IN THE COURT OF COMMON PLEAS OF PHILADELPHIA
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

JOSEPH A. CALTAGIRONE, as Administrator Ad Prosequendum for the Estate of JOSEPH F. CALTAGIRONE, Deceased and JOSEPH A. CALTAGIRONE, Individually	:	SEPTEMBER TERM, 2016
Plaintiffs	:	NO. 2877
vs.	:	
CEPHALON, INC. and TEVA PHARMACEUTICALS USA, INC.	:	
Defendants	:	
RE: JOSEPH A. CALTAGIRONE, as Administrator Ad Prosequendum for the Estate of JOSEPH F. CALTAGIRONE, Deceased and JOSEPH A. CALTAGIRONE, Individually	:	**SUPERIOR COURT**
	:	**1303 EDA 2017**
APPELLANTS	:	

OPINION TO THE HONORABLE
SUPERIOR COURT

MASSIAH-JACKSON, J.

Date: May 2nd, 2017

In 2005, Joseph F. Caltagirone went to his doctor with complaints of migraine headaches. His doctor prescribed ACTIQ, a solid form of fentanyl. ACTIQ is manufactured by Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. Mr. Caltagirone, then age 30, became addicted to his medication. In 2006, he was admitted to Thomas Jefferson University Hospital to be medically detoxified from ACTIQ. By 2011, Mr. Caltagirone was no longer using ACTIQ.

In 2016, the Estate of Joseph F. Caltagirone and his family filed this Wrongful Death and Survival Act litigation against the manufacturers of ACTIQ. This is not a claim for failure to warn due to missing or inadequate labeling. This is a claim by Plaintiffs who assert that the Defendant pharmaceutical companies violated FDA and FDCA rules and statutes when they promoted and marketed the known off-label use of ACTIQ for migraine headaches. Plaintiffs contend the Defendants "are not legally permitted to [do so]."

On January 25, 2017, Cephalon and Teva filed numerous Preliminary Objections to the Second Amended Complaint, including but not limited to Rule 1028(a)(4) in the nature of demurrer. The Defendants provided a detailed and comprehensive overview in support of their contentions that all of the Plaintiffs' claims are impliedly preempted by the FDA and federal laws. See Defendants' Memorandum, pages 7-17, dated January 25, 2017. In response, Plaintiffs' were unable to identify averments in their Second Amended Complaint which distinguished their claims from conduct already prohibited by the FDA and FDCA. See, Plaintiffs' Memorandum, pages 10-14, dated February 13, 2017.

On March 16, 2017, oral argument was presented. On March 23, 2017, this Court accepted the material facts and reasonable inferences and concluded that Plaintiffs' claims are impliedly preempted. The demurrer was Sustained and Plaintiffs' Second Amended Complaint was Dismissed With Prejudice. See Court Exhibit "A", attached hereto.

Plaintiffs filed a timely Notice of Appeal. In accordance with Rule 1925(a) of the Pennsylvania Rules of Appellate Procedure, this Court respectfully refers the Honorable Superior Court to the **Memorandum in Support of Order Dismissing Plaintiffs' Second Amended Complaint, dated March, 23, 2017**, attached hereto as Court Exhibit "B", as the reason for the ruling and the final Order.

BY THE COURT:

FREDERICA A. MASSIAH-JACKSON, J.

Control No. 17013103

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Defendants	:	

ORDER

And Now, this 23rd day of March, 2017, upon consideration of the Preliminary Objections of Defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. to Plaintiffs' Second Amended Complaint, Plaintiffs' Response thereto, after oral argument held on March 16, 2017, and for the reasons set forth in the Memorandum filed this date, it is hereby **ORDERED** that the Preliminary Objections are **SUSTAINED**. Plaintiffs' Second Amended Complaint is **DISMISSED With Prejudice.**

BY THE COURT:

Massiah-Jackson

FREDERICA A. MASSIAH-JACKSON, J.

