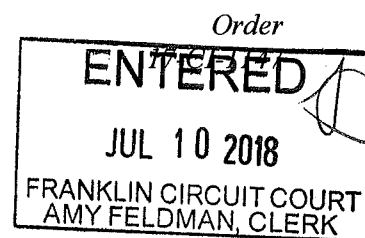


COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
DIVISION II

CIVIL ACTION No. 17-CI-1147



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

PLAINTIFF

vs.

ENDO HEALTH SOLUTIONS INC.; and
ENDO PHARMACEUTICALS INC.

DEFENDANTS

ORDER

This matter is before the Court upon Defendants' *Motion to Dismiss* and Defendants' *Motion to Strike*. The case was called before the Court during for a hearing on Tuesday, May 22, 2018 at 10:00 a.m. Upon review of the parties' briefs and papers, and after being sufficiently advised, the Court hereby **DENIES** Defendants' *Motion*.

STANDARD OF REVIEW

Under Kentucky law, when a court considers a motion to dismiss under Civil Rule 12.02, "the pleadings should be liberally construed in a light most favorable to the plaintiff and all allegations taken in the complaint to be true." *Gall v. Scroggy*, 725 S.W.2d 867, 869 (Ky. Ct. App. 1987) citing *Ewell v. Central City*, 340 S.W.2d 479 (Ky. 1960). "The court should not grant the motion unless it appears the pleading party would not be entitled to relief under any set of facts which could be proved in support of his claim." *Mims v. W.-S. Agency, Inc.*, 226 S.W.3d 833, 835 (Ky. Ct. App. 2007) quoting *James v. Wilson*, 95 S.W.3d 875, 883-84 (Ky. Ct. App. 2002). In *D.F. Bailey, Inc. v. GRW Engineers Inc.*, 350 S.W.3d 818 (Ky. Ct. App. 2011), the Kentucky Court of

Appeals discussed a trial court's standard of review when ruling on a motion to dismiss. "[T]he question is purely a matter of law. [...] Further, it is true that in reviewing a motion to dismiss, the trial court is not required to make any factual findings, and it may properly consider matters outside of the pleadings in making its decision. *Id.* at 820 (internal citations omitted).

ANALYSIS

I. Causation

Defendants argue that the Commonwealth's claims require more specific proof of causation than what it pled in its complaint. The Commonwealth alleged a causal theory of loss it has suffered because Defendants misrepresented the risks of opioid medications it manufactured and marketed; physicians heard and believed the representations Defendants made about the product, which undermined the warning labels contained on the medication packaging; the misrepresentations caused physicians to administer pharmaceutical opioids to patients in higher doses, which created a greater risk of addiction; the effects of this over prescription of opioids caused a concurrent rise in opioid-related criminal activity as well as an increase in addiction and opioid-related health problems; and the activity caused Kentucky Medicaid program to spend over \$117 million in 2016 to treat opioid addiction while Defendants continue to profit on drug sales in the Commonwealth. The Court will address Defendants' specific arguments for dismissal based on the causation alleged in the Commonwealth's argument below.

a. Remoteness of damages

Defendants argue that the derivative injury rule, the doctrine that precludes recovery against an alleged wrongdoer for losses derived from an injury to a third-party,

bars the Commonwealth's suit. *Fireman's Fund Ins. Co. v. Gov't Emps. Ins. Co.*, 635 S.W.2d 475, 475 (Ky. 1982). In *Kentucky Laborers District Council v. Hill & Knowlton, Inc.*, 24 F. Supp. 2d 755 (W.D. Ky. 1998), the Western District Court held that the plaintiff could not bring an aggregate claim on behalf of thousands of individuals, both directly and indirectly injured, who did not meet the class certification requirements. Duplicative recovery would occur for directly injured plaintiffs who had already brought suit against the tobacco company. *Id.* at 763. Defendants assert that the third-party payor claims, just like those in *Kentucky Laborers*, cannot be brought against the drug manufacturer because the Commonwealth's damages are too remote to seek third party recovery for damages in the form of Medicaid and workers' compensation programs in an indirect injury setting.

Conversely, the Commonwealth contends that its suit does not fall under the derivative injury rule. The Commonwealth brings suit under the law of public nuisance and the Kentucky Consumer Protection Act (KCPA) in its role as *parens patriae*, rather than as an insurer. The Office of the Attorney General is uniquely situated to take legal action on behalf of citizens of the Commonwealth, and it asserts claims against Defendants for their actions related to the marketing and sale of their products in Kentucky. Further, the Commonwealth argues that, even if the rule did apply, the derivative injury rule would not bar its claim against Defendants. The Commonwealth contends that an insurance "carrier's rights against a third-party tortfeasor are entirely derivative and are not independent of the injured party's tort claim. *Fireman's Fund Ins.*, 635 S.W.2d at 476.

