IN THE SUPERIOR COURT OF PENNSYLVANIA

Docket No. 1303 EDA 2017

JOSEPH A. CALTAGIRONE, as Administrator Ad Prosequendum for the Estate of JOSEPH F. CALTAGIRONE, deceased, and JOSEPH A. CALTAGIRONE, individually,

Plaintiffs-Appellants,

v.

CEPHALON, INC., and TEVA PHARMACEUTICALS USA, INC.,

Defendants-Appellees.

BRIEF FOR APPELLEES CEPHALON, INC. AND TEVA PHARMACEUTICALS USA, INC.

On appeal from an Order of the Court of Common Pleas of Philadelphia County, entered March 23, 2017 in September Term 2016, No. 02887

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INTRODUCTION

This is not a normal prescription drug products liability case. There are no allegations that Defendants designed or manufactured a defective product. There are no failure-to-warn claims, nor any allegations that Defendants failed to furnish adequate labeling or adequate warnings that the product posed a particular risk of harm. In fact, the relevant risks were prominently and unequivocally disclosed in the drug's labeling and, as Plaintiffs admit, "common knowledge in the medical community." R.R. 422a (¶ 42). Plaintiffs advance vague and conclusory allegations that Defendants engaged in deception, but never identify a single false or misleading statement or omission by Defendants in any of their three successive complaints in this matter. Plaintiffs nevertheless request that this Court simply ignore their pleading deficiencies and give them a "fourth bite" at the proverbial apple. Unsurprisingly, the trial judge correctly dismissed Plaintiffs' claims as a result.

Plaintiffs' sole contention in this case is that Defendants allegedly promoted a prescription drug for use in treating a condition or "indication" different from the indication that the federal Food and Drug Administration ("FDA") had approved. Plaintiffs allege that this "off-label" promotion of FDA-unapproved uses violated the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.* R.R. 419a (¶ 30). In other words, Plaintiffs charge Defendants only with an

alleged violation of the FDCA, a federal statute, presenting *this* alleged violation as the breach of legal duty giving rise to all of their state-law claims. Plaintiffs do not (and cannot) cite any state-law source of legal duty independent of the FDCA for the legal duty that they now seek to place on Defendants.

That failure dooms all of Plaintiffs' claims, just as the Court of Common Pleas held. Correctly applying *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the trial court dismissed Plaintiffs' claims against Defendants in their entirety because, as *Buckman* recognizes, there is no private right of action to enforce the FDCA. On the contrary, the FDCA specifically provides that its requirements may be enforced by the federal government only. 21 U.S.C. § 337(a). Under *Buckman*, then, state-law claims like Plaintiffs', which are completely premised on alleged FDCA violations, are impliedly preempted by that statute and its no-private-enforcement provision. Otherwise such claims would interfere with the delicate balance that federal regulators must strike in regulating the prescription drug industry. Mindful of these concerns and binding Supreme Court precedent, courts around the country have refused to permit state law claims premised on off-label promotion of FDA-unapproved uses in alleged violation of the FDCA (and not based on independent state-law duties), and the trial court rightly drew the same conclusion below. *See* Trial Ct. Op. 6 (citing *Buckman*, 531 U.S. 341).

Plaintiffs offer no reason to reverse the trial court's application of *Buckman*. To avoid implied preemption under *Buckman*, a plaintiff must first assert a claim that does not exist "solely by virtue of the FDCA"; instead, the claim must be supported by independent "state tort law which had predated the federal enactments in questions." 531 U.S. at 353. Plaintiffs' appellate brief only confirms their continuing inability to satisfy this threshold legal requirement: it does not, and cannot, identify any independent Pennsylvania legal duty to promote a prescription drug only for an indication approved by the FDA.

But even if Plaintiffs' claims did not all fail for that reason, they would fail for others. *First*, to the extent the Complaint's allegations might be read as going beyond federal food and drug law by alleging fraudulent statements, those allegations fail to satisfy basic pleading requirements—let alone the heightened particularity demanded for pleading claims that sound in fraud. Conclusory labels aside, Plaintiffs do not (and cannot) identify any particular false or misleading statements or omissions by Defendants despite having amended their Complaint multiple times already.

Second, Plaintiffs' case also fails because of the Learned Intermediary doctrine, which forecloses liability against a drug manufacturer in situations where a well-informed treating physician decides to prescribe the drug in the exercise of his or her professional judgment. This independent problem dooms all Plaintiffs'

claims as a matter of law and justifies demurrer, for, as the trial court noted (albeit in dicta), Plaintiffs' own allegations establish that the treating physician in this case had all the relevant information about Defendants' product and its risks when he decided to prescribe the product to the decedent.

Third, Plaintiffs cannot prevail on any claim because they cannot show that Defendants' conduct was the proximate cause of the alleged injury. Plaintiffs' own allegations establish that the decedent here had stopped using Defendants' product two and a half years before his death, that he was addicted to other opiates after he stopped using Defendants' product, and that he ultimately died from an entirely separate prescription drug that was prescribed to treat that addiction. Accepting these pleaded allegations as true, Plaintiffs cannot prove causation as a matter of law.

Fourth, if these reasons were not enough to warrant dismissal of the case in its entirety, it would still be necessary to dismiss Plaintiffs' claim under the Unfair Trade Practices and Consumer Protection Law, Act of December 17, 1968, P.L. 1224, as amended, 73 P.S. § 201-1 *et seq.* ("UTPCPL"). By its plain language, the UTPCPL does not impose liability for bodily harm, which is all Plaintiffs allege here.

Finally, while Plaintiffs now suggest in passing that the Court should remand to allow them to amend their complaint, the Court should refuse that

request. Plaintiffs never asked for leave to amend before the trial court, and so the argument is waived on appeal. Besides, Plaintiffs have already amended their complaint twice—and have filed three complaints in all—in response to a series of Preliminary Objections filed by Defendants all identifying the same fundamental problems foreclosing Plaintiffs' claims. Yet Plaintiffs remain unable to overcome the many independent problems that Defendants and the court below have identified and further amendment would be futile.

For these reasons, the trial court's order must be affirmed.

COUNTERSTATEMENT OF THE SCOPE AND STANDARD OF REVIEW

When the Superior Court is tasked with reviewing a trial court's grant of preliminary objections, "the standard of review is *de novo* and the scope of review is plenary." *Martin v. Rite Aid of Pa., Inc.*, 80 A.3d 813, 814 (Pa. Super. 2013) (quoting *Keller v. Scranton City Treasurer*, 29 A.3d 436, 443 n.12 (Pa. Commw. 2011)) (internal citations omitted in original). In reviewing the decision to grant preliminary objections, the Superior Court must "determine whether the trial court committed an error of law" and "apply the same standard as the trial court." *Adams v. Hellings Builders, Inc.*, 146 A.3d 795, 798 (Pa. Super. 2016) (quoting *Feingold v. Hendrzak*, 15 A.3d 937, 941 (Pa. Super. 2011)) (internal citation omitted in original). Generally, the court derives the facts "solely from the complaint and . . . accepts all well-pleaded material facts in the complaint, and all

inferences reasonably deduced therefrom[.]" *Martin*, 80 A.3d at 814 (quoting *Keller*, 29 A.3d at 443 n.12). But the court may also consider "the documents and exhibits attached" to the complaint. *B.N. Excavating, Inc. v. PBC Hollow-A, L.P.*, 71 A.3d 274, 278-79 (Pa. Super. 2013) (citation and emphasis omitted). And when the complaint discusses and relies on additional documents that the plaintiff fails to attach, the court may consider them as well. *Perelman v. Perelman*, 125 A.3d 1259, 1266 n.3 (Pa. Super. 2015).

Indeed, contrary to Plaintiffs' claim that the scope of this Court's review is restricted to only certain items in the record, Caltagirone Br. 1-2, the scope of this Court's review is plenary and encompasses "the whole record." *Morley v. Gory*, 814 A.2d 762, 764 (Pa. Super. 2002) (citing *Ham v. Sulek*, 620 A.2d 5, 8 (Pa. Super. 1993)); *see also B.N. Excavating*, 71 A.3d at 278.

COUNTERSTATEMENT OF THE QUESTIONS INVOLVED

QUESTION 1: Did the trial court correctly conclude that Plaintiffs' claims, which are entirely premised on alleged violations of the federal Food, Drug, and Cosmetic Act, are preempted because binding U.S. Supreme Court precedent forecloses efforts to enforce that Act's requirements through state tort claims?

Answer Below: Yes.

QUESTION 2: Are Plaintiffs' claims foreclosed because the claims sound in fraud and Plaintiffs have not identified a single misleading or untrue statement by Defendants?

Answer Below: Not reached.