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Court Exhibit "A"

Control No. 17013103

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA
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Plaintiffs	:	NO. 2877
vs.	:	
CEPHALON, INC. and TEVA PHARMACEUTICALS USA, INC.	:	
Defendants	:	

MEMORANDUM in SUPPORT OF ORDER DISMISSING PLAINTIFFS' SECOND AMENDED COMPLAINT

MASSIAH-JACKSON, J.

March 23rd, 2017

Court Exhibit "B"

I. FACTUAL BACKGROUND

In 2005, Joseph F. Caltagirone became a patient of Dr. Thomas C. Barone for treatment of migraine headaches. Paragraph 33. For seven years, from 2005 through 2011, Dr. Barone prescribed the opioid medication ACTIQ. Paragraphs 36-37. ACTIQ was approved by the Food and Drug Administration as a pain medication for cancer pain. Paragraphs 10-12. The prescription of ACTIQ for the pain of migraines was a known but off-label use. ACTIQ, a form of Fentanyl, is highly addictive. Mr. Caltagirone was admitted to Thomas Jefferson University Hospital for detoxification in April, 2006. Paragraph 46. On release, he returned to Dr. Barone for more prescriptions for ACTIQ until the end of 2011. Paragraphs 42-47.

During the next four years, Mr. Caltagirone was in and out of drug treatment programs. His addictions to multiple Schedule II opiates and other illicit drugs were on-going. He died on May 15, 2014 at age 39. Paragraphs 48-53. His cause of death was "drug addiction" and "methadone toxicity." Paragraph 3.

Mr. Caltagirone's father, the Administrator of the Estate, initiated this Wrongful Death and Survival Act litigation against Defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. ("Cephalon and Teva"), asserting claims for negligence, fraud, misrepresentation and violation of UTPCPL.

In their Memorandum at pages 20-21, the Plaintiffs explain the basis for the assertion that the Defendant pharmaceutical companies caused the 2014 death of Joseph F. Caltagirone. Paragraph 54 states:

> "54. As indicated above, Mr. Caltagirone's need for methadone treatment and his ultimate death was directly related to his 'addiction' which was proximately caused by the Defendants' plan, scheme and design to fraudulently market Actiq to the medical community which Defendants' knew would result in individuals like Mr. Caltagirone being prescribed Actiq."

Cephalon, a pharmaceutical company, manufactures, sells, and distributes ACTIQ and Fentora. At some time in 2011, Teva acquired Cephalon. Both Defendants are existing corporate pharmaceutical entities. ACTIQ was approved by the FDA in 1998, as a solid form of Fentanyl. Paragraph 9 states:

> "9. In November of 1998, the Federal Drug Administration ("FDA") granted restricted marketing approval for Actiq, limiting its lawful marketing ***only*** for malignant cancer patients experiencing breakthrough cancer pain who had developed a tolerance to less dangerous therapies for their underlying cancer pain. The FDA further specified that Actiq should not be marketed for off-label uses and that the drug must be prescribed solely to cancer patients by oncologists and pain specialists specifically trained in the use of schedule II opioids to treat pain in cancer patients." (emphasis in original)

The Second Amended Complaint alleges that despite the dangers of addiction and death, as well as a specific mandate to "actively discourage non-cancer uses of ACTIQ", these Defendants marketed, promoted and sold ACTIQ for treatment of pain "with a wide range of conditions," including migraine headache pain. Paragraphs 11-27.

The underlying basis for the entire litigation and each averment of negligence, fraud and/or deception, is Plaintiffs' position that these Defendants engaged in conduct that was "specifically forbidden by the FDA." Paragraph 16.

