NON-PRECEDENTIAL DECISION - SEE SUPERIOR COURT I.O.P. 65.37

JOSEPH A. CALTAGIRONE, AS ADMINISTRATOR AD PROSEQUENDUM FOR THE ESTATE OF JOSEPH F. CALTAGIRONE, DECEASED AND JOSEPH A. CALTAGIRONE, INDIVIDUALLY, Appellant v. CEPHALON, INC. AND TEVA PHARMACEUTICALS USA, INC., Appellees	IN THE SUPERIOR COURT OF PENNSYLVANIA No. 1303 EDA 2017

Appeal from the Order Entered March 23, 2017
in the Court of Common Pleas of Philadelphia County
Civil Division at No.: September Term, 2016 No. 02877

BEFORE: LAZARUS, J., OTT, J., and PLATT, J.*

MEMORANDUM BY PLATT, J.: **FILED MAY 09, 2018**

Appellant, Joseph A. Caltagirone, appeals individually and as administrator of the estate of his deceased son, Joseph F. Caltagirone, from the order sustaining preliminary objections of Appellees, Cephalon, Inc. and Teva Pharmaceuticals, USA, Inc., to his second amended complaint, and dismissing it with prejudice.[1] We conclude that the trial court properly

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* Retired Senior Judge assigned to the Superior Court.

[1] On October 14, 2011, Cephalon was acquired by Teva Pharmaceuticals, USA, Inc. Once Teva completed its acquisition of Cephalon, Cephalon became a wholly owned subsidiary of Teva and ceased to be publicly traded.

determined that Appellant's wrongful death and survival claims, premised on asserted violations of the Federal Food, Drug, and Cosmetic Act (FDCA),[2] (and implementing regulations), are pre-empted by the federal system of regulation and enforcement by the United States Food and Drug Administration (FDA). Accordingly, we affirm.

We derive the facts of this case from the trial court's opinion, (***see*** Memorandum in Support of Order Dismissing Plaintiffs' Second Amended Complaint, 3/23/17, at 1-4), and our independent review of the record.

The decedent, Joseph F. Caltagirone, suffered from migraine headaches. In 2005, he began treating with Thomas C. Barone, D.O., who prescribed ACTIQ, a form of fentanyl marketed and sold by co-Appellee Cephalon, Inc.

ACTIQ is a very powerful opioid approved by the FDA in 1998 only for "breakthrough" cancer pain of opioid-tolerant patients.[3] It is packaged and sold as a berry-flavored "lollipop" on a stick.[4] ACTIQ carries a "Black Box" warning label, (the most serious type of FDA warning, named for the required distinctive black perimeter), advising of the risk of serious adverse health

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[2] 21 U.S.C.[A.] §§ 301-399.

[3] Breakthrough pain "breaks through" despite the pain relief medication the patient is already taking.

[4] ACTIQ is a "transmucosal immediate–release fentanyl" (TIRF) product, which means the drug is delivered across mucous membranes, such as inside the cheek or under the tongue. This is particularly useful for cancer patients who have difficulty swallowing or taking medication in other ways.

consequences from the use of ACTIQ, including respiratory depression, addiction, and death. The Black Box label warns against the use of ACTIQ for any condition other than cancer pain, including, specifically, migraine headaches.

Appellant acknowledges that physicians may **prescribe** medications for purposes other than those approved by the FDA, (known as "off-label" uses). However, he maintains that Appellees unlawfully and recklessly **promoted**, **marketed and sold** ACTIQ for off-label uses **not approved by the FDA**, in violation of the FDCA, and the FDA's implementing regulations, to increase sales. (***See*** Second Amended Complaint, 1/05/17, at 8 ¶ 30).

Dr. Barone prescribed ACTIQ to Decedent for about six years, from 2005 to 2011, for the relief of pain from his migraine headaches. This period included at least two episodes of inpatient hospitalization for Mr. Caltagirone's detoxification and related treatment. In 2011, Dr. Barone stopped prescribing ACTIQ for Mr. Caltagirone and moved him to other opioids. About two and a half years later, on May 15, 2014, Mr. Caltagirone died. The autopsy stated the cause of Mr. Caltagirone's death was "drug intoxication" from "methadone toxicity."

Appellant brought a wrongful death and survival action suit against Cephalon and Teva. In pertinent part, the complaint alleged:

> 16. Despite Actiq's very limited purpose, approval and instructions for use, during the period from 2000 through at least 2011, Defendants engaged in an unlawful, deceptive and reckless pattern and practice of marketing, promoting and selling Actiq, for

> *inter alia*, the treatment of pain of patients with a wide range of conditions for which Actiq was inappropriate, highly dangerous, contradicted **and specifically forbidden by the FDA as further set forth herein.**

(Second Amended Complaint, at 4-5, ¶ 16) (emphasis added).

Appellant maintains that Appellees engaged in a deliberate comprehensive marketing campaign to boost sales of ACTIQ beyond pain relief for cancer patients by promoting off-label use, including for migraine headaches. He asserts this program set higher quotas for sales representatives than could be met solely by sales for cancer patients. It also allegedly encompassed promotional distribution of "free" coupons for ACTIQ, the preparation of pertinent marketing materials for promotion of other uses including for migraine headaches, and commissioning key opinion leaders to write articles, do studies, and make presentations at medical conferences on the use of ACTIQ for pain management by non-cancer patients.