QUESTION 3: Are Plaintiffs' claims foreclosed under the Learned Intermediary doctrine, which precludes recovery based on allegedly inadequate information supplied by a drug manufacturer when greater information would not have affected the prescribing physician's treatment decisions?

Answer Below: Yes (but in dicta).

QUESTION 4: Are Plaintiffs' claims foreclosed because Plaintiffs' allegations demonstrate the injuries were not proximately caused by Defendants' actions?

Answer Below: Not reached.

QUESTION 5: Is Plaintiff's Unfair Trade Practices and Consumer Protection Law ("UTPCPL") claim foreclosed because the statute provides no recovery for bodily injury?

Answer Below: Not reached.

COUNTERSTATEMENT OF THE CASE

I. Form of Action and Procedural History

Joseph A. Caltagirone, in his personal capacity and in his capacity as Administrator Ad Prosequendum for the Estate of Joseph F. Caltagirone, filed this civil action in the Philadelphia County Court of Common Pleas against Defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc.

Plaintiffs filed their initial Complaint on September 26, 2016. R.R. 15a-75a. Plaintiffs sought unspecified civil damages arising out of the death of Joseph F. Caltagirone ("the Decedent"). The initial Complaint attempted to assert claims for alleged negligence (Count I), common law fraud (Count II), negligent misrepresentations (Count III), violation of unfair trade practices/consumer protection law (Count IV), and also wrongful death (First Cause of Action) and survival action (Second Cause of Action). R.R. 27a-36a. The gravamen of Plaintiffs' Complaint was that Defendants had allegedly unlawfully promoted their prescription drug product for off-label uses not specifically approved by the FDA. *Id.*

Defendants filed Preliminary Objections on the grounds that the claims in the Complaint were legally insufficient because of (1) implied preemption under the FDCA, (2) the Learned Intermediary doctrine, (3) lack of proximate causation, (4) failure to plead fraud with particularity, and (5) the fact that the UTPCPL does

not permit recovery for personal injuries. R.R. 76a-201a. In response, Plaintiffs filed an Amended Complaint, making minor additions of factual allegations but again attempting to assert the same causes of action. R.R. 202a-69a. Defendants again filed Preliminary Objections on the same grounds. R.R. 270a-410a. Plaintiffs then filed a Second Amended Complaint, again making only minor additions of factual allegations but asserting all of the same purported claims. R.R. 411a-77a. Once again Defendants filed Preliminary Objections on the same grounds. R.R. 478a-624a.

After a hearing, the trial court issued an order and memorandum sustaining Defendants' Preliminary Objections and dismissed the Second Amended Complaint in its entirety with prejudice.

II. Prior Determinations

There have been no prior determinations in this case.

III. Lower Court Judge

Judge Frederica A. Massiah-Jackson, of the Court of Common Pleas of Philadelphia County, entered the order under appeal.

IV. Chronological Statement of the Facts

Plaintiffs allege in their Second Amended Complaint[1] that Defendants manufacture, sell, and distribute synthetic opioids, including ACTIQ® (fentanyl citrate) oral transmucosal lozenge CII ("ACTIQ"). R.R. 413a-14a (¶¶ 4-5, 10). ACTIQ has been approved by the Food and Drug Administration ("FDA") to be marketed for use in treating breakthrough pain in opioid-tolerant adult patients who have cancer. R.R. 414a (¶ 9). In approving ACTIQ for this purpose, the FDA mandated the implementation of a Risk Management Program ("RMP") intended to encourage proper patient selection. R.R. 415a (¶¶ 11-12). The existence of this program recognizes that ACTIQ carries with it a "danger of addiction," *id.*, a fact which Plaintiffs concede "is common knowledge in the medical community and confirmed by the Centers for Disease Control and Prevention," R.R. 422a (¶ 42). The FDA's approval of ACTIQ also required that the product be accompanied by a detailed label, which Plaintiffs refer to in their pleading as its "instructions for use." R.R. 415a (¶ 16); *see also* R.R. 623a-24a.[2] The ACTIQ label advised

[1] The statement of facts derives from the allegations in the Second Amended Complaint, as well as documents referenced in and relied on by the Second Amended Complaint, without any admission as to the veracity of those allegations.

[2] Without any objection from Plaintiffs below, Defendants properly attached the ACTIQ label as an exhibit to their Preliminary Objections to the Second Amended Complaint, and it is part of the Reproduced Record. R.R. 623a-24a; *see also Perelman*, 125 A.3d at 1266 n.3 (materials which had been discussed in a

prescribing physicians about the product's addictive qualities and about the fact that it was approved for use only in a limited subset of patients. R.R. 623a-24a. Specifically, the label's "black-box warning" cautioned that ACTIQ "**is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.** . . . [and] contraindicated in the management of acute or postoperative pain. This product **must not** be used in opioid non-tolerant patients." R.R. 623a (emphasis in original). Elsewhere the label repeated in several locations that ACTIQ is "indicated" for use in a limited subset of patients and not for the treatment of acute pain. *Id.* In addition, the label contained the following language: "**WARNING: May be habit forming**." *Id.* It further advised prescribers that ACTIQ "may be subject to misuse, abuse, and addiction." R.R. 624a. For this reason, the label explained, "[t]he administration of [ACTIQ] should be guided by the response of the patient." *Id.*The label also provided prescribers with detailed instructions on the proper dosing of ACTIQ. *Id.*

Plaintiffs contend that notwithstanding the RMP and the advisories contained in the label, Defendants allegedly marketed ACTIQ to physicians in violation of federal law for the treatment of pain in patients who do not have

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plaintiff's complaint "could properly be considered by the trial court in the context of a demurrer").

cancer. R.R. 415a-16a. Plaintiffs allege that such promotion of ACTIQ for a use not approved by the FDA violates the Federal Food, Drug, and Cosmetic Act. R.R. 419a (¶ 30). Defendants aver that among the doctors influenced by these purported marketing practices was Thomas C. Barone, D.O. ("Dr. Barone"). R.R. 420a-22a (¶¶ 33-41). According to Plaintiffs, on unspecified dates, certain unidentified "sales representatives, agents, workpersons and employees" made "sales calls" to the offices of Dr. Barone in order to promote ACTIQ. R.R. 420a (¶ 34). From approximately August 2005 until December 2011, Dr. Barone prescribed ACTIQ to the Decedent in an attempt to treat the pain associated with the Decedent's migraine headaches. R.R. 420a-23a (¶¶ 36, 47). According to Plaintiffs, the Decedent "was initially prescribed the 400 mcg. dosage strength in August of 2005 and within four (4) months, the previous potency had doubled to 800 mcg. . . ." R.R. 422a (¶ 44). During the same time period Dr. Barone also prescribed the Decedent "other Schedule II opiate medications . . . ." R.R. 422a-23a (¶ 47).

According to Plaintiffs, Defendants' alleged promotion of ACTIQ for "off-label" use caused the Decedent to become addicted to opioids. R.R. 422a (¶ 45). Beginning in April 2006, he received continuous treatment for his addiction, including inpatient treatment on at least five occasions between April 2006 and December 2012. R.R. 422a-23a (¶¶ 46-50). Defendants further aver, without specifying when, that as part of the Decedent's treatment, Dr. Barone "determined

that Methadone was warranted to curtail Decedent's need" for opioids. R.R. 423a (¶ 51).

The Decedent died on May 15, 2014. R.R. 423a (¶ 52). Plaintiffs allege that his death was "due to an adverse reaction to the prescription medication being prescribed by Dr. Barone." *Id.* The Decedent's autopsy reported the cause of his death as "drug intoxication" and the manner of his death as "methadone toxicity." R.R. 423a (¶ 53).

SUMMARY OF THE ARGUMENT

Binding Supreme Court precedent holds that plaintiffs may not do what Plaintiffs in this case seek to do: premise state tort claims solely on alleged violations of the FDCA where the defendant's conduct would not be actionable under state tort law in the absence of the FDCA. State law is preempted when it conflicts with federal law, such as when it is impossible to comply with both state and federal law (which sometimes occurs in the context of generic drugs) or when, as in this case, state law acts as an obstacle to the accomplishment of federal law's purposes.

In *Buckman*, the Supreme Court recognized that attempts to enforce the FDCA's requirements using state tort litigation interfere with the purposes embodied in the FDCA. The FDCA expressly provides that it may be enforced only by the federal government, and as the Court has emphasized, federal enforcers

balance competing interests in ensuring that prescription drugs and devices are approved for their intended use while also allowing and indeed encouraging medical professionals on the ground to exercise their expert judgment in deciding whether to prescribe a particular drug or device for an FDA-unapproved use. Although Plaintiffs cast their claims in the garb of state law tort claims such as negligence and fraud, they are all in substance claims alleging that promoting drugs for FDA-unapproved, off-label uses is a violation of federal law (specifically the FDCA). Plaintiffs' claims therefore threaten that delicate balance and are preempted by federal law under *Buckman* and its progeny, just as the trial court held. The Court can and should affirm on this basis alone.

