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FLYING FIRST CLASS: THE THIRD CIRCUIT ESTABLISHES A METHODOLOGY FOR IMPLIED PREEMPTION ANALYSIS OF FEDERAL PREMARKET APPROVAL REGULATIONS IN SIKKELEE v. PRECISION AIRMOTIVE CORP.

JASON A. KURTYKA*

“A Law, by the very meaning of the term, includes supremacy. It is a rule which those to whom it is prescribed are bound to observe . . . . If a number of political societies enter into a larger political society, the laws which the latter may enact . . . must necessarily be supreme . . . . It would otherwise be a mere treaty . . . and not a government.”

I. FLIGHT DELAYED: AN INTRODUCTION

The implied preemption doctrine illustrates the struggle between consumer rights advocates who want multinational companies to be held accountable for defective products and conservative proponents of tort reform who want to diminish liability for manufacturers traditionally subject to state tort law. This tension often materializes in products liability litigation involving goods that have followed a federal administrative agency’s

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premarket approval process that mandates minimum standards and design quality. Courts are then tasked with considering whether state causes of action seeking compensation from injuries caused by a product are preempted by federal standards that, if complied with, absolve liability. In *Sikkelee v. Precision Airmotive Corp.*, the Third Circuit addressed this issue by integrating Supreme Court precedent on federal premarket approval regulations to develop a new, synthesized rule. Specifically, the Third Circuit held that federal premarket approval processes do not preempt state products liability law, unless (a) the regulations or overarching statute contains an express preemption clause or (b) "traditional conflict preemption principles" make it impossible for the manufacturer to comply with both the federal and state standards.

In a case of first impression, *Sikkelee* creates an instructive analytical framework by unifying prior Third Circuit holdings that analyzed whether premarket approval regulations implicitly preempted state law causes of action. Part II of this Casebrief develops the context in which *Sikkelee* was decided by providing an overview of the relevant regulations and Supreme Court and Third Circuit precedent dealing with federal premarket approval processes. have been vital avenues for critics of Washington deregulation. Federal policy makers, having caught onto the game, are now striking back.


6. For a further discussion of the Third Circuit’s opinion and rule statement in *Sikkelee*, see infra notes 86–118 and accompanying text.

7. See *Sikkelee*, 822 F.3d at 702 (holding that Federal Aviation Administration premarket approval regulations do not broadly preempt state law; rather, preemption only results through express mandate or impossibility of compliance).

8. See infra notes 119–33 and accompanying text for a critical analysis that concludes *Sikkelee* unifies the reasoning developed in previous Third Circuit cases.
proval.\textsuperscript{9} Part III then turns to the core analysis of \textit{Sikkelee} that identifies how the Third Circuit established its implied preemption framework.\textsuperscript{10} Next, because \textit{Sikkelee} crystalizes the Third Circuit’s premarket approval preemption framework, Part IV provides recommendations to Third Circuit practitioners on how to incorporate \textit{Sikkelee} into their arguments.\textsuperscript{11} Finally, Part V of this Casebrief concludes that \textit{Sikkelee} marks an appropriate preservation of state police powers in the face of an ever expanding federal regulatory system.\textsuperscript{12}

\section{Never-Ending Security Line: Interaction Between Implied Preemption and Federal Premarket Approval Processes}