II. PROCEDURAL HISTORY

The Defendant pharmaceutical companies seek dismissal of the Second Amended Complaint. They filed Preliminary Objections pursuant to Rule 1028(a)(4) of the Pennsylvania Rules of Civil Procedure in the nature of a demurrer. Defendants contend, **first**, that all of the Plaintiffs' claims are impliedly preempted by the FDA and federal law, and, **second**, that all claims are barred as a matter of law by Pennsylvania's Learned Intermediary rule. In addition, the Defendants filed Preliminary Objections per Rules 1019(b), 1019(i), 1028(a)(2) and 1028(a)(4), challenging, inter alia, the legal sufficiency of certain pleadings, the absence of legal causation to certain counts, failure to plead with particularity to certain counts, failure to attach certain writings, and, challenging inclusion of impertinent matters. **Note:** to the extent that Plaintiffs suggest that certain preliminary objections are defective on the grounds that they should have been presented as an affirmative defense, the Plaintiffs could have filed preliminary objections to Defendants' preliminary objections. Lexis Nexis Practice Guide: Pennsylvania Civil Pre-Trial Practice 2017 Edition §§4.06, 4.13.

All issues were fully briefed by all parties. Counsel presented oral argument on March 16, 2017. After careful consideration this Court concludes that the Complaint should be dismissed with prejudice.

III. LEGAL DISCUSSION

When deciding preliminary objections in the nature of a demurrer, all material facts are admitted as true as well as all inferences reasonably deducible. Preliminary objections which seek dismissal of a cause of action should be sustained only when it is clear and free from doubt that a Plaintiff will be unable to establish the right to relief. If any doubt exists as to whether a demurrer should be sustained, the Court should overrule the preliminary objections.

A. Plaintiffs' Claims are Impliedly Preempted By Federal Law.

In this case, the Defendants assert in pertinent part, Memorandum, pages 16-17:

> "The gravamen of Counts I through IV is that Defendants promoted ACTIQ for uses not specifically approved by the FDA. Count I asserts that Defendants breached a duty to promote ACTIQ 'pursuant to the limited purpose and specific guidelines set forth by the FDA' and to be 'truthful as to [its] true warnings and dangers,' Count II avers that they engaged in fraud by representing that ACTIQ could be prescribed 'off-label' despite knowing 'it was only approved by the FDA for [a] very limited purpose,' Count III claims that they had a duty to convey to physicians that ACTIQ 'was not approved by the FDA' for the treatment of non-cancer pain, and Count IV incorporates these allegations in pleading that Defendants 'engaged in unfair and deceptive acts or practices.' (SAC, ¶¶ 57, 66, 74, 83). Plaintiffs' claims do nothing more than attempt to hold Defendants liable for

> promoting their product outside the scope of what is permitted by the FDA. Their claims 'exist[] solely by virtue of' the FDCA, which, as pleaded is the basis for Plaintiffs' allegations of wrongdoing. *See Buckman*, 531 U.S. at 353."

In response, the Plaintiffs look to Wyeth v. Levine, 555 U.S. 555 (2009) to broadly assert that implied preemption is limited to medical device claims. In their challenge to conduct relating to off-label pharmaceutical use, the Plaintiffs' Memorandum highlights Congressional interests to bolster consumer protection and disclosures of safety risks to the public. At our Hearing, Plaintiffs explained that this litigation involves parallel state tort claims which preclude preemption. N.T. 24-26, 49.

A reading of the Second Amended Complaint reveals these Plaintiffs acknowledge that generally off-label sales, promotions and prescriptions are proper, however, in Mr. Caltagirone's case the off-label conduct is charged as "unlawful" by the Plaintiffs solely by virtue of FDA regulations relating to ACTIQ. Paragraphs 30-31 state:

> 30. It is not uncommon in the medical community for drugs to be prescribed for off-label purposes; however, drug manufacturers are not legally permitted to encourage or promote the use of regulated drugs for any indications that have not been formally approved by the FDA and the Food, Drugs and Cosmetics Act ("FDCA"), 21 U.S.C. section (sign) 301, *et seq.*, requires drug manufacturers like Defendants to obtain FDA approval before promoting drugs for expanded indications. Indeed, under the FDCA, a drug cannot be marketed in the United States unless the manufacturer of the drug or its successor submits a New Drug Application (NDA) and demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses.