But if the Court goes further, it will discover that Plaintiffs' claims have other insurmountable problems. *First*, despite the Plaintiffs' efforts to label Defendants' acts and omissions as deceptive, when Plaintiffs' allegations are stripped of the legal conclusions, the Second Amended Complaint contains not a single specific factual allegation of a genuinely misleading or false statement. Plaintiffs thus have failed to state a claim for fraud, much less satisfy the heightened particularity requirements that apply to such claims.

Second, Plaintiffs' whole case relies on information that they claim was improperly provided, or improperly not provided, about Defendants' product and its risks. But Plaintiffs have not asserted a claim for failure to warn, and rightly so:

the information Plaintiffs contend should have been provided—that ACTIQ was indicated only for the FDA-approved treatment of breakthrough cancer pain and contraindicated for FDA-unapproved treatment of acute pain—was clearly and repeatedly expressed on ACTIQ's very label. The risk of addiction was also prominently disclosed on the label and, moreover, Plaintiffs' own Complaint acknowledges that the risk of addiction was well-known in the medical community. Plaintiffs' claims therefore fail under the Learned Intermediary doctrine, which provides that manufacturers may not be held liable for prescribing decisions made by well-informed medical professionals. The treating physician here had all the relevant information and prescribed the product based on his assessment of the Decedent's specific medical needs according to Plaintiffs' own allegations. Under the Learned Intermediary doctrine, Defendants' conduct could not have been the legal cause of the Decedent's death.

Third, Plaintiffs' allegations also undermine any purported causal connection between Defendants' conduct and Plaintiffs' injuries more broadly. Plaintiffs acknowledge that Decedent had stopped using Defendants' product years before his death, had become addicted to other opiates, and that Decedent's death was actually caused by a separate medication prescribed by his physician. Taking these allegations as true, there is no reasonable argument that Defendants' products were the proximate cause of Plaintiffs' injuries.

Fourth, Plaintiffs' Unfair Trade Practices and Consumer Protection Law ("UTPCPL") claim fails because the statute's text does not provide for recovery in cases of bodily injury.

Finally, the trial court was correct to dismiss Plaintiffs' Second Amended Complaint—their third overall—with prejudice. Plaintiffs never asked the trial court for leave to amend and even now do not explain how they could replead so as to avoid these many fatal legal problems evidencing the futility in this approach.

This Court should affirm the decision below in its entirety.

ARGUMENT

I. All Of Plaintiffs' Claims Are Impliedly Preempted By The Federal Food, Drug, And Cosmetic Act Under *Buckman* and its Progeny.

The trial court correctly concluded that Plaintiffs' claims must be dismissed because all are impliedly preempted by the FDCA under binding precedent from the Supreme Court of the United States. Trial Ct. Op. 6. *Buckman* holds that state law claims premised on alleged violations of the FDCA and associated federal regulations are preempted because they conflict with the provision of the statute that gives the federal government exclusive enforcement power over the FDCA and associated FDA regulations. As the trial court observed, "[t]his is not a claim for failure to warn due to missing or inadequate labeling." Trial Ct. 1925(a) Op. 2. "This is a claim by Plaintiffs who assert that the Defendant[s] . . . violated FDA and FDCA rules and statutes . . . ." *Id.* Given Plaintiffs' inability to ground their

claims in state law and the firmly established fact that "[t]here is no private right to enforce the FDCA," Trial Ct. Op. 6, Plaintiffs' claims necessarily fail as a matter of law and the judgment below should be affirmed.

A. State Tort Claims That Conflict With Federal Law Are Preempted Under The U.S. Constitution's Supremacy Clause.

The federal Constitution's Supremacy Clause preempts state law contrary to federal law by recognizing federal law as "the supreme Law of the Land." U.S. CONST. art. VI, cl. 2; *see also, e.g.*, *Hughes v. Talen Energy Mktg., LLC*, 136 S. Ct. 1288, 1297 (2016). State law, including state common law causes of action, can be preempted as inconsistent with federal statutes for several different reasons.

Sometimes Congress's purposes are made clear through language that explicitly prohibits or overrides certain categories of state laws—so-called "express preemption."[3] Separately, regardless of whether the federal statute contains an express preemption provision, it can *implicitly* preclude the operation of certain state law—so-called "implied preemption." There are different and distinct recognized bases for implied preemption:

[3] *E.g.*, *Coventry Health Care of Mo., Inc. v. Nevils*, 137 S. Ct. 1190, 1194 (2017) (federal statute providing that certain federal contracts "shall supersede and preempt" certain state laws); *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (federal statute superseding state laws that "relate to any employee benefit plan."); *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 458 (2012) (federal statute forbidding states from imposing certain "[r]equirements . . . in addition to, or different than those made under" the Federal Meat Inspection Act).

- Implied "field" preemption occurs when Congress has manifest an intention of forbidding states to take action in a regulatory field Congress wishes to be governed exclusively under the federal statute.[4]
- Implied "impossibility" preemption occurs when compliance with both state and federal law is impossible. In such cases, federal law binds and state law is without effect.[5]
- Implied "obstacle" preemption occurs when the state law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"[6]

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[4] *E.g.*, *Hughes*, 136 S. Ct. at 1297 (Federal Power Act grants federal regulators exclusive authority over interstate wholesale electricity rates); *Arizona v. United States*, 567 U.S. 387, 399, 402 (2012) (enforcement of federal immigration laws is a field of exclusively federal concern); *Kurns v. R.R. Friction Prods. Corp.*, 565 U.S. 625, 634 (2012) (Locomotive Inspection Act manifests intention of exclusively occupying field of regulating locomotive equipment).

[5] *E.g.*, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013) (state design-defect claim preempted where FDCA and FDA regulations prohibit manufacturer from altering generic drug's composition); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (state failure-to-warn claims preempted where FDCA and FDA regulations prohibit manufacturer from altering generic drug's labeling).

[6] *Arizona*, 567 U.S. at 406-07 (certain state penalties for violations of federal immigration laws impermissibly conflict with Congress's chosen method of enforcement); *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333 (2011) (state common law doctrines disfavoring arbitration agreements are preempted as obstacle to Federal Arbitration Act provision making arbitration agreements enforceable).

Impossibility and obstacle preemption are often grouped together by courts in a broader category of implied "conflict" preemption because each involves a palpable conflict between federal and state law.

The Supreme Court has recently stressed that the second category of implied preemption—impossibility preemption—is particularly important in the context of generic drugs. Some state tort liability would effectively require generic manufacturers to change their products or labeling in ways that the federal laws governing generic drugs would forbid, thereby making compliance with both state and federal law impossible. *See Bartlett*, 133 S. Ct. at 2473 (design defect claims); *Mensing*, 564 U.S. at 618 (failure-to-warn claims). This case does not involve impossibility preemption.

Instead, this case involves obstacle preemption. Under the obstacle preemption analysis employed in *Buckman*, Plaintiffs' state law claims are foreclosed because allowing them to proceed would frustrate Congress's purposes and objectives as clearly manifested in the FDCA.

B. Claims Premised On FDCA Violations Conflict With Congress's Purposes And Objectives Because They Amount To Private Attempts To Enforce The FDCA.

The FDCA provides that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a); *see also* Pub. L. No. 717, § 307, 52 Stat. 1040, 1046

(1938).[7] That language was included when the FDCA was first enacted, in conscious rejection of an earlier version that permitted private actions for injuries "proximately caused by a violation of [the] Act." S. 1944, § 24, 73rd Congress, 1st Session (June 6, 1933), *reprinted in* 1 FDA, A LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND ITS AMENDMENTS 31 (1979).

Buckman recognized that section 337 "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA]" and is "clear evidence that Congress intended that the [statute] be enforced exclusively by the Federal Government." 531 U.S. at 349 n.4, 352. Given this clear statement of Congress's intention that the FDCA's provisions be enforceable only by the federal government, the Court held that section 337 impliedly preempts state tort claims that, in *Buckman*'s words, exist "solely by virtue of the FDCA" rather than by virtue of independent "state tort law which had predated the federal enactments in question." 531 U.S. at 353.