The Court holds that the Commonwealth's claims do not fail for remoteness.

First, the Court holds that the derivative injury rule does not bar the Office of the Attorney General from redress in this matter. This Court has previously addressed this issue in *Commonwealth of Kentucky ex rel. Andy Beshear, Attorney General v. Fresenius Medical Care Holdings, Inc., et al.*, Civ. Action No. 16-CI-946, Order on Motion to Dismiss at 6-7 (Franklin Circuit Court Feb. 15, 2017). In that case, the defendant "cites *Kentucky Laborers Dist. Council Health & Welfare Trust Fund v. Hill & Knowlton, Inc.*, 24 F.Supp.2d 755 (W.D. Ky. 1998), for the proposition that the remoteness doctrine bars insurers, and other benefit providers, from bringing claims and recovering for injuries to third parties." This argument is strikingly similar to that which Defendants raise in the current case make. However, the Court distinguished the Fresenius matter from that in *Kentucky Laborers* because in *Kentucky Laborers* the Western District, which based its decision in the "law of anti-trust, held that strong anti-competitive consequences to the marketplace from which the fund suffered must be present to recover for a claim based on misrepresentation. *Id.* at 766." *Id.*

The Court reaches the same conclusion in this case as it did in its February 15, 2017 order on the issue of remoteness of injury for the Attorney General's claim:

Unlike Kentucky Laborers, in this case the Commonwealth raised claims based upon the alleged misrepresentations of Fresenius, none of which are based in the law of anti-trust. The Court, taking the pleadings in the light most favorable to the Commonwealth, at this juncture, finds that remoteness does not bar the Commonwealth's claims. The Commonwealth seeks to recover for expenditures it made in purchasing GranuFlo with Medicaid funds based upon Fresenius' misrepresentations. The Court finds that the expenditures constitute a claim of injury unique to the Commonwealth that is not founded upon the medical expenses or bills the Fresenius users acquired. Therefore, remoteness does not bar the Commonwealth's claims.

Id. The injury the Commonwealth has allegedly suffered due to Defendants' marketing and alleged misrepresentations of the health effects and consequences is an injury specific to the Commonwealth. The expenditures made in workers compensation and Medicaid claims to treat Kentuckians who, after receiving improper medical prescriptions and advisement, became addicted and experienced various opioid related injuries and illnesses, are injuries the Commonwealth allegedly inured, despite not being the individual who experienced opioid addiction. Therefore, the Commonwealth's claims are not too remote for the Commonwealth's theory of causation.

b. Knowledge of risks and the causal chain

Next, Defendants contend that the Commonwealth's long-standing knowledge of the risk of opioid medications breaks the causal connection between Defendants' marketing and representations about their products and the injuries suffered by Kentuckians. Defendants cite *Sandoz Inc. v. Commonwealth*, 405 S.W.3d 506 (Ky. App. 2013), for the proposition that if the state knew of the risks of the prescription drugs and did nothing with that knowledge to prevent the widespread use and misuse of the products, the state cannot recover damages. In *Sandoz*, the Commonwealth knew of inflated average wholesale pricing for drugs. The state used this inflated formula for over-reimbursing pharmacies. The Court of Appeals held that the Commonwealth's awareness of the inflation prevented the state from proving that the defendants caused harm in the state's systematic over-reimbursing pharmacies. *Id.* In this case, Defendants argue that the Commonwealth knew of the risks of addiction, abuse, and diversion of opioids from FDA-approved warnings, statewide drug taskforces and policy investigations, and other reported information. Thus, Defendants contend that the

Commonwealth cannot now, after having significant information relating to the dangers of opioid addiction, seek redress for Defendants' alleged misrepresentations.

The Commonwealth argues that it never "acquiesced" in this case, as the state did in *Sandoz* to the inflation information. *Id.* at 511. Over the last fifteen years, the state has taken measures to combat opioid abuse. Here, the Commonwealth contends that when it learned of Defendants' alleged fraudulent conduct it timely acted to fight Defendants' conduct. Further, the Attorney General avers that whether the Commonwealth took action in a timely fashion against Defendants or acquiesced to Defendants' conduct is a matter of fact that is improper for decision at this time.