Depending on how Congress has articulated its will through legislation or regulation, preemption can be either express or implied.\textsuperscript{13} Express preemption can be either express or implied, and 'is compelled whether Congress’ command is explicitly stated in the statute’s language or implicitly contained in its structure and purpose.’” (quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)); Lozano v. City of Hazelton, 724 F.3d 297, 302 (3d Cir. 2013) (“Pre-emption may be either express or implied . . . .” (citing Gade v. Nat’l Solid Waste Mgmt. Ass’n, 505 U.S. 88, 98 (1992)); see also JAMES T. O’REILLY, FEDERAL PREEMPTION OF STATE AND LOCAL LAW 14 (2006) (stating that “preemption may be either express or implied” depending on whether it is explicitly stated in federal statute or implied by its “structure and purpose”); KENNETH STARR ET. AL., THE LAW OF PREEMPTION 15, 18 (1991) (noting that preemption is derived from congressional intent, which can be arrived at either expressly or implicitly). The doctrine of preemption itself is derived from the Supremacy Clause of the Constitution. See U.S. CONST. ART. VI, CL. 2; see, e.g., Hillman v. Maretta, 133 S. Ct. 1943, 1949 (2013) (“Under the Supremacy Clause Congress has the power to pre-empt state law expressly.” (citing Brown v. Hotel & Rest. Emps. & Bartenders Intern. Union Local 54, 468 U.S. 491, 500–01 (1984))). In this sense, supremacy is a delegated and defined power of Congress; therefore, any federal law “made in pursuance” of the Constitution has the propensity to preempt state law. See Geier v. Am. Honda Motor Co., 529 U.S. 861, 873 (2000) (describing Supremacy Clause as having “nullifying” effect on state law that conflicts with federal law); N.Y. Cent. R.R. Co. v. Winfield, 244 U.S. 147, 148 (1917) (“[I]t is settled that when Congress acts upon the subject all state laws covering the same field are necessarily superseded by reason of the supremacy of the national authority.”); see also ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES § 5.21, at 412 (5th ed. 2015) (noting that preemption doctrine is derived from Supremacy Clause). Despite the uniform consensus that Congress’s power to preempt derives from the Supremacy Clause, Professor Stephen A. Gardbaum makes a compelling argument that it is the Necessary and Proper Clause, not the Supremacy Clause that generates Congress’s power to preempt. See Stephen A. Gardbaum, \textit{The Nature of Preemption}, 79 CORNELL L. REV. 767, 770 (1994) (describing it as “consequential error”). Supremacy and preemption, Gardbaum argues, are quite different legal concepts. See Stephen A. Gardbaum, \textit{Congress’s Power to Preempt the States}, 33 PEPP. L. REV. 39,
Press preemption is typically effectuated through a written preemption clause in the federal statute where Congress makes its intent to displace state law evident. Conversely, implied preemption results when a court

40 (2005) (“Supremacy and preemption are distinct constitutional concepts . . . .”). His first premise is that the Supremacy Clause, on its face, is a dispute resolution mechanism and does not grant any affirmative powers. See Gardbaum, The Nature of Preemption, supra, at 774–75 (stating use of Supremacy Clause). The Supremacy Clause only applies in instances of conflict between federal and state law, where the federal law trumps or displaces the state law. See Gardbaum, Congress’s Power to Preempt the States, supra, at 41 (explaining when Supremacy Clause applies). Preemption, on the other hand, means the displacement of non-conflicting state law, which is a process that occurs automatically when the federal law is passed. See id. (contrasting preemption). As such, the power to preempt exists before the underlying conflict arises and can displace state law immediately, conflict or not. See Gardbaum, The Nature of Preemption, supra, at 776–77. Thus, preemption, as a power, is greater than supremacy because of its automatic operation. See id. at 774–75. Gardbaum sums up his hypothesis with the following syllogism:

A greater power cannot (logically) derive from a lesser one. Preemption is a greater federal power than supremacy (that is, the ability of congressional legislation to preempt state lawmaking power constitutes a greater inroad on state power than the principle that federal law trumps state law when the two conflict). Therefore, preemption cannot (logically) derive from supremacy.

Id. After determining that it is neither the Supremacy nor the Commerce Clause that gives Congress the power of preemption, Gardbaum arrives at the Necessary and Proper Clause. See Gardbaum, The Nature of Preemption, supra, at 781; Gardbaum, Congress’s Power to Preempt State Law, supra, at 49–50. He argues that, historically, it is the Necessary and Proper Clause which gives Congress the power to enact uniform laws as a method to regulate interstate commerce. See Gardbaum, The Nature of Preemption, supra, at 781. If Congress desires to enact uniform federal law, it has the power to preempt state law, whether conflicting or not. See id. at 781–82. Understanding preemption this way, Gardbaum argues, leads to the conclusion that preemption can only be achieved via express preemption because Congress is exercising an enumerated power. See id. at 783. Gardbaum’s hypothesis, unfortunately, has not caught on, at least among Supreme Court Justices. See, e.g., Hughes v. Talen Energy Marketing, LLC, 136 S. Ct. 1288, 1297 (2016) (citing Supremacy Clause as source of preemption).