Buckman involved FDA-approved medical devices, but pharmaceutical drugs are also subject to its holding. *See infra* pp. 27-28. Plaintiffs are flatly wrong to suggest that "a separate federal statute" governed in *Buckman*. Caltagirone Br. 14. While medical devices are *additionally* covered by an express

[7] In its current form, the provision has a narrow exception, but that exception has no relevance here because it addresses suits by states to enforce some of the FDCA's food-related provisions. *See* 21 U.S.C. § 337(b)(1).

preemption provision specific to them, 21 U.S.C. § 360(k), section 337's no-private-actions provision applies to the full FDCA and in fact predates the federal government's regulation of medical devices. *See* Pub. L. No. 717, § 307, 52 Stat. at 1046. The express preemption provision for devices is irrelevant and, as *Buckman* recognized, has no effect on "the ordinary working of conflict pre-emption principles." 531 U.S. at 352 (citation omitted); *see also Arizona*, 567 U.S. at 406 ("[T]he existence of an 'express preemption provisio[n] does *not* bar the ordinary working of conflict preemption principles' or impose a 'special burden' that would make it more difficult to establish the preemption of laws falling outside the clause.'") (citation omitted).

Nor, contrary to what Plaintiffs misleadingly suggest, *see* Caltagirone Br. 8-9, did the *Buckman* Court limit its holding to claims overtly styled as claims for FDCA enforcement, while leaving all state law causes of action intact. The Court rejected the *Buckman* plaintiffs' efforts to premise a common law claim—fraud—on violations of FDCA provisions. That was a direct repudiation of the Third Circuit decision that *Buckman* reversed, which had permitted the plaintiffs' claims to go forward after noting that they were "drafted to track the elements of a common law cause of action for fraudulent misrepresentation[.]" *In re Orthopedic Bone Screw Liab. Litig.*, 159 F.3d 817, 822 (3d Cir. 1998), *rev'd sub nom. Buckman*, 531 U.S. 341.

The Supreme Court instead sided with the federal trial court, which (like the Court of Common Pleas in this case) had found the claims impliedly preempted because they "amounted to an improper assertion of a private right of action" for FDCA violations. *Buckman*, 531 U.S. at 347. The substance of the *Buckman* plaintiffs' fraud allegations was that the medical device manufacturer had "made fraudulent representations to the FDA as to the intended use of the [device] . . . ." *Id.* at 347. That would have violated disclosure requirements designed to help the FDA determine whether to approve the device for its stated intended use. *See id.* at 345-46.

But in the Supreme Court's view, allowing a private citizen to enforce the FDCA through state tort litigation would undermine the FDA's "authority . . . to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. On the one hand, the FDA seeks "to ensure . . . that medical devices are reasonably safe and effective," but on the other hand it also seeks to ensure that they are promptly approved and that physicians remain free to engage in "'off-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA)." *Id.* at 349-50. Because "the existence of the[] federal enactments [was] a critical element in their case," unlike a traditional state law claim for fraud, the plaintiffs' claims would have "exert[ed] an extraneous pull

on the scheme established by Congress" and were accordingly preempted. *Id.* at 353.

Buckman's reasoning has also been followed in other Supreme Court decisions outside the FDCA context. These cases have similarly recognized that Congress intended certain federal statutes to be enforceable by the federal government only. For instance, the Court recently concluded, citing *Buckman*, that the statutory framework Congress enacted in immigration law precludes state enforcement of federal alien registration requirements: "Permitting the State to impose its own penalties for the federal offenses here would conflict with the careful framework Congress adopted." *Arizona*, 567 U.S. at 402 (citation omitted). And in a series of decisions stretching back decades, the Court has held that states may not provide "their own regulatory or judicial remedies for conduct prohibited or arguably prohibited by the [National Labor Relations] Act." *Wisc. Dep't of Indus., Labor & Human Relations v. Gould Inc.*, 475 U.S. 282, 286 (1986) (citation omitted). Where Congress manifests a clear intention not to let one of its statutes be enforced through state law mechanisms, the Supremacy Clause and the doctrine of implied obstacle preemption preclude state-law enforcement.

C. State Claims Premised On The Propriety Or Scope Of FDA Approval—Including Claims Premised On "Off-Label" Promotion—Are Preempted By The FDCA.

Since *Buckman*, many courts have rejected attempts by civil plaintiffs to enforce the FDCA's unique requirements through state tort law. All manner of tort claims—including the types of claim alleged in this case (negligence, fraud, and consumer protection), R.R. 424a-30a (¶¶ 56-87)—have been held preempted when premised on such allegations of FDCA violation. Where, as here, a plaintiff cannot identify any independent pre-existing state law authority prohibiting the conduct that allegedly violates the FDCA, the plaintiff in reality is improperly trying to enforce the FDCA's requirements.

For instance, a *negligence* claim arguing that a defendant breached the standard of ordinary care by violating the FDA's conditions of approval is simply "a disguised fraud on the FDA claim" and squarely foreclosed by *Buckman*. *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 423-24 (6th Cir. 2005). *Fraud* claims may not go forward based solely on "failure to disclose lack of FDA approval." *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (citation omitted). Neither may state *consumer-protection* claims alleging that products were illegal solely because their labeling violated FDCA requirements: "[t]he statute's public enforcement mechanism is thwarted if savvy plaintiffs can label as arising under a state law . . .

a claim that in substance seeks to enforce the FDCA." *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013).

The same reasoning precludes Plaintiffs' claims, which are premised entirely on alleged off-label promotion and so arise solely under the FDCA. Plaintiffs do not offer any state law legal duty basis for their claims. They do not contend—and cite no cases suggesting—that off-label promotion is independently controlled or prohibited by Pennsylvania statutory or common law. Instead, they argue there is liability here because *the FDCA* prohibits "promot[ing] the use of regulated drugs for any indications that have not been formally approved by the FDA . . . ." R.R. 419a (¶ 30).

At bottom, the trial judge recognized that Plaintiffs are alleging much the same FDCA violation as the plaintiffs in *Buckman—i.e.*, that a manufacturer who intends its product to be put to off-label uses needs to secure FDA approval for those uses. *See Buckman*, 531 U.S. at 347. But *Buckman* forecloses state-law claims based on allegations that a manufacturer exceeded FDA approval and violated the FDCA, because "the relationship between a federal agency and the entity it regulates is inherently federal in character." *Buckman*, 531 U.S. at 347. As *Buckman* explained, the FDCA gives the FDA a variety of means of enforcing the FDCA and carrying out its mission. *Id.* at 349. The FDA can conduct investigations, 21 U.S.C. § 372, seek injunctive relief, *id.* § 332, seize misbranded

drug products, *id.* § 334(a), and request monetary or criminal penalties, *id.* § 333(a). This "variety of enforcement options" allows the FDA "to make a measured response" to any FDCA violations and, such "flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing objectives)." *Buckman*, 531 U.S. at 349.

As *Buckman* itself recognized, off-label use presents particularly difficult calculations for the FDA. Federal law has long recognized potential health benefits from allowing physicians to prescribe drugs and devices for off-label uses when in their specialized medical judgment that is the best treatment. *See id.* at 350-51 & n.5. At the same time, federal law requires manufacturers to establish the efficacy and safety of all intended uses of their products and not promote off-label uses that have not yet secured FDA approval. The FDA therefore must "balance[] recognized benefits of off-label uses with potential harms associated with promotion of such use." *Perdue v. Wyeth Pharms., Inc.*, 209 F. Supp. 3d 847, 852 (E.D.N.C. 2016) (citing *Buckman*, 531 U.S. at 351 & n.5). Claims like Plaintiffs' here, which are premised on the FDCA's prohibition of off-label promotion, risk interfering with the FDA's delicate balance of competing objectives and would strip the FDA of the enforcement authority and discretion that *Buckman* sought to preserve.

Thus, when a plaintiff attempts to premise state-law claims on alleged promotion of prescription drugs for unapproved, off-label uses, courts regularly hold such claims preempted by *Buckman* and its progeny. Such decisions follow directly from the Supreme Court's reasoning in *Buckman* because "[t]he restrictions and guidelines placed upon pharmaceutical companies for off-label promotion are entirely dependent upon the statutory and regulatory scheme created by the FDCA." *Perdue*, 209 F. Supp. 3d at 852 (dismissing negligence *per se* claims). Put differently, "[a]s the concept of 'off-label' is entirely federal," claims for off-label promotion "would not exist in the absence of the FDCA and are therefore impliedly preempted under *Buckman*." *McDaniel v. Upsher-Smith Pharms., Inc.*, 229 F. Supp. 3d 707, 713 (W.D. Tenn. 2017) (dismissing negligence and negligence *per se* claims). That is exactly what the trial court correctly held here (*see* Trial Ct. Op. 6) in line with many other courts nationwide. *E.g.*, *Markland v. Insys Therapeutics, Inc.*, — F. Supp. 3d —, 2017 WL 4102300, at *11 (M.D. Fla. Sept. 15, 2017) (dismissing negligence claim); *McLeod v. Sandoz, Inc.*, No. 16-01640, 2017 WL 1196801, at *7 (D.S.C. Mar. 31, 2017) (dismissing negligence and negligence *per se* claims); *Connolly v. Sandoz Pharms. Corp.*, No. 14-152, 2014 WL 12480025, at *6 (N.D. Ga. Dec. 23, 2014) (dismissing negligence/fraud claims); *Goldsmith v. Allergan, Inc.*, No. 09-7088, 2011 WL