> 31. Defendants schemed, planned and unlawfully marketed and promoted off-label usage of Actiq throughout the medical community, knowing that physicians would believe its off-label usage was safe for non-cancer patients due to the misrepresentations and false information being provided by Defendants directly and indirectly through paid spokespersons and key opinion leaders."

The negligence, misrepresentation, fraud and UTPCPL claims could not exist in the absence of federal laws and regulations. These Plaintiffs are suing because the promotions of the drug ("an extremely powerful, addictive, dangerous and lethal drug") caused addiction in Mr. Caltagirone. The same drug would cause addiction in a cancer patient. The sole basis for these Plaintiffs to believe they have a claim is because the conduct of promoting the drug for migraine headaches violates the FDCA. e.g. Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001); Perdue v. Wyeth Pharmaceuticals, Inc., 2016 WL 3951091 (E.D. North Carolina 2016). There is no private right to enforce the FDCA.

B. The Learned Intermediary Doctrine.

COMMENT:

It is undisputed in this litigation that the Defendants' warning labels about ACTIQ are not being challenged by these Plaintiffs. In Pennsylvania, in failure to warn cases the Learned Intermediary rule applies. Query whether the Learned Intermediary rule is applicable here? That question was not raised in any of the Memoranda nor at our Hearing. It may be that the principles of the Learned Intermediary rule are more appropriately

considered an expansion of the Defendants' concerns about the deficits of proof in Plaintiffs' proximate causation arguments. See generally the discussions set forth in Daniel v. Wyeth Pharmaceuticals, Inc., 15 A.3d 909, 923-925 (Pa. Superior Ct. 2011); Cochran v. Wyeth, Inc., 3 A.3d 673, 676-678 (Pa. Superior Ct. 2010); Simon v. Wyeth Pharmaceuticals, Inc., 989 A.2d 356, 368-370 (Pa. Superior Ct. 2009).

♦ ♦ ♦ ♦

Because all parties herein have presented vigorous written and oral argument on the Learned Intermediary rule and have asked this Court to determine its impact on the Second Amended Complaint, the following is submitted for consideration:

In Coyle v. Richardson-Merrill, Inc., 584 A.2d 1383 (Pa. 1991), the Supreme Court set forth Pennsylvania's Learned Intermediary rule, at 1385:

> "Since 1971, when this Court decided [Incollingo v. Ewings, 282 A.2d 206 (Pa. 1971)], it has been clear that when a drug 'is available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor.' 444 Pa. at 288, 282 A.2d at 220. We formulated this rule with reference to comment k and the policies expressed therein. As Superior Court succinctly stated in [Makripodis v. Merrill-Dow Pharmaceuticals, Inc., 523 A.2d 374 (Pa. Superior Ct. 1987)],
>
> > 'it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the physician to advise the patient of any dangers or side effects associated with the use of the drug

> as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as '[i]t is for the prescribing physician to 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.''
>
> 361 Pa.Super. at 596-97, 523 A.2d at 378, quoting *Leibowitz v. Ortho Pharmaceutical Corporation,* 224 Pa.Super. 418, 431, 307 A.2d 449, 457 (1973)."

e.g. Rosci v. Acromed, Inc., 669 A.2d 959 (Pa. Superior Ct. 1995); Leibowitz v. Ortho Pharmaceutical Corporation, 307 A.2d 449 (Pa. Superior Ct. 1973).