14. See N.Y. State Dept. of Soc. Servs. v. Dublino, 413 U.S. 405, 413 (1973) ("If Congress is authorized to act in a field, it should manifest its intent clearly. It will not be presumed that a federal statute was intended to supersede the exercise of power of the state . . . .") (quoting Schwartz v. Texas, 334 U.S. 119, 202–03 (1952))); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 220 (1947) ("clear and manifest purpose of Congress" (citations omitted)); see also Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit, 547 U.S. 71, 88 n.13 (2006) ("[W]e are concerned instead with Congress’ intent in adopting a pre-emption provision, the evident purpose of which is to limit the availability of remedies under state law."); Barber v. Unum Life Ins. Co. of Am., 383 F.3d 134, 136 (3d Cir. 2004) (finding express text of ERISA preempts state law claim). A clear-cut example of express preemption comes from Jones v. Rath Packing Co., which involved a conflict between California law and the Federal Meat Inspection Act (FMIA). 490 U.S. 519 (1977). On one hand, the state statute required that packages of bacon weigh an amount equal to or greater than what was listed on its packaging, while the federal law allowed for reasonable variations due to moisture loss. See id. at 526–28 (explaining pair of regulations appellee was subject to). Stuck between two contradictory requirements, the plaintiff turned to a federal law provision that prohibited the implementation of "[m]arketing, labeling, packaging, or ingredient requirements in
determines that despite Congress not articulating its intent in writing, state law is nonetheless preempted based on the structure or objective of the federal law. Implied preemption operates through either conflict or field preemption—both of which will be explained in Section II(A).

15. See de la Cuesta, 458 U.S. at 152–53 (reasoning that preemption may be implied when “implicitly contained in [a statute’s] structure and purpose” (quoting Jones, 430 U.S. at 525)); Buzzard v. Roadrunner Trucking, Inc., 966 F.2d 777, 780 (3d Cir. 1992) (“In the absence of explicit statutory language, however, Congress implicitly may indicate an intent to occupy a given field to the exclusion of state law.”); Pa. Med. Soc’y v. Marconis, 942 F.2d 842, 848 (3d Cir. 1991) (“Congress’ intent to preempt nonetheless can be inferred . . . .”); see also Starr, supra note 13, at 18 (“[T]he Court typically has not denied preemption challenges solely because statutory language and history were insufficiently clear.”).

16. See Starr, supra note 13, 18–30 (dividing implied preemption into multiple categories, most important of which are conflict and field preemption).
A. Have Your ID and Boarding Pass Ready: Analysis of Implied Preemption Rules Applicable to Premarket Approval Schemes

Determining whether federal premarket approval processes preempt state causes of action begins with an application of the presumption against preemption. To overcome this presumption, the preemption advocate must demonstrate Congress’s “clear and manifest” intent to preempt. In some cases “where there has been a history of significant obstacle preemption, a spinoff of conflict preemption that this Casebrief does not address. See also generally Kenneth W. Starr, Reflections on Hines v. Davidowitz: The Future of Obstacle Preemption, 33 Pepp. L. Rev. 1, 2 (2005) (discussing seminal case of obstacle preemption).

17. See McGarity, supra note 2, at 61 (describing arguments that federal approval processes preempt state law claims as among most common of preemption claims); Betsey J. Grey, Make Congress Speak Clearly: Federal Preemption of State Tort Remedies, 77 B.U. L. Rev. 599, 584, 586 (1997) (discussing cases where preemptory effect of premarket approval schemes were at issue); Noah, supra note 2, at 925–26, 928, 932 (noting cases involving medical devices, pesticides and other chemicals, as well as various modes of transportation cases that where parties have proffered premarket approval implied preemption arguments).

18. See infra notes 44–75 and accompanying text for background of federal premarket approval regulations and cases that analyze them.


20. See Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) (“So we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest intent of Congress.” (citations omitted)); see also Ass’n N.J. Rifle & Pistol Clubs v. Governor of N.J., 707 F.3d 238, 240 (3d Cir. 2013) (citing Rice for presumption against preemption); Holk v. Snapple Beverage Corp., 575 F.3d 329, 336 (3d Cir. 2009)
federal presence” the presumption is nonexistent or not applied at all. 21 Nevertheless, in products liability claims where states have historically compensated victims, the presumption casts a shadow of skepticism on preemption arguments. 22

21. See United States v. Locke, 529 U.S. 28, 108 (2000) (“[A]ssumption of non-preemption is not triggered when the State regulates in an area where there has been a history of significant federal presence.” (citing Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977))); Lozano v. City of Hazelton, 724 F.3d 297, 314 n.23 (3d Cir. 2013) (citing Locke for proposition that when state regulates in area of federal interest, such as immigration, presumption against preemption need not be applied). Relative pervasiveness of the presumption differs from case to case. See Hillsborough Cty., Fla. v. Automated Med. Labs, Inc., 471 U.S. 707, 715–16 (1985) (finding that when matters of “local health and safety” are involved, high barrier of presumption is erected); Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 144 (1963) (applying stronger presumption against preemption when in area “traditionally regarded as properly within the scope of state superintendence”). But see Chemerinsky, supra note 2, at 1324 (arguing that presumption against preemption is only paid lip service to and not actually employed); Dinh, supra note 14, at 2087 (demonstrating “illogic