147714, at *2-3 (C.D. Cal. Jan. 13, 2011) (dismissing statutory fair advertising and unfair competition claims).[8]

The present case bears a striking legal resemblance to the recent *Markland* decision.[9] There, as here, the plaintiff brought a wrongful death action alleging that a manufacturer of a fentanyl product was liable for negligence on the ground that it allegedly had promoted its product for off-label use when the product was FDA-approved only for treatment of breakthrough cancer pain. *Markland*, 2017 WL 4102300, at *2-3. The plaintiff nevertheless insisted he was "not seeking to bring a private right of action under the FDCA," but rather was seeking to use the

[8] Following the same rationale as these drug cases, there also are a great number of decisions finding preemption of claims premised on off-label promotion of FDA-approved medical devices. *E.g.*, *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 857, 862 (W.D. Tenn. 2015) ("Any claim based solely on off-label promotion would thereby be impliedly preempted.") (negligence claims); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1219-20 (W.D. Okla. 2013) ("While plaintiff couches her claim as a state law fraudulent misrepresentation/fraud in the inducement claim, this claim is in substance a claim for violating the FDCA and, thus, is clearly preempted under Buckman and § 337(a).") (fraud claims), *aff'd on other grounds*, 784 F.3d 1335 (10th Cir. 2015); *Aaron v. Medtronic, Inc.*, No. 13-202, 2016 WL 5242957, at *12 (S.D. Ohio Sept. 22, 2016) ("'[T]here is no state-law duty to abstain from off-label promotion.'" (citations omitted)) (failure to warn, design defect, negligence, and breach of implied warranty claims).

[9] One significant factual difference, however, is that the death of the decedent in *Markland* was directly caused by the fentanyl product, 2017 WL 4102300, at *2, whereas in this case the decedent's cause of death was a different drug, occurring years after the Decedent had stopped using ACTIQ. *See infra* Section II.C. That factual difference thus points to an additional problem for Plaintiffs' claims, namely lack of legal causation. *Id.*

"alleged violation of federal law as evidence to support his negligence claim." *Id.* at *3. The court nevertheless saw through that argument because "throughout his complaint, [he] repeatedly refer[red] to [the defendant's] alleged violations of the FDCA." *Id.* at *9. The "substance" of the plaintiff's complaint, "while framed in the language of negligence, appear[ed] to derive from [the] alleged off-label promotion." *Id.* "Because the 'existence of [off-label promotion] . . . is a critical element in [his] case,'" the plaintiff's claim was preempted. *Id.* (quoting *Buckman*, 531 U.S. at 353). As shown below, the same is true here for every one of Plaintiffs' claims.

D. All Of Plaintiffs' Claims Are Premised On Allegations Of Off-Label Promotion And So Are Preempted.

Plaintiffs' claims all run headlong into *Buckman* preemption because they are premised entirely on alleged off-label promotion of an FDA-unapproved use of ACTIQ. That is, Plaintiffs fail to articulate any independent state law duty under Pennsylvania law as the basis for their claims in the absence of the FDCA.[10] Allegations of off-label promotion run throughout the Second Amended Complaint

[10] Plaintiffs' general assertion of a duty of "due care" does not suffice. The plaintiffs in *McLeod* also alleged that the defendant owed a duty to "exercise due care," but the court recognized that such allegations were insufficient to maintain negligence or negligence *per se* claims premised entirely on off-label promotion. *McLeod*, 2017 WL 1196801, at *3, *7.

and are the beginning and end of Plaintiffs' allegations that Defendants breached any legal duty.

Hence Plaintiffs' negligence claim (Count I) faults Defendants for allegedly marketing ACTIQ "as safe, appropriate and effective for medical conditions not approved by the FDA . . . ." R.R. 425a (¶ 62). The fraud claim (Count II) similarly alleges such promotion despite Defendants' knowledge that ACTIQ "was only approved by the FDA for the very limited purpose of treating patients with breakthrough cancer pain . . . ." R.R. 426a (¶ 66). The negligent misrepresentation claim (Count III) alleges that Defendants "had a duty to accurately and truthfully represent . . . that [ACTIQ] was only approved by the FDA to be safe and effective for the treatment of patients with breakthrough cancer pain . . . and that it was not approved by the FDA as safe and effective for the treatment of non-cancer pain." R.R. 428a (¶ 74). The UTPCPL claim (Count IV) rests on the same allegations. R.R. 430a (¶ 82).

As a consequence, Plaintiffs do not "rely[] on traditional state tort law which had predated the federal enactments" of the FDCA and accompanying regulations. *Buckman*, 531 U.S. at 353. For example, they do not, and cannot, allege any of the "classic and well known triumvirate of grounds for liability" in products-liability law: "defective manufacture, inadequate directions or warnings, and defective design." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 232 (2011) (citing W. KEETON

ET AL., PROSSER AD KEETON ON LAW OF TORTS 695 (5th ed. 1984); RESTATEMENT (THIRD) OF TORTS § 2 (1999)). There is no challenge whatsoever to the warnings provided in, or any other content of, ACTIQ's label. To the contrary, as the trial court observed, "[t]his is not a claim for failure to warn due to missing or inadequate labeling." Trial Ct. 1925(a) Op. 2.

Instead, Plaintiffs allege that Defendants "violated FDA and FDCA rules and statutes when they purportedly promoted and marketed the off-label use of ACTIQ for migraine headaches." Trial Ct. 1925(a) Op. 2. Such claims "'exist[] solely by virtue of the FDCA requirements' with respect to approved use of [Defendants' product]." *Perez*, 711 F.3d at 1119 (quoting *Buckman*, 531 U.S. at 353). Like the fraud claims in *Buckman* and *Perez* and the negligence claim in *Markland*, the claims here are dressed up in the trappings of state law, but at their core they are nothing more than an effort to enforce the FDCA's requirements through private litigation. Under *Buckman* and its progeny, Plaintiffs' claims are impliedly preempted by the FDCA and thus the trial court's decision should be affirmed.

E. Plaintiffs' Cited Cases Have No Bearing On The Preemption Issue Here.

Plaintiffs try to fault the trial court for not relying on cases that address entirely different issues. None of these cases calls the trial court's reasoning into question.

To begin with, the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), involved a traditional failure-to-warn products-liability claim—namely, an allegation that a drug's label failed to warn that one method of administering the drug posed an increased health risk. *Id.* at 559-60. That claim was premised not on the violation of any FDCA regulation, but on traditional product liability tort law principles.[11] That is exactly why the Court applied the "presumption against preemption," which Plaintiffs mistakenly invoke in their opening brief even though it is clearly inapplicable here. Caltagirone Br. 11 & n.7. The *Wyeth* majority noted that the case before it involved well-established methods of state regulation through standard tort law. 555 U.S. at 565 n.3. *Buckman* and this case, on the other hand, involve "the relationship between a federal agency and the entity it regulates [which] is inherently federal in character," making the presumption against preemption inapplicable just as the *Buckman* court recognized. 531 U.S. at 347-48; *see also Wyeth*, 555 U.S. at 565 n.3.

The same is true of *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553 (E.D. Pa. 2008). There the plaintiffs alleged that the defendant "failed to warn

[11] *Amicus* Pennsylvania Association for Justice ("PAJ") additionally rely on three cases from this Court that apply *Wyeth* in scenarios similar to *Wyeth*. PAJ Br. 4-5. None involved claims premised on FDCA violations, as the claims here do. They instead involved the *Wyeth* failure-to-warn fact pattern. *See Gurley v. Janssen Pharms., Inc.*, 113 A.3d 283, 289-90 (Pa. Super. 2015); *Czimmer v. Janssen Pharms., Inc.*, 122 A.3d 1043, 1052-53 (Pa. Super. 2015); *Maya v. Johnson & Johnson, Inc.*, 97 A.3d 1203, 1213 (Pa. Super. 2014).

either the public or the medical community of [newly discovered] dangers associated with [its] drug[.]" *Id.* at 597 (citation omitted). That too is a traditional failure-to-warn products-liability claim. But here, Plaintiffs in this case have not brought any failure-to-warn claim and Defendants did not fail to warn anyone of any dangers associated with ACTIQ. In fact, the ACTIQ label unequivocally disclosed that the product was "indicated only for the management of breakthrough cancer pain" and "[m]ay be habit forming" and "subject to misuse, abuse and addiction." R.R. 623a-24a.