The overarching theme of the complaint is that even though Mr. Caltagirone died from methadone toxicity, an adverse reaction to the methadone he was taking as prescribed by Dr. Barone, his underlying addiction was proximately caused by Appellees' program of promoting ACTIQ for non-FDA approved pain management. (***See id.*** at 12 ¶ 54).

The trial court sustained Appellees' preliminary objections and dismissed the second amended complaint with prejudice, on March 23, 2017, with a supporting memorandum. Appellant timely appealed on April 13, 2017. The trial court did not order a Rule 1925(b) statement of errors. On May 2, 2017,

the trial court filed a Rule 1925(a) opinion referring to its memorandum of March 23, 2017 for the reasons of its decision. ***See*** Pa.R.A.P. 1925.

Appellant raises nine questions on appeal:

> 1. Did the trial court err in holding that federal law preempts the state law tort claims presented in the second amended complaint?
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> 2. Did the trial court err in holding that the "learned intermediary" doctrine bars the claims here?
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> 3. Did the complaint have attached to it all requisite writings?
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> 4. Are causation elements of negligence and negligent misrepresentation claims for a jury to determine?
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> 5. Was fraud pled with sufficient particularity?
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> 6. Did the complaint allege sufficient elements?
>
> 7 Was the complaint free of scandalous or impertinent matter?
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> 8. In the alternative, did the court erred [sic] under Pa. R. Civ. Proc. [sic] 1028(e)?

(Appellant's Brief, at 2-3).[5]

> Our standard of review of an order granting preliminary objections is well-settled:
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> > Preliminary objections in the nature of a demurrer should be granted where the contested pleading is legally insufficient. ***Cardenas v. Schober***, 783 A.2d 317, 321 (Pa.

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[5] We also have the benefit of a brief filed on behalf of *amici curiae,* the Chamber of Commerce of the United States of America, the Pennsylvania Chamber of Business and Industry and the Pennsylvania Coalition for Civil Justice Reform, as well as an *amicus curiae* brief filed on behalf of the Pennsylvania Association for Justice.

> Super. 2001) (citing Pa.R.C.P. 1028(a)(4)). "Preliminary objections in the nature of a demurrer require the court to resolve the issues solely on the basis of the pleadings; no testimony or other evidence outside of the complaint may be considered to dispose of the legal issues presented by the demurrer." ***Hess v. Fox Rothschild, LLP***, 925 A.2d 798, 805 (Pa. Super. 2007) (quoting ***Cardenas***, 783 A.2d 317 at 321). All material facts set forth in the pleading and all inferences reasonably deducible therefrom must be admitted as true. ***Id.***
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> ***Cooper v. Church of St. Benedict***, 954 A.2d 1216, 1218 (Pa. Super. 2008). In 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 Pennsylvania, Inc.***, 80 A.3d 813, 814 (Pa. Super. 2013). Moreover, we review the trial court's decision for an abuse of discretion or an error of law. ***Lovelace ex rel. Lovelace v. Pennsylvania Prop. & Cas. Ins. Guar. Ass'n***, 874 A.2d 661, 664 (Pa. Super. 2005).

Kilmer v. Sposito, 146 A.3d 1275, 1278 (Pa. Super. 2016).

Here, the trial court reasoned that Appellant's claims for negligence, misrepresentation, fraud, and violation of the Unfair Trade Practices and Consumer Protection Law (UTPCPL), explicitly premised on violation or disregard of FDCA and FDA regulation, "could not exist in the absence of federal laws and regulations." (Trial Court Memorandum, 3/23/17, at 6). We agree.

Appellant's pleadings are legally insufficient. Even admitting as true all well-pled material facts set forth in the pleading and all inferences reasonably deducible therefrom, as we must under our rules, our independent review confirms that the pervasive claim of Appellant's complaint is that Appellees' various derelictions, (principally, promoting sales for off-label purposes), were

not approved or were in direct violation of the FDCA or its implementing regulations.

However, with narrow exceptions not asserted and not applicable here, the general rule is that there is no private right to enforce the law and regulations of the FDCA. ***See*** 21 U.S.C.A. § 337(a) ("Except as provided in subsection (b) of this section, **all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States**.") (emphasis added); ***see also Buckman Co. v. Plaintiffs' Legal Comm.***, 531 U.S. 341 (2001) (where federal enactments form critical element of plaintiff's case, litigation over "fraud-on-the-agency" claims do not rely on traditional state tort law, and are pre-empted).

Because Appellant's claims rely on asserted violations of the FDA's "off-label" restrictions, which are pre-empted, the trial court properly sustained Appellees' preliminary objections to his complaint. Accordingly, it is unnecessary for us to review the remainder of Appellant's issues, and we decline to do so.

Order affirmed.

Judgment Entered.

Joseph D. Seletyn, Esq.
Prothonotary

Date: 5/9/18