The Court holds that the Attorney General timely brought suit in this matter. The Commonwealth notably knew of the dangers and ongoing societal problems caused by the abuse of opioids by Kentuckians over the past fifteen years. However, the Court agrees with the Commonwealth that knowing of the harm a product may create does not equate to knowing of specific alleged misrepresentations made about the properties of Defendants' products nor the improper, unnecessarily induced prescriptions of Defendants' drugs for which the state paid. The date the Commonwealth learned of any alleged malfeasance by Defendants tolled the statute of limitations for bringing this action. Neither party has presented the Court with any factual pleadings related to Defendants' claim that the Commonwealth acquiesced to Defendants' specific marketing and prescription strategies. The Commonwealth learned of Defendants' alleged misconduct and timely brought this lawsuit.

c. Doctors as learned intermediaries and the chain of causation

Next, Defendants argue that the learned intermediary doctrine bars the Commonwealth's liability theory. A physician is an intermediary between Defendants and the patient, and the intermediary bears the responsibility to 'read and understand all warnings from the manufacturer and relay them to the patient.' See *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 770 (Ky. 2004). Defendants contend that their products contained adequate warning labels, which therefore absolves them of liability. *Id.* The FDA approved Defendants' warning labels on their products; and, Defendants contend, because the Commonwealth recognizes the presence of the warnings on the prescription bottles it cannot state a claim against Defendants based upon misleading physicians. See *Larkin*, 153 S.W.3d at 763.

The Commonwealth, alternatively, argues that the learned intermediary doctrine requires Defendants to provide an adequate warning to doctors about the potential effects of their products. *Id.* at 764. Defendants' warnings on the prescription bottles, the Attorney General avers, failed to apprise physicians of the harmful nature of the product. Further, the Commonwealth asserts that the adequacy of warnings provided to physicians constitutes an issue of material fact that cannot be dealt with on a motion to dismiss.

In *Commonwealth of Kentucky ex rel. Andy Beshear, Attorney General v. Johnson & Johnson, et al.*, Civ. Action No. 16-CI-867, Order on Motion to Dismiss at 6-7 (Franklin Circuit Court June 7, 2017), this Court held that

...the learned intermediary doctrine applies in this jurisdiction. Physicians, who have studied medicine, are better learned in medical science than the average consumer to interpret Defendants' marketing of products. Therefore, Plaintiff must distinguish claims brought on behalf of physicians who relied on the alleged misrepresentations when prescribing the surgical mesh product to patients, and claims brought on behalf of

consumers who relied on Defendants' specific representations about the product when choosing to use the product.

The Court holds that the Office of the Attorney General must distinguish claims that it brings on behalf of physicians who relied on Defendants' representations, and those on which the consumers of the prescriptions relied. To hold in opposition to the *Johnson & Johnson* ruling in this matter would imply that doctors issuing prescription opioids are held to a different standard than those who treat any other ailment Kentuckians suffered. Therefore, the Court requires the Commonwealth, pursuant to the learned intermediary doctrine, to specify claims of misrepresentation as they relate to consumers who chose to use Defendants' products and physicians who prescribed opioids to patients.

d. Causation and costs of Commonwealth addressing consequence of diversion and abuse

Defendants' final attack on the Commonwealth's causation argument is that the Office of the Attorney General cannot prove a causal link between Defendants' alleged misrepresentations and all opioid diversion and abuse costs that the state has incurred. Defendants contend that under the theory of proximate causation other illegal acts surrounding the misuse of opioids and other opiate abuse and problems in the Commonwealth constitute superseding causes and intervening acts that break the chain of causation from any alleged misrepresentations Defendants made about their products. *Bruck v. Thompson*, 131 S.W.3d 764, 767-69 (Ky. App. 2004).

The Commonwealth counters Defendants' arguments with the notion that intervening acts only break the causal chain if an act is a superseding cause, which is rooted in an event entirely independent of the original liability and that the original actor could not reasonably foresee. *Bruck v. Thompson*, 131 S.W.3d at 767-68. The Attorney General contends that the third-party actions that contributed to Kentucky's opioid crisis

were foreseeable and were, in fact, a direct consequence of Defendants' alleged misrepresentations. The Commonwealth asserts that it has adequately alleged that Defendants' conduct served as the proximate cause for the harms.

The Court holds that the issue of proximate cause is a factual determination that is unsuited for a decision at the juncture of a motion to dismiss. The Commonwealth has adequately pled that the results of Defendants' alleged misrepresentations served as a proximate cause for the harms the Commonwealth has endured from the opioid epidemic. The presence of intervening causes and the relative foreseeability of each superseding event is a factual question that is inappropriate for the Court to decide at this time.