Plaintiffs' citation of *Hassett v. Dafoe*, 74 A.3d 202 (Pa. Super. 2013), is similarly misguided. That case addresses the entirely different type of preemption—impossibility preemption—that arises for generic drugs when it is impossible for generic drug manufacturers to comply with both state and federal law. *See Bartlett*, 133 S. Ct. at 2473; *Mensing*, 564 U.S. at 618; *supra* Section I.A. In *Hassett*, the Court explicitly said that the issue before it was "whether all claims asserted by Plaintiffs against generic drug manufacturers are failure-to-warn claims pre-empted by *Mensing*." *Hassett*, 74 A.3d at 209. So too with *In re Reglan/Metoclopramide Litig.*, 81 A.3d 80, 87 (Pa. Super. 2013). Nothing in either opinion involves a cause of action premised on the FDCA, attempts to define the scope of conflict preemption under *Buckman*, or even attempts to enforce FDCA requirements through civil lawsuits. In fact, neither opinion so much as cites

Buckman or section 337. Thus, they fail to address the *Buckman* preemption issues presented here.[12] Finally, *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), is also inapposite. Contrary to what Plaintiffs say, Caltagirone Br. 15, *Lance* was not a preemption case at all. The question instead was whether one of the traditional types of products-liability claims—defective product design—is available at all in suits against drugmakers as a matter of substantive Pennsylvania common law. Although Plaintiffs emphasize two paragraphs that discuss *Levine* and inherent limits in the FDA's efforts to ensure product safety, Caltagirone Br. 15 n.12, the *Lance* court did not address efforts to premise state law claims on FDCA violations, did not address *Buckman*, and did not address the preemptive effect of section 337, *Lance*, 85 A.3d at 456-57.

Plaintiffs unfairly criticize the judge below for not addressing these cases, Caltagirone Br. 8, 11-12, 15 n.11 (to say nothing of Plaintiffs' other unfair accusations against the court below, *see, e.g.*, *id.* at 6 n.3). But trial court judges are under no obligation to address every cited authority, particularly when the cited cases are irrelevant. The *relevant* authorities, meanwhile, plainly confirm that the trial court was correct to dismiss the Second Amended Complaint in full. Plaintiffs' alleged off-labeling claims are premised entirely on violations of the

[12] PAJ makes the same error in relying on *Hassett* in its amicus brief. PAJ Br. at 3-4.

FDCA, in contravention of Congress's recognized intent that the statute be enforced only by the federal government and not by private litigants.

II. Independent Of Implied Preemption, Plaintiffs' Claims Face Multiple Further Problems.

Even aside from implied preemption, the Complaint's dismissal must stand for the following separate and independent reasons.[13]

A. Plaintiffs Have Failed To Allege Any False Or Misleading Statement Or Omission And Have Failed To State A Claim For Fraud.

Although Plaintiffs repeatedly allege that Defendants made untruthful statements, in substance these allegations all reduce to allegations of off-label promotion. Plaintiffs accuse Defendants of misrepresenting the fact that ACTIQ was approved and indicated only for the treatment of breakthrough cancer pain and unapproved and contraindicated for the treatment of other pain. *E.g.*, R.R. 426a-28a (¶¶ 66, 70, 74-76). But even if these off-label promotion accusations were grounded in common law principles rather than the FDCA, they would fall far short of the pleading requirements for fraud claims. The most glaring problem is that Plaintiffs, despite setting forth a sea of unsupported conclusory allegations,

[13] Even if this Court disagrees with the trial court's holding that this case is impliedly preempted under *Buckman*, it may affirm the decision below on alternate grounds. *See, e.g.*, *Commonwealth v. Allem*, 532 A.2d 845, 848 (Pa. Super. 1987) ("[a] ruling or decision of a lower court will be affirmed if it can be supported on any basis despite the lower court's assignment of a wrong reason") (quoting *Commonwealth v. Terry*, 521 A.2d 398, 409 (1987)) (internal citation omitted).

have not managed to identify any untruthful statements allegedly made by Defendants.

A party alleging fraud or mistake in a pleading must do so "with particularity." Pa.R.C.P. 1019(b). That means, "at the very least[,] a plaintiff must set forth the exact statements or actions plaintiff alleges constitute the fraudulent misrepresentations." *Youndt v. First Nat'l Bank of Port Allegany*, 868 A.2d 539, 545 (Pa. Super. 2005) (internal quotation marks, brackets, and citation omitted); *see also, e.g., Commonwealth ex rel. Pappert v. TAP Pharms. Prods., Inc.*, 868 A.2d 624, 636 (Pa. Commw. 2005) (dismissing claims where pleadings identified purportedly fraudulent documents but "fail[ed] to reflect the information contained in those documents").

The Second Amended Complaint does not identify even *one* allegedly false or misleading factual statement or omission. While Plaintiffs assert many conclusory allegations that Defendants' marketing strategy was "deceptive," "false," or "misleading," Plaintiffs do not allege any specific factual statements by Defendants that were purportedly untrue.

Rather, Plaintiffs return again and again to allegations that Defendants engaged in off-label promotion. But they never identify any specific instance of off-label promotion that included a false or misleading factual statement or omission, and "the promotion of off-label drug use is not in and of itself false or

misleading." *United States v. Caronia*, 703 F.3d 149, 165 (2d Cir. 2012); *see also In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 06-5774, 2009 WL 2043604, at *33 (D. N.J. July 10, 2009) (dismissing fraud and negligent misrepresentation claims premised on off-label drug promotion because plaintiffs did not plead "a single instance in which they, themselves, or any of their prescribing doctors received a misrepresentation of fact from Defendants and relied upon that misrepresentation in deciding to prescribe one of the Subject Drugs to Plaintiffs.").

Similarly, Plaintiffs accuse Defendants of falsely representing that ACTIQ was "safe and effective for the treatment of non-cancer pain" and "disregard[ing] the extreme danger of causing serious illness, addiction and death to non-cancer patients . . . ." R.R. 426a (¶ 66). But nowhere do Plaintiffs carry their burden of "set[ting] forth the exact statements or actions" to that effect. *See Youndt*, 828 A.2d at 545 (citation and quotation marks omitted). Instead, even now in their appellate brief, Plaintiffs simply cross-reference a broad swath of paragraphs from the Second Amended Complaint, none of which identifies any concrete false statement by Defendants or anyone else. Caltagirone Br. 22 (citing R.R. 419a-23a, 426a-27a (¶¶ 31-48, 65-72)).[14]

[14] Plaintiffs' conclusory allegations of "fraud" are further refuted by the "instructions for use" that Plaintiffs allege were provided by defendants. R.R. 415a-16a (¶ 16). The ACTIQ label clearly sets forth the scope of the product's

The closest Plaintiffs come to identifying any specific statement is citing an article written by a non-party physician and researcher, Dr. Stephen H. Landy, attached as Exhibit 3 to the Second Amended Complaint. *See* Caltagirone Br. 22. But while Plaintiffs assert broadly that Dr. Landy's article "was false and misleading," *id.*, they never explain *what* "was false and misleading" in the article. Nothing in the article minimizes the risks of addiction, and the ultimate conclusion was tentative: "Further controlled studies are warranted." R.R. 470a.

But the failure to identify any false or misleading representation is only the beginning of the claims' failings. The plaintiff must "establish *every* element of its fraud claim with sufficient particularity" in order to proceed, which includes not just the false representations, but also their materiality, the defendant's intent to mislead, and the proximate causation between the representation and the injury. *Presbyterian Med. Ctr. v. Budd*, 832 A.2d 1066, 1073 (Pa. Super. 2003) (emphasis added).[15] Plaintiffs do not even attempt to plead these elements with particularity,

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FDA-approved indications and details its risks. *See supra* pp. 10-11. Plaintiffs do not identify any statement that contradicts the statements in this labeling, nor do they identify any omission that the label should have included.

[15] The elements of a fraud claim are: "(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." *Youndt*, 868 A.2d at 545 (citing *Gibbs v. Ernst*, 647 A.2d 882, 889 (Pa. 1994)).

but instead rely completely on conclusory assertions that restate the elements of the fraud and misrepresentation claims. *See* R.R. 426a-29a.

The Second Amended Complaint's allegations of fraud and deception, which run throughout all of Plaintiffs' claims, fall far short of what is required under Pennsylvania law. That is not a mere oversight, but an incurable lack of factual support for Plaintiffs' fraud and misrepresentation claims (which Plaintiffs failed to correct despite multiple amendments). Before Plaintiffs filed their Second Amended Complaint, Defendants raised this pleading problem in the Preliminary Objections to Plaintiffs' initial Complaint, R.R. 93a-94a, 123a-25a, and then raised it again in the Preliminary Objections to the First Amended Complaint, R.R. 291a-93a, R.R. 325a-27a. Despite multiple chances, Plaintiffs remain unable to cure the problem and furnish the particularity that the law requires. For this additional reason, the trial court correctly decided to dismiss the Second Amended Complaint with prejudice and the judgment should be affirmed.

