Received 9/29/2017 1:31:54 PM Superior Court Eastern District

Filed 9/29/2017 1:31:00 PM Superior Court Eastern District
1303 EDA 2017

SUPERIOR COURT OF PENNSYLVANIA

1303 EDA 2017

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.

BRIEF OF AMICI CURIAE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE PENNSYLVANIA CHAMBER OF BUSINESS AND INDUSTRY, and the PENNSYLVANIA COALITION FOR CIVIL JUSTICE REFORM In Support of Appellees

Appeal from the Order of the Philadelphia County Court of Common Pleas entered on March 23, 2017

Robert L. Byer
Robert M. Palumbos
Andrew R. Sperl
30 South 17th Street
Philadelphia, PA 19103
Phone: (215) 979-1000
Fax: (215) 979-1020
RLByer@duanemorris.com
RMPalumbos@duanemorris.com
ARSperl@duanemorris.com

Counsel for Amici Curiae Chamber of Commerce of the United States of America, the Pennsylvania Chamber of Business and Industry, and the Pennsylvania Coalition for Civil Justice Reform

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

STATEMENT OF INTEREST

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation, representing 300,000 direct members and indirectly representing an underlying membership of more than three million U.S. businesses and professional organizations of every size and in every economic sector and geographic region of the country. One of the Chamber's most important responsibilities is to represent its members' interests before the courts, Congress, and the Executive Branch. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of vital concern to the nation's business community.

The Pennsylvania Chamber of Business and Industry ("PA Chamber") is the largest broad-based business association in Pennsylvania. Thousands of members throughout the Commonwealth employ greater than 50 percent of Pennsylvania's private workforce. The PA Chamber's mission is to improve Pennsylvania's business climate and increase the competitive advantage for its members.

The Pennsylvania Coalition for Civil Justice Reform is a statewide, bipartisan organization representing businesses, health care and other perspectives. The coalition is dedicated to improving Pennsylvania's civil justice system by elevating

awareness of problems and advocating for legal reform in the legislature and fairness in the courts.

SUMMARY OF ARGUMENT

"The Supremacy Clause invalidates state laws that 'interfere with, or are contrary to,' federal law." *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714-15 (1985) (quoting *Gibbons v. Ogden*, 9 Wheat. 1, 211 (1824) (Marshall, C.J.)) (citation omitted). Among the circumstances in which federal law preempts state law are those in which state law "actually conflicts with federal law." *Id.* at 713. "Such a conflict arises when . . . state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (citations and quotation marks omitted.)

The gravamen of Plaintiff's claims is that Cephalon and Teva violated the federal Food, Drug, and Cosmetics Act ("FDCA") by marketing ACTIQ, which is approved to treat breakthrough pain in opioid-tolerant adult patients with cancer, for off-label use. However, Plaintiff's attempt to enforce the FDCA through a state law tort claim necessarily "stands as an obstacle" to the FDA's administrative discretion and is preempted under the Supreme Court's reasoning in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Preemption is essential to avoid interference with federal regulatory schemes and to protect regulated businesses, their employees, and consumers. Allowing plaintiffs to enforce violations of federal law under the guise of state tort law risks undermining federal enforcement efforts by creating different standards for compliance in different states and significant discrepancies in penalties in the state tort system and under federal law. Further, allowing state law tort claims that are predicated on violations of federal law risks deterring conduct that, in the expert judgment of the federal agency, is beneficial. Disregarding the Supreme Court's conflict preemption jurisprudence will have negative effects for numerous federally regulated businesses, not only in the pharmaceutical and medical device industries.

This Court should affirm because the trial court was correct on the law, and because a contrary decision would have significant, harmful effects on Pennsylvania's businesses and citizens.

ARGUMENT

The trial court correctly held that Plaintiff's claims are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, plaintiffs who claimed to be injured by orthopedic bone screws sued the manufacturer's regulatory consultant under state tort law, claiming that the consultant had obtained approval for the screws by making fraudulent representations to the FDA. 531 U.S. at 343.

The plaintiffs' claims in *Buckman* were preempted because they "would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case." *Id.* at 353.The Supreme Court expressly rejected the proposition that "any violation of the FDCA will support a state-law claim." *Id*.

As in *Buckman*, the existence of federal law regarding off-label marketing "is a critical element in [Plaintiff's] case." *Id.* The trial court properly recognized that Plaintiff is attempting to create a private right of action to enforce the FDCA. Because such a cause of action necessarily poses obstacles to the accomplishment of federal policy legislated in the FDCA, Plaintiff's claims are preempted.