II. Particularity

Defendants next assert that the Commonwealth's claims do not meet the particularity required by CR 9.02, Kentucky's pleading standard for claims based in fraud. Conversely, the Office of the Attorney General contends that CR 9.02 does not apply to the Commonwealth's claims for public nuisance, unjust enrichment, which do not sound in fraud and are subject to CR 8.01(1); nor the claims founded in the Kentucky Consumer Protection Act, which contains its own standard for pleading.

The Court holds that the Commonwealth is not required to meet the pleading standards in CR 9.02 because the Attorney General does not bring fraud claims, but rather it asserts claims based on other common law causes of action or the Kentucky Consumer Protection Act. This Court previously addressed this issue, as it pertained to the Kentucky Consumer Protection Act in *Commonwealth of Kentucky ex rel. Andy Beshear, Attorney General v. Johnson & Johnson, et al.*, Civ. Action No. 16-CI-867, Order on Motion to Dismiss at 4-5 (Franklin Circuit Court June 7, 2017):

The KCPA deems “unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce” unlawful. Ky. Rev. Stat. § 367.170(1). To bring a claim under the KCPA against Defendants for misleading and omitted representations about a surgical mesh device, Plaintiff must show that Defendants committed an act or engaged in a practice in the conduct of trade or commerce of the surgical mesh product that was unfair, false, misleading, or deceptive. *Id.* The legislature enacted this statute with the intention to provide a remedy for consumers who have allegedly suffered wrongs based upon consumer transactions with an entity engaged in commerce. The nature of the claim, limited in this way to “unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce” specify the nature of the claims that qualify under the KCPA. Unlike common law fraud claims for which CR 9.02 requires heightened pleading particularity standards, the legislature has determined the qualities of claims brought under the KCPA. Therefore, the Court rejects Defendants’ argument that Plaintiff’s claims are based in fraud and must comply with CR 9.02. This matter falls under the purview of KCPA, and the pleading particularity enumerated in CR 9.02 is irrelevant.

Similarly, in this case, the Court holds that the Commonwealth need not meet the heightened fraud pleading requirements contained in CR 9.02. Rather, the state must meet the requirements set forth in CR 8.01 for the nuisance and unjust enrichment claims and the requirements set forth in the Kentucky Consumer Protection Act for the consumer protection claims.

The Court holds the Commonwealth’s pleadings to be sufficient to plead claims for which relief may be granted, and the Court denies Defendants’ arguments that the Commonwealth must be required to abide by a standard of heightened particularity in pleading. However, as noted above, this is a jurisdiction that recognizes the learned intermediary doctrine. The Commonwealth must specify the claims of misrepresentation that relate to doctor and those that relate to patients.

III. Claim Specific Reasons
a. Statutory false claims

Defendants contend that the Medicaid Fraud Statute, KRS § 205.8451(2), imposes civil liability exclusively for providers, which the statute defines as an entity “which is providing or has been approved to provide medical services, goods, or assistance to recipients under the Medical Assistance Program.” *Id.*, at (17). Defendants manufacture pharmaceutical drugs and do not supply patients with prescriptions, therefore they argue that they are not liable under KRS § 205.8451 for any alleged Medicaid Fraud. Further, Defendants similarly assert that they are not liable under the Assistant Program Fraud Statute and the Fraudulent Insurance Acts Statute because they do not receive benefits from any assistance program. Ky. Rev. Stat. § 194.A505(6); Ky. Rev. Stat. § 304.47-020(1)(a). Reimbursement for these assistance programs exclusively goes to physicians who participate in the Kentucky Medicaid Program, not drug manufacturers. 907 KAR 3:010 § 2. Courts in other jurisdictions, Defendants aver, have dismissed analogous claims against pharmaceutical drug manufacturers because they do not meet the statutory definitions for providers or recipients of payments from state assistance funds. *See In re Miss. Medicaid Pharm. Average Wholesale Price Litig.*, 190 So. 3d 829, 857-58 (Miss. 2015).

Conversely, the Attorney General asserts that Defendants’ arguments fail for three reasons. First, the Commonwealth contends that the scopes of each of the fraud statutes in question reach any defendant that causes physicians to submit false claims for payment or participate in fraudulent schemes. Defendants’ alleged misrepresentations, according to the Commonwealth, satisfy this component of liability. Next, the Commonwealth argues that KRS 446.070, Kentucky’s negligence *per se* statute, allows recovery for damages

even if the violated statute does not explicitly provide civil damages. Third, the Attorney General argues that the Medical Fraud Statute and the Fraudulent Insurance Act do not require the Commonwealth to prove the six element of common law fraud.