B. The Learned Intermediary Doctrine Bars All Of Plaintiff's Claims Because The Treating Physician Chose To Prescribe Defendants' Product Based On Complete Information And Professional Judgment.

As the trial court observed in dicta, all of Plaintiffs' claims are also barred by Pennsylvania's "Learned Intermediary" doctrine. The court recognized that "Defendants' warning labels about ACTIQ[®] are not being challenged by these Plaintiffs." Trial Ct. Op. 6. It therefore discussed the Learned Intermediary

doctrine not as a defense to a (non-existent) failure-to-warn claim but as "an expansion of the Defendants' concerns about the deficits of proof in Plaintiffs' proximate causation arguments." *Id.* at 6-7. While it did not premise its dismissal of Plaintiffs' claims on the doctrine's application, the trial court correctly recognized that Plaintiffs' own allegations about Dr. Barone's knowledge of ACTIQ's indication and risks preclude any argument that Defendants could have caused the Decedent's death.

The Learned Intermediary doctrine holds that a manufacturer's duty to disclose risks is owed "not to the general public or to the patient, but to the prescribing doctor." *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971) (citation omitted). A physician is obligated to be a *learned* intermediary between manufacturer and patient and "to make an independent medical judgment in determining whether a given drug is appropriate for a particular patient." *Brecher v. Cutler*, 578 A.2d 481, 485 (Pa. Super. 1990). Apart from information provided by the manufacturer, the physician has a "duty . . . to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can safely be administered, and (3) the different medications the patient is taking." *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1385 (Pa. 1991) (quoting *Makripodis v. Merrell-Dow Pharms., Inc.*, 523 A.2d 374, 378 (Pa. Super. 1987)). Armed with all this information, the physician must "use his independent medical

judgment, taking into account the data supplied to him by the manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug." *Id.* at 1386 (citations and quotation marks omitted).

This doctrine bars all of Plaintiffs' claims. Plaintiffs' own allegations show that Dr. Barone's decision to prescribe ACTIQ for the Decedent was not the result of any alleged off-label promotion by Defendants, but an exercise of his medical judgment.

To begin with, and as explained above, Defendants clearly disclosed on the ACTIQ label the product's risks and indications. *See supra* pp. 10-11. Like any prescribing physician, the Decedent's physician is "presumed to have knowledge of [the] drug label's contents." *Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon*, No. 13-7167, 2014 WL 2115498, at *6 (E.D. Pa. May 21, 2014) (citations omitted).

Moreover, Dr. Barone was obligated to know of the risks of addiction even apart from this label. Plaintiffs expressly claimed that it was "common knowledge in the medical community" that ACTIQ is "highly addictive." R.R. 422a (¶ 42). And as the trial court explained in its discussion of the Learned Intermediary doctrine, Plaintiffs' own allegations demonstrate that "in addition to his own medical background and independent judgment, Dr. Barone had actual knowledge

that his patient became addicted to Fentanyl as early as April, 2006," when the Decedent was allegedly admitted for inpatient treatment to detoxify him from ACTIQ. Trial Court Op. at 9; *see also* R.R. 422a-23a (¶¶ 46-47). Pennsylvania courts have long recognized that physicians are obligated to consider precisely this type of information—"the characteristics of the drug" and "the personal medical history of" their patients—in determining whether to prescribe a drug to a particular patient. *Coyle*, 584 A.2d at 1385-86 (citations omitted); *see also Lineberger v. Wyeth*, 894 A.2d 141, 150 (Pa. Super. 2006), (citation omitted); *Brecher*, 578 A.2d at 219 (citation omitted); *cf. Council of Carpenters Welfare Fund*, 2014 WL 2115498, at *6.

Yet despite prominent warnings on the ACTIQ label and the Decedent's growing addiction, Dr. Barone continued to prescribe ACTIQ to the Decedent. According to the Second Amended Complaint itself, Dr. Barone chose to prescribe ACTIQ to the Decedent with all the relevant information in hand. There is no suggestion, nor could there be, "that a different warning would have altered [the treating physician's] prescribing methods vis-à-vis [the patient]"—a key factor in overcoming an argument that the Learned Intermediary doctrine breaks the chain of causation, as is the case here. *See Lineberger*, 894 A.2d at 150; *see also Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. 1996) (the causal connection between a defendant's conduct and the plaintiff's injury is

absent where the plaintiff fails to prove that if the defendant had provided different information the physician "would have altered his behavior and the injury would have been avoided.") (citation omitted). Thus, Defendants cannot reasonably be held to be the proximate cause of Dr. Barone's decision to prescribe ACTIQ to the Decedent.[16]

Faced with their Complaint's own allegations and well-settled precedent, Plaintiffs attempt to circumvent the Learned Intermediary doctrine by selectively quoting *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), in an attempt to call the doctrine into doubt. But *Lance* was (unlike this matter) a traditional product liability case and merely explained the doctrine's application "in a situation in which no warning would be sufficient" because the product was so dangerous "it should not have been ingested by anyone." 85 A.3d at 457. This case of course does not present such a situation, nor does it involve traditional product liability or failure-to-warn claims. Further, unlike *Lance*, the prescriber here was not denied relevant information about the product's risks. On the contrary and as noted already, the allegations of the Second Amended Complaint establish that Dr. Barone was

[16] Plaintiffs' reliance on *Daniel v. Wyeth Pharmaceuticals, Inc.*, 15 A.3d 909 (Pa. Super. 2011) and *Terrell v. Davol, Inc.*, No. 13-5074, 2014 WL 3746532 (E.D. Pa. July 30, 2014), is misplaced and only underscores the weakness of Plaintiffs' case, as does the reliance of *amicus* PAJ on *Czimmer*, 122 A.3d at 1058 and *Gurley*, 113 A.3d at 294. Unlike this case, each of those cases involved plausible assertions that the physician lacked material information about the defendants' pharmaceutical products. (Furthermore, *Terrell* does not bind this court.)

informed of all the relevant risks and knew of the Decedent's specific addiction as early as 2006 but continued to prescribe ACTIQ for years.

In sum, even if Plaintiffs' claims could avoid preemption and the utter absence of any untruthful statements by Defendants, the Learned Intermediary doctrine would still sever any causal connection between Defendants' conduct and the Decedent's death. Accordingly, the trial court's decision may be affirmed in full on this alternative basis.

C. Plaintiffs' Allegations Establish That Defendants' Acts Or Omissions Were Not The Legal Cause Of Plaintiffs' Alleged Injuries For Additional Reasons.

The allegations in the Second Amended Complaint effectively concede there was no causal connection between Defendants' purported breach of any duty and the injury alleged. Pennsylvania law requires a plaintiff alleging negligence to plead, among other things, "a causal connection between the [defendant's] conduct and the resulting injury." *R.W. v. Manzek*, 888 A.2d 740, 746 (Pa. 2005) (citations omitted). The required "causal connection" must be sufficient to constitute proximate cause. *See, e.g.*, *Young v. Commw. Dep't of Transp.*, 744 A.2d 1276, 1277-78 (Pa. 2000) (citation omitted). Similarly, a plaintiff must aver the existence of a causal connection in order to plead negligent-misrepresentation, fraud, and UTPCPL claims. *Bortz v. Noon*, 729 A.2d 555, 561 (Pa. 1999); *Youndt*, 868 A.2d at 545; *Weinberg v. Sun Co.*, 777 A.2d 442, 446 (Pa. 2001).

The Second Amended Complaint establishes that there is no colorable question of causation that should be reserved for discovery and the trier of fact. As explained above in Section II.B, Plaintiffs' own allegations establish that it was not the actions of Defendants that caused the Decedent's addiction and death. Plaintiffs allege that the Decedent took ACTIQ only until 2011. R.R. 422a-23a (¶ 47). They concede, moreover, that Dr. Barone had prescribed the Decedent "other Schedule II opiate medications" in addition to ACTIQ. *Id.* They further allege that the Decedent received treatment for his addiction throughout 2012 and that it was Dr. Barone who eventually determined "that Methadone was warranted" to treat the Decedent's ongoing opiate addiction. R.R. 423a (¶¶ 50-51). And then Plaintiffs concede that in 2014—*more than two and a half years after he had stopped using ACTIQ*—the Decedent died from "methadone toxicity" as a result of Dr. Barone's treatment (and an entirely separate drug). R.R. 423a (¶ 53).