This brief addresses the critical policy objectives that animate the *Buckman* rule and the effect that a contrary rule would have on Pennsylvania businesses.

I. *Buckman* Serves Essential Policy Goals that a Reversal Would Undermine.

A. *Buckman* ensures that the FDA retains the legislatively mandated flexibility needed to enforce the FDCA to achieve its policy objectives.

The Supreme Court's reasoning in *Buckman* highlights the importance of its preemption holding: "[T]he federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Buckman*, 531 U.S. at 348.

Exactly those concerns require preemption in this case. Off-label marketing is prohibited under FDA regulations and is regularly subject to enforcement actions by the FDA. In enacting these regulations and deciding how and when to bring enforcement actions in a particular case, the FDA exercises its administrative judgment in order to "achieve a . . . delicate balance of statutory objectives." *Id.* For instance, the FDA recently issued a 60-page draft memorandum stating its

position on off-label marketing communications. *See FDA Memorandum – Public Health Interests and First Amendment Considerations Related to Manufacturer Communications*, FDA Dkt. No. FDA-2016-N-1149-0040 (Jan. 18, 2017) (https://www.regulations.gov/document?D=FDA-2016-N-1149-0040). The FDA memorandum illustrates how the FDA exercises its administrative discretion. For instance,

> FDA's current implementation approach does not proscribe all firm communications about unapproved uses of approved or cleared medical products. FDA has issued guidance documents to describe some of the circumstances when it would not consider a manufacturer's distribution of reprints, clinical practice guidelines, or reference texts regarding unapproved uses of approved/cleared medical products to be evidence of intended use and/or false or misleading. . . .
>
> In addition, it has long been FDA policy not to consider a firm's presentation of truthful and non-misleading scientific information about unapproved uses at medical or scientific conferences to be evidence of intended use when the presentation is made in non-promotional settings and not accompanied by promotional materials.

Id. at 20-21. Allowing the law of each state to develop its own standard for determining what constitutes a violation of the FDA's ban on off-label marketing will inevitably result in inconsistent standards that contradict the FDA's guidance,

undermining the FDA's ability to strike the policy balance that it deems appropriate.

That the FDA may balance competing objectives in deciding how to enforce the FDCA does not suggest that violators of the FDCA can act with impunity. To the contrary, the FDA is empowered to obtain significant monetary penalties and criminal liability against entities that engage in prohibited off-label marketing. *See Buckman*, 531 U.S. at 349 (citing 18 U.S.C. § 1001 (criminalizing fraud against federal government); 21 U.S.C. § 332 (authorizing injunctive relief); § 333(f)(1)(A) (authorizing civil penalties); § 334(a)(2)(D) (authorizing seizure of device); § 333(a) (authorizing criminal prosecutions)).

Allowing agencies, rather than the tort system, to set the standard of care has significant benefits. "Agency staff members come from professions that are often trained in matters relating to the industry they regulate. Juries, however, are not only untrained but subject to biases that tend to overinflate the costs of accidents and understate the costs of care." Mark Seidenfeld, *Who Decides Who Decides: Federal Regulatory Preemption of State Tort Law*, 65 N.Y.U. Ann. Surv. Am. L. 611, 617 (2010). In contrast to agency employees who "have no direct stake in the ultimate standard of care that is adopted by rule . . . [t]he tort system . . . uses an adversarial

process that has been criticized for allowing hired guns to confuse even fairly accepted issues of scientific fact." *Id.* at 618.

The FDA, as a subject area expert, is better suited than the tort systems of various states to determine what level of enforcement would most effectively and efficiently achieve the objectives of Congress in enacting the FDCA. As the FDA wrote in an amicus brief in a case relating to preemption of a claim that a medical device was defective:

> State actions are not characterized by centralized expert evaluation of device regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population – the central role of FDA – sometimes on behalf of a single individual or group of individuals. That individualized redetermination of the benefits and risks of a product can result in relief – including the threat of significant damage awards or penalties – that creates pressure on manufactures to add warnings that FDA has neither approved, nor found to be scientifically required, or withdrawal of FDA-approved products from the market in conflict with the agency's expert determination that such products are safe and effective.

See Horn v. Thoratec Corp., 376 F.3d 163, 178 (3d Cir. 2004) (quoting FDA Amicus Br.); *see also* FDA Amicus Br., *In re Paxil Litigation*, available at 2001 WL 34883537 (C.D. Cal. 2001) ("A regime in which lawsuits motivated by individual, local

concerns (even though sincere) may overrule FDA's considered actions in its own defined area of expertise clearly poses an obstacle to the full accomplishment [of] Congressional objectives.")