The Kentucky Medicaid Fraud Statute imposes civil liability against any person who “intentionally, knowingly, or wantonly...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. Ky. Rev. Stat. § 205.8463(2). The Court holds that the Commonwealth has sufficiently pled allegations against Defendants that satisfy this component of Medicaid Fraud liability. Further, under the Kentucky Assistance Program Fraud Statute, the Court holds that the Commonwealth has sufficiently pled allegations as to Defendants “scheme or artifice to obtain benefits from any assistance program by means of false or fraudulent representations...” Ky. Rev. Stat. § 194.A505(6). Similarly, under the Fraudulent Insurance Acts Statutes, the Attorney General has sufficiently pled allegations that would impose potential liability against Defendants. Ky. Rev. Stat. § 304.47-020(1)(a). Whether or not Defendants were “providers,” as defined by the statute, the Court is persuaded that KRS 446.070 creates a cause of action for civil damages is irrelevant because the statutes on which the Commonwealth relies serve the purpose of ferreting out fraudulent behavior in Kentucky. Therefore, any allegedly fraudulent action conducted in concert with the causes of action in each statute create a viable claim for civil liability.

b. Public nuisance

Defendants also assert that the Commonwealth failed to plead an essential element of public nuisance: the interference with a public right. “A public right is one common to all members of the general public. It is collective in nature and not like the individual right that everyone has not to be assaulted or defamed or defrauded or negligently injured.” Restatement (Second) of Torts § 821B cmt. G (Am. Law Inst. 1979). Defendants contend that the injuries experienced by individual patients by the mis-prescription of Defendants’ pharmaceuticals constitute private rights, not public rights. Defendants also express concern about the policy of potentially expanding the public nuisance doctrine.

The Attorney General argues that the Restatement identifies three circumstance that may “sustain a holding that an interference with a public right is unreasonable”:

- (a) whether 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) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or
- (c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon a public right.

Restatement (Second) of Torts § 821B. The Commonwealth argues that Defendants’ alleged conduct interferes with public health, violates Kentucky laws, and has produced harmful effects in the state, and therefore Defendants violated Kentucky’s public rights.

The Court holds that the Commonwealth has sufficiently pled its public nuisance claim. The Kentucky Supreme Court adopted the Restatement Second of Torts’ definition of public nuisance. The opioid crisis in Kentucky has caused a public health crisis and crime crisis throughout the Commonwealth. The Commonwealth’s pleadings have

alleged a claim that Defendants have interfered with public health, Defendants have violated a Kentucky statute, and Defendants misrepresented the effects of its products to physicians in the Commonwealth. The Court holds that the Attorney General has clearly pled that Defendants' conduct allegedly violates a public right in the state and may proceed with the public nuisance claim.

c. Kentucky Consumer Protection Act

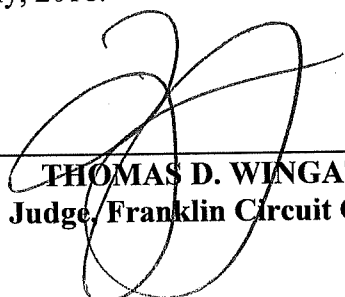
Finally, Defendants argue that the claim under the Kentucky Consumer Protection Act fails to allege conduct that would qualify as an unfair act or practice, and the Attorney General conflates restitution and damages with the remedy it prays from the Court.

The Court holds that the Attorney General's Kentucky Consumer Protection Act pleadings are sufficient to survive a motion to dismiss. The Commonwealth pled that the Defendants' conduct was "false, misleading, and deceptive," which meet the statutory language of the Kentucky Consumer Protection Act, in addition to being "unfair." Next, the Court holds that the Commonwealth has pled a remedy adequate for the claim it brings in its complaint. The Court, at the final disposition of the case, if a remedy is in fact warranted from the merits of this case, will resolve any problems related to damages or restitution at that time.

CONCLUSION

The Court **DENIES** Defendants' *Motion to Dismiss*. Plaintiff has alleged claims for which relief may be granted against Defendants. The Commonwealth, however, must specify any claims of misrepresentation Defendants made to physicians directly and to consumers of opiate prescription drugs directly.

SO ORDERED, this 10th day of July, 2018.



THOMAS D. WINGATE
Judge, Franklin Circuit Court

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Order was mailed, this 16 day of July, 2018, to the following:

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