In short, Plaintiffs' Second Amended Complaint alleges that the Decedent had stopped using Defendants' product, but had become addicted to other opiates and required treatment for the ongoing addiction, and that it was the drug Dr. Barone prescribed to treat that ongoing addiction, not ACTIQ, that caused his death. Accepting Plaintiffs' allegations as true, ACTIQ and Defendants' conduct cannot reasonably satisfy the requirement to plead proximate cause of Plaintiffs'

alleged injuries and thus the trial court's judgment in favor of Defendants should be affirmed.[17]

D. Personal Injury Claims Are Not Cognizable Under The UTPCPL.

Though the trial court did not need to reach the question of whether, preemption aside, Plaintiffs had stated a claim under Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), that claim fails as a matter of law for reasons Defendants explained in their Preliminary Objections. *See* R.R. 503a-06a; R.R. 542a-45a.

By its plain language, the UTPCPL does not permit recovery for personal injuries. Instead, the statute provides relief only in cases of economic loss or damage to property. It provides in relevant part that "any person who purchases or leases goods or services primarily for personal, family or household purposes *and thereby suffers any ascertainable loss of money or property*, real or personal, as a result of the use or employment by any person of a method, act or practice declared unlawful by [§ 201-3], may bring a private action to recover actual damages . . . ." 73 P.S. § 201-9.2(a) (emphasis added).[18]

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[17] In addition, as explained above in Section II.B, the Learned Intermediary Doctrine severs any causal link (to the extent one otherwise might exist) between Defendants' conduct and Decedent's death.

[18] Section 201-3, in turn, declares it unlawful to engage in "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce as defined by" section 201-2. Under section 201-2, "unfair methods

Although Defendants are unaware of any decisions from this Court or the Supreme Court addressing the question, federal courts applying the UTPCPL's language routinely hold that personal injury claims are outside the statute's scope. *See, e.g.*, *Walkup v. Santander Bank, N.A.*, 147 F. Supp. 3d 349, 358 (E.D. Pa. 2015) (holding that, because they are "personal injuries," shame, embarrassment, and emotional distress are "not cognizable under the UTPCPL"); *Arndt v. Johnson & Johnson*, 67 F. Supp. 3d 673, 682 (E.D. Pa. 2014) (recognizing that "it is true that personal injury claims are not permitted under the Pennsylvania [UTPCPL] statute") (citation omitted); *Krisa v. Equitable Life Assurance Soc.*, 113 F. Supp. 2d 694, 706-07 (M.D. Pa. 2000) (observing that "damages for anxiety, emotional distress, depression and aggravation of physical illness are not recoverable under the UTPCPL" because they do not fall within the definition of "ascertainable loss of money or property" and holding that a plaintiff was thus barred from recovering "emotional distress type damages" under the statute). In addition, at least one Court of Common Pleas decision has drawn similar conclusions. *Crumm v. Murphy & Co., Inc.*, 10 Pa. D. & C.5th 268, 282 (Com. Pl. Sept. 16, 2009)

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of competition" and "unfair or deceptive acts or practices" include "[c]ausing likelihood of confusion or misunderstanding as to the source, sponsorship, approval or certification of goods or services," "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have . . . ," and "[r]epresenting that goods or services are of a particular standard, quality or grade . . . if they are of another."

(concluding that plaintiffs "cannot recover damages for pain and suffering" under the UTPCPL because such recovery "is not permitted under the UTPCPL as it does not fall within the express limitations of the statute which recognizes as actual damages only 'any ascertainable loss of money or property'" (citation and quotation marks omitted)).

Plaintiffs have failed to allege any "ascertainable loss of money or property" in their UTPCPL claim. They instead set forth only a speculative estimate of "Wrongful Death damages." R.R. 430a (¶ 85); *see also Jarznya v. Home Props., L.P.*, 185 F. Supp. 3d 612, 626 (E.D. Pa. 2016) (recognizing that damages claimed under the UTPCPL "cannot be speculative"); *Allen v. Wells Fargo, N.A.*, No. 14-5283, 2015 WL 5137953, at *8 (E.D. Pa. Aug. 28, 2015) (same).

Perhaps recognizing this weakness in their UTPCPL claim, Plaintiffs do not even attempt to address the statutory text or decisions set forth above, even though these same arguments were presented in Defendants' Preliminary Objections. Instead, Plaintiffs mischaracterize Defendants' arguments as contending that "the 'learned intermediary doctrine . . . preclude[s] [UTPCPL] claims related to prescription drugs." Caltagirone Br. 23. While the Learned Intermediary doctrine does bar all of Plaintiffs' claims, *see supra* Section II.B, Defendants' argument regarding the UTPCPL claim specifically is independent of that doctrine and

grounded in the statute's text. Plaintiffs have done nothing to rebut these arguments, which require dismissal of Count IV.

III. The Trial Court Correctly Dismissed The Second Amended Complaint With Prejudice And Plaintiffs' Argument To The Contrary Is Waived.

Plaintiffs contend that "the court erred under Pa. R. Civ. Proc. 1028(e)."[19] Caltagirone Br. 24-25. They appear to be arguing that the trial court should have given them leave to amend their pleading, and they request that such relief be granted now.

As a threshold matter, Plaintiffs have waived any right to seek amendment as they failed to assert such a request before the trial court. *See generally* R.R. 625a-92a; 700a-51a. "Issues not raised in the lower court are waived and cannot be raised for the first time on appeal." Pa.R.A.P. 302(a).

But even if Plaintiffs had preserved their right to seek leave to amend, amendment would be improper. Plaintiffs have now had three opportunities to properly assert their claims against Defendants: they filed a Complaint on September 26, 2016, to which Defendants filed detailed and substantial Preliminary Objections that closely resembled the Preliminary Objections that

[19] In reality, Rule 1028(e) provides that "*If* the filing of an amendment, an amended pleading or a new pleading is allowed or required, it shall be filed within twenty days after notice of the order or within such other time as the court shall fix." Pa.R.C.P. 1028(e) (emphasis added). The Rule does not address when leave to amend is appropriate.

ultimately were sustained below. *See* R.R. 15a-75a (Complaint); R.R. 76a-201a (Preliminary Objections to Complaint). In response, Plaintiffs filed an Amended Complaint which was nearly identical to their original pleading, and Defendants once again filed extensive Preliminary Objections. *See* R.R. 202a-69a (First Amended Complaint); R.R. 270a-410a (Preliminary Objections to First Amended Complaint). Plaintiffs then attempted to assert their claims a third time, filing a Second Amended Complaint which was again nearly identical to their earlier pleadings. *See* R.R. 411a-77a (Second Amended Complaint). Once again, Defendants objected. *See* R.R. 478a-624a (Preliminary Objections to Second Amended Complaint). Even now, Plaintiffs offer no hint at how they could cure the fatal deficiencies affecting each of the Second Amended Complaint's claims for relief.[20] *See generally* Caltagirone Br. 24-25. Their silence on this point speaks volumes.

"[A] court is not required to permit amendment of a pleading if a party is unable to state a claim on which relief could be granted." *Bayada Nurses, Inc. v.*

[20] Among the deficiencies in Plaintiffs' Second Amended Complaint is their inclusion of impertinent matter in violation of Pa.R.C.P. 1028(a)(4). Defendants objected to this content in their Preliminary Objections to the Second Amended Complaint, but the trial court did not have occasion to reach their objection. *See* R.R. 509a-11a, 549a-52a; *see also generally* Trial Ct. Op. Should this Court decline to affirm the trial court's dismissal with prejudice of the Second Amended Complaint, Defendants respectfully request that the matter be remanded so that Plaintiffs' improper inclusion of impertinent matter in their pleading can be addressed by the court below.

Commonwealth, 8 A.3d 866, 884 (Pa. 2010) (citation omitted). Because Plaintiffs remain unable to state cognizable claims against Defendants—after three full opportunities—they do not deserve a fourth "bite at the apple."[21]

CONCLUSION

The order of the Court of Common Pleas should be affirmed.

Respectfully submitted,

Dated: October 2, 2017

s/ John P. Lavelle, Jr.

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[21] Were this Court to order the trial court to grant Plaintiffs leave to amend another time, Defendants reserve the right to raise the same procedural objections that were asserted in their Preliminary Objections to the Second Amended Complaint—*i.e.*, that (a) Plaintiffs have failed to attach writings upon which their claims are based, as required by Pa.R.C.P. 1019(i); (b) Plaintiffs' Wrongful Death Claim and Survival Action are legally insufficient; (c) Plaintiffs' claim for punitive damages is legally insufficient; and, as noted already, (d) Plaintiffs have improperly included impertinent matter in their pleading in violation of Pa.R.C.P. 1028(a)(4). *See* R.R. 492a-95a, 506a-11a, 530a-32a, 546a-52a.

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with Pa.R.A.P. 2135(a)(1) because it includes 11,863 words according to the word count feature of Microsoft Word 2010, excluding the parts exempted by Pa.R.A.P. 2135(b).

Dated: October 2, 2017

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CERTIFICATE OF SERVICE

I hereby certify that on this date, I served a true and correct copy of this filing by this Court's electronic filing system to:

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