When looking at the well-pleaded facts and inferences as we must at this procedural juncture, Plaintiffs aver at Paragraphs 42-46:

> "42. Actiq (Fentanyl lollipops) is 80-100 times more powerful than morphine, highly addictive, highly dangerous and lethal, which is common knowledge in the medical community and confirmed by the Centers for Disease Control and Prevention.
>
> 43. Actiq was available in various dosage strengths which were 200 mcg., 400 mcg., 600 mcg., 800 mcg., 1200 mcg., and 1600 mcg.
>
> 44. 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., clearly due to the highly addictive properties of Actiq.
>
> 45. Within eight (8) months of decedent taking Actiq, he became hooked and addicted due to the extremely powerful and addictive propensities of fentanyl.

> 46. Due to Decedent's addiction to fentanyl, in April of 2006, decedent had to be admitted to Thomas Jefferson University Hospital to be medically detoxified from the Actiq."

The Plaintiffs' reliance on Barton v. Wyeth Pharmaceuticals, 2012 WL 112613 (Pa. Superior Ct. 2012), an unpublished non-precedential Memorandum Decision is unpersuasive. The Court there noted that under Illinois law doctors who are not given sufficient or adequate warnings cannot be considered "learned." At our Hearing, the Plaintiffs argued that Mr. Caltagirone's doctor was not "learned" because he was given "misinformation" by the Defendants and others. N.T. 14.

The record as set forth in the Second Amended Complaint is much more expansive. The knowledge of Dr. Barone was not limited to off-label promotions and literature from these Defendants. Rather, in addition to his own medical background and independent judgment, Dr. Barone had actual knowledge that his patient became addicted to Fentanyl at least as early as April, 2006. The harms complained of were known. Despite this knowledge the doctor continued to prescribe ACTIQ for many years.

According to the facts and reasonable inferences as set forth in the Second Amended Complaint, Dr. Barone was fully aware of the characteristics and properties of Fentanyl. Its "highly addictive" qualities were "common knowledge in the medical community." Paragraph 42. Fentanyl's dangerous propensities were "confirmed" by the Centers for Disease Control and Prevention. Paragraph 42. This prescribing physician knew the amount which could be safely administered because his patient had to be "medically

detoxified from ACTIQ" at Thomas Jefferson University Hospital in April, 2006. Paragraph 45. Moreover, as indicated by Defendants' Memorandum at page 22, Dr. Barone was put on notice of the risks associated with ACTIQ by its labeling. Further, as the treating physician it was the duty of this doctor to know other medications his patient may have been taking.

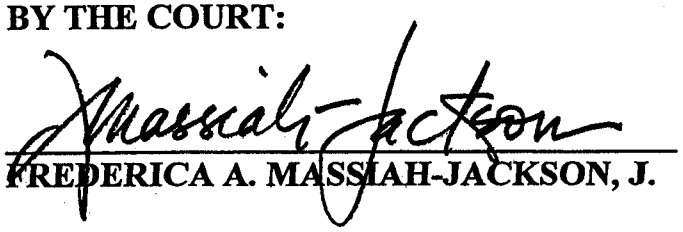
The prescribing physician is the actual consumer when considering the Learned Intermediary rule. This is not a situation involving managed care or direct-to-consumer advertising. Dr. Barone maintained his personal knowledge, education, training and experience combined with his personal judgments. He had the duty to read and consider the materials from the CDC and writings from the Defendant manufacturers (labels as well as promotional materials). Dr. Barone was "learned" within the meaning of Pennsylvania's Learned Intermediary rule. His duty to Joseph F. Caltagirone was to prescribe safe and effective migraine headache treatment.

Plaintiffs' argument is that Dr. Barone could not be "learned" because he read and was subject to sales and promotional conduct discounts the unique situation here. See Plaintiffs' Memorandum at pages 16-19. Dr. Barone had the opportunity to evaluate Mr. Caltagirone's medical needs with a clear understanding of the risks and benefits of ACTIQ starting at least as early as April, 2006.

IV. CONCLUSION

For all of the reasons set forth above, the Plaintiffs' Second Amended Complaint is **DISMISSED With Prejudice.**

BY THE COURT:



FREDERICA A. MASSIAH-JACKSON, J.