Granting plaintiffs what amounts to a private right of action to enforce the FDCA under the guise of state tort law "will dramatically increase the burdens facing" regulated entities, "burdens not contemplated by Congress in enacting the FDCA." *Buckman*, 531 U.S. at 350. "Faced with conflicting standards of care, producers who wish to avoid liability have no choice but to differentiate their products to meet the standards of each jurisdiction or forbear from participating in some markets." Seidenfeld, *supra*, at 625.

Allowing the tort system to establish standards for complying with federal law also reduces predictability, because the tort system necessarily evaluates conduct after the fact. "Tort suits . . . create significant potential to interfere with reliance interests and to generate continuing uncertainty about the costs a producer will incur" because "[t]he very nature of tort law requires suit after injury has occurred. By necessity, it takes an ex post perspective on the conduct at issue when assessing whether it was reasonable." *Id.* In contrast, through guidance like the FDA memorandum described above, agencies

can provide businesses with consistency and predictability in the enforcement of federal law.

Another important function of the FDA's administrative discretion is to avoid the negative consequences of over-deterrence. This balancing is not unique to the FDA. For instance, in promulgating proposed rules regarding roof crush resistance, the National Highway Traffic Safety Administration indicated its intention that the proposed rule would preempt state tort law because, among other things, "any effort to impose either more stringent requirements or specific methods of compliance would frustrate our balanced approach to preventing rollovers from occurring as well as the deaths and injuries that result when rollovers nevertheless occur." Federal Motor Vehicle Safety Standards; Roof Crush Resistance, Notice of Proposed Rulemaking, 70 Fed. Reg. 49,223, 49,245 (Aug. 23, 2005); *see also* Federal Motor Vehicle Safety Standards; Designated Seating Positions and Seat Belt Assembly Anchorages, Notice of Proposed Rulemaking, 70 Fed. Reg. 36,094, 36,098 (June 22, 2005).

Not only do agencies have expertise to evaluate the potentially unforeseen consequences of over-deterrence, the tort system is particularly ill-equipped to recognize those consequences. "The adversarial nature of the trial process . . .

works to exclude the voice of many who have an interest in the regulatory standard established by the tort system" including "non-injured users as well as diverse groups such as employees and those who live near production facilities who may benefit from economic activity generated by production." Seidenfeld, *supra*, at 632.

In addition, the over-deterrence problem is magnified by the risk of significant punitive damages that are far greater than what an agency would seek for violation of a federal regulation. The FDA expressed concern about this possibility in its amicus brief in the *Buckman* case, noting that "allowing fraud-on-the-FDA claims would distort the penalty scheme established by the statute" because "[w]hile the FDCA contains a wide range of possible remedies for fraud on the FDA, neither compensatory relief nor punitive damages is among them." Amicus Br. of United States, *Buckman Co. v. Plaintiffs' Legal Committee*, available at 2000 WL 1364441, at *23 (Sept. 13, 2000) (quotation marks and citation omitted). Likewise, "if common law fraud-on-the-FDA claims are permitted, it would interfere with FDA's discretion to decide which of the statutorily prescribed remedies, if any, to pursue." *Id.* at *24.

Finally, just as allowing fraud-on-the FDA claims to be enforced under state tort law might create "an incentive to

submit a deluge of information that the Administration neither wants nor needs," *Buckman*, 531 U.S. at 351, allowing litigants to advance state law claims based on off-label marketing allegations could create an incentive for manufacturers to avoid even communications that the FDA deems permissible. This would stifle beneficial communications about drugs.

B. A failure to recognize conflict preemption would have negative consequences in numerous regulated industries.

The disruptive consequences of disregarding the Supreme Court's preemption jurisprudence in this case would not be limited to the pharmaceutical industry. Courts in a variety of contexts and industries apply conflict preemption principles to protect the objectives of federal law.

For example, conflict preemption has been applied to ensure that federal laws relating to a state regulated profession are applied uniformly. In *In re Proceeding in Which Pa. Seeks to Compel the Defender Ass'n of Philadelphia to Produce Testimony*, No. 13-cv-1871, 2013 U.S. Dist. LEXIS 115309 (E.D. Pa. Aug. 15, 2013), the Commonwealth of Pennsylvania sought to have the Federal Community Defender Organization disqualified as counsel in a state post-conviction relief act case on the basis that it was using federal grant money to support its activities in

state court, which would violate federal law. *Id.* at *1-2. The Commonwealth argued that even if it lacked a private right of action to enforce the federal funding law, it could do so indirectly by "incorporating federal law into its rules for professional conduct." *Id.* at *44. However, like this case, the Commonwealth's claims arose from an alleged violation of federal law. *See id.* at *49 (noting that the "allegations [were] all 'coming from' the unauthorized use of federal money.") As such, conflict preemption applied to bar the Commonwealth's claims.

The court was motivated by the same policy concerns identified in *Buckman*. First, the Commonwealth's attempt to enforce federal law would interfere with the federal government's ability to "consider a number of priorities" in deciding how to enforce the funding provisions. *Id.* at *60. The court also expressed concern that "[t]he potential for intrusion increases if the PCRA hearing would reach one conclusion as to whether a violation of the CJA occurred, and the [federal] Administrative Office would reach another." *Id.* at *60-61 (citing *Arizona v. United States*, 567 U.S. 387, 402 (2012), which noted that permitting mirror image state immigration statutes would give the state the "power to bring criminal charges against individuals for violating a federal law even in

circumstances where federal officials in charge of the comprehensive scheme determine that prosecution would frustrate federal policies."). "The problem is further exacerbated if different state courts were to reach conflicting conclusions on the issue." *Defender Ass'n*, 2013 U.S. Dist. LEXIS 115309, at *61. "Finally, there exists the high likelihood of conflict in the difference in remedy[,]" where the liability arising from a violation of state tort law may differ from the penalty imposed for violating federal law. *Id.* at *62.

A failure to apply conflict preemption would also have negative consequences for the regulatory schema in other manufacturing industries. For instance, in *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002), the plaintiff manufactured a nylon bag designed to protect food items from contamination during fumigation with the defendant's chemical. *Id.* at 1202. The defendant requested and obtained permission from the EPA to change the label on its product to require that only a bag that the defendant licensed was indicated for use. *Id.* Plaintiff sued, alleging that the defendant had submitted false statements to the EPA, and asserted state law claims for unfair business practices and intentional interference with a prospective economic advantage. *Id.* at 1202-03. However, "[t]he gravamen of [plaintiff's] state

damages claim for intentional interference with a prospective economic advantage is that [defendant] knowingly submitted false information to the EPA . . ." *Id.* at 1203.

Citing *Buckman*, the court held that federal law preempted plaintiff's damages claims, reasoning that "just as Congress made available to the FDA regulatory enforcement mechanisms . . . Congress has afforded the EPA substantial enforcement powers . . . that enable the EPA to make a measured response to suspected fraud against it." *Id.* at 1205-06. A contrary approach "would force . . . applicants to ensure that their disclosures to the EPA would satisfy not only the standards imposed by that agency under federal law, but also the potentially heterogeneous standards propounded by each of the 50 States." *Id.* at 1207.

The same concerns motivated the court in *Offshore Serv. Vessels, LLC v. Surf Subsea, Inc.*, No. 12-1311, 2012 U.S. Dist. LEXIS 150103 (E.D. La. Oct. 7, 2012), which involved federal regulation of vessel documentation and coastwise trade. The plaintiffs in that case provided offshore marine services and sued their competitor, a foreign corporation, alleging that defendants obtained certification for a new vessel by submitting false information to the Coast Guard. *Id.* at *1-2. Plaintiffs asserted state law claims for injunctive relief and

damages pursuant to the Louisiana Unfair Trade Practices and Consumer Protection Law. *Id.* at *5-7. Plaintiffs' claims were preempted. Unlike claims arising from "parallel state tort law duties which do not conflict with federal law," *id.* at *45, plaintiffs' claims "'exist solely by virtue of the [certification] requirements' and do not turn on traditional state tort law principles." *Id.* at *45-46 (quoting *Buckman*, 531 U.S. at 353).

The court was concerned that the claims, if allowed to proceed, "would exert an impermissible 'extraneous pull' on the comprehensive regulatory scheme established by Congress and administered by the Coast Guard to regulate federal vessel documentation and coastwise trade." *Id.* at *34 (quoting *Buckman*, 531 U.S. at 353). Plaintiffs' claims would have economic consequences not anticipated in the federal regulatory scheme: "The additional burdens of litigation over representations made in the course of a federally administered application process would increase the cost of obtaining vessel documentation and frustrate coastwise trade." *Id.* at *43. As the court explained, "Fraud-on-the-Coast Guard claims have the potential to result in state law penalties which are greater (or less) than those which would otherwise be deemed appropriate by the Coast Guard, if penalties were deemed appropriate at all. There is also a danger that state or federal

courts would find (or reject) liability based on a construction or application of law that conflicts with an interpretation originating from the agency charged with administering the law." *Id.* at *44.

As these cases exemplify, conflict preemption as articulated by the Supreme Court in *Buckman* is essential to preserving the federal government's prerogative to regulate a variety of industries, and it is essential to uniform and consistent application of federal regulations. Disregarding the preemptive effect of federal law in this case would subject numerous businesses in the Commonwealth to cost and uncertainty and would undermine, not enhance, federal regulators' ability to do their jobs.

II. Plaintiff's reliance on inapposite case law obscures the policy ramifications of ignoring conflict preemption as recognized by *Buckman*.

The Supreme Court has recognized two forms of conflict preemption: one based upon the "physical impossibility" of simultaneously complying with both state and federal law, and the other based upon the state law's interference with the objectives of federal law. *See Hillsborough County*, 471 U.S. at 713. Therefore, it is misleading for amicus Pennsylvania Association of Justice to suggest that "so long as state-law

claims do not make compliance with federal requirements impossible, the claims are not preempted and can go forward." *See* Brief of Amicus Curiae Pennsylvania Association for Justice ("PAJ Br.") at 2. The basis for preemption in this case is not that it would be impossible for Cephalon and Teva to comply both with the FDCA provisions regarding off-label marketing and their duties under state tort law. Rather, the basis for preemption is that injecting the requirements of the FDCA into state tort law would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See Hillsborough*, 471 U.S. at 713 (quotation marks omitted).

For that reason, Plaintiff's efforts to distinguish *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013) and *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) are unavailing. *See* Appellant Br. at 12. Even if those cases involved a physical impossibility conflict that does not exist here, that does not change the fact that enforcing Plaintiff's claims would stand as an obstacle to the federal regulatory regime. To hold that Plaintiff's claims "are only preempted if the FDCA makes it impossible for drug manufacturers to truthfully market their

drugs," PAJ Br. at 2, would read a significant part of conflict preemption out of the Supreme Court's jurisprudence.[1]

Plaintiff suggests that the Court compare *Buckman* with *Wyeth v. Levine*, 555 U.S. 555 (2009). *See* Appellant Br. at 8-9. That comparison only serves to illustrate that the off-label marketing claims in this case are analogous to the preempted claims in *Buckman* and not the state common law claims in *Wyeth*. *Wyeth* involved a state law failure-to-warn claim arising from injury due to the method of administration of a pharmaceutical. Unlike *Wyeth*, Plaintiff does not assert failure-to-warn claims.

Plaintiff and his amicus also cite the decision of a panel of this Court in *Hassett v. Dafoe*, 74 A.3d 202 (Pa. Super. 2013). *See* Appellant Br. at 12-13; PAJ Br. at 4, 8-9. The plaintiff in *Hassett* sued two generic pharmaceutical companies for injuries allegedly caused by ingestion of metoclopramide. 74 A.3d at 205. The defendants argued that all of the plaintiff's claims constituted failure to warn claims and were therefore

---

[1] Plaintiff's claim is that Calphalon and Teva promoted ACTIQ for an off-label use, not that they failed to "tell the truth" about it in some other way. *See* PAJ Br. at 2, 4. This further underscores that the claims at issue here emanate from an alleged violation of the FDCA's off-label marketing ban, not from traditional duties of state tort law.

preempted under the Supreme Court's reasoning in *Mensing*. *See Hassett*, 74 A.3d at 205-06. This Court agreed that certain of the plaintiff's negligent failure to warn claims were preempted under *Mensing*. *Id.* at 205. However, this Court also held that plaintiff's other claims either "do not sound in failure to warn, arose after the passage of the 2007 Act, or involve a generic manufacturer's failure to conform its label to that of the name brand, none of which is preempted under . . . *Mensing*." *Id.* at 217.

Hassett is inapposite. First, it did not involve off-label marketing claims. Also, although the Court in *Hassett* held that certain of the plaintiff's claims survived, it did so specifically on the basis that they were not failure to warn claims that were preempted under *Mensing*. *See id.* at 210 ("At issue herein is impossibility pre-emption, the type of implied conflict pre-emption that arises when it is impossible to comply with both federal and state law."); *id.* at 215 (stating that plaintiff's "allegations of false advertising and promotion are not failure to warn claims based on the label pre-empted by *Mensing*.") The Court drew no conclusion about whether the claims in *Hassett* – or any claims similar to the Plaintiff's in this case – would be preempted under *Buckman* because they stand as an obstacle to the purposes and objectives of Congress.

Claims like Plaintiff's, which essentially assert a private cause of action to enforce federal law, are particularly disruptive to the administrative discretion of federal agencies. Preemption is necessary to preserve the integrity of the federal regulatory scheme for the reasons the Supreme Court articulated in *Buckman*. If this Court holds to the contrary, it risks making Pennsylvania an outlier and imposing expense and uncertainty on many of the Commonwealth's businesses as well as their employees and consumers.

CONCLUSION

This Court should affirm.

Respectfully submitted,

/s/ Robert L. Byer
Robert L. Byer (No. 25447)
DUANE MORRIS LLP
600 Grant Street, Suite 5010
Pittsburgh, PA 15219-2802
Phone: (412) 497-1083
Fax: (412) 202-2787
RLByer@duanemorris.com

Robert M. Palumbos (No. 200063)
Andrew R. Sperl (No. 311467)
DUANE MORRIS LLP
30 South 17th Street
Philadelphia, PA 19103
Phone: (215) 979-1000
Fax: (215) 979-1020
RLByer@duanemorris.com
RMPalumbos@duanemorris.com
ARSperl@duanemorris.com

Counsel for Amici Curiae Chamber of Commerce of the United States of America, the Pennsylvania Chamber of Business and Industry, and the Pennsylvania Coalition for Civil Justice Reform

September 29, 2017

CERTIFICATE OF WORD COUNT

I certify that this brief is 4,111 words long and therefore complies with the word count limit in Pa.R.A.P. 531(b)(3).

September 29, 2017

/s/ Robert L. Byer

DM1\8122855.3

Received 9/29/2017 1:31:54 PM Superior Court Eastern District

Filed 9/29/2017 1:31:00 PM Superior Court Eastern District
1303 EDA 2017

IN THE SUPERIOR COURT OF PENNSYLVANIA

Joseph A. Caltagirone, as Administrator Ad Prosequendum for the Estate of Joseph F. Caltagirone, Deceased and Joseph A. Caltagirone, Individually Appellant	:	1303 EDA 2017
v. Cephalon, Inc. and Teva Pharmaceuticals USA, Inc.		

PROOF OF SERVICE

I hereby certify that this 29th day of September, 2017, I have served the attached document(s) to the persons on the date(s) and in the manner(s) stated below, which service satisfies the requirements of Pa.R.A.P. 121:

Service

Served:	Alfred Joseph Falcione
Service Method:	eService
Email:	marlton@tflynnlaw.com
Service Date:	9/29/2017
Address:	FLYNN & ASSOCIATES PC 2091 Springdale Rd., Ste. 2 Cherry Hill, NJ 08003
Phone:	856--66-9-6100
Representing:	Appellant Joseph A. Caltagirone

Served:	John P. Lavelle Jr.
Service Method:	eService
Email:	jlavelle@morganlewis.com
Service Date:	9/29/2017
Address:	Morgan, Lewis & Bockius LLP 1701 Market Street Philadelphia, PA 19103
Phone:	215--96-3-4824
Representing:	Appellee Cephalon, Inc., et al.

IN THE SUPERIOR COURT OF PENNSYLVANIA

PROOF OF SERVICE

(Continued)

Served:	Richard John Hollawell
Service Method:	eService
Email:	rhollawell@consoleandhollawell.com
Service Date:	9/29/2017
Address:	525 Route 73 North Suite 117 Marlton, NJ 08053
Phone:	856--77-8-5500
Representing:	Appellant Joseph A. Caltagirone

Courtesy Copy

Served:	Gregory Buchwald Heller
Service Method:	eService
Email:	gheller@yrchlaw.com
Service Date:	9/29/2017
Address:	1600 Market St. Suite 3800 Philadelphia, PA 19103-7240
Phone:	267-546-1004
Representing:	Amicus Pennsylvania Association for Justice

/s/ Robert L. Byer

(Signature of Person Serving)

Person Serving:	Byer, Robert L.
Attorney Registration No:	025447
Law Firm:	Duane Morris LLP
Address:	Duane Morris Llp 30 South 17th Philadelphia, PA 19103
Representing:	Amicus Chamber of Commerce of the United States of America Amicus Pennsylvania Chamber of Business and Industry Amicus Pennsylvania Coalition for Civil Justice Reform