading marketing schemes, targeting the elderly and other vulnerable populations, with the intent to increase its profits through Medicaid. These allegations are sufficient to constitute "fraud," and the Commonwealth may recover punitive damages against Janssen.

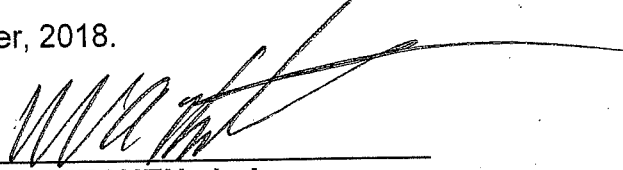
CONCLUSION

Having assessed each argument asserted by Janssen, the Court finds that the Commonwealth has pled each allegation sufficiently to survive Janssen's Motion to Dismiss.

ORDER

Therefore, **IT IS HEREBY ORDERED** that the Defendant's Motion to Dismiss is **DENIED**.

ENTERED this 20 day of November, 2018.



W. A. KITCHEN, Judge
McCracken Circuit Court
Division No. II

CLERK'S CERTIFICATE

The foregoing Order was entered this 20 day of November, 2018 and copies were mailed to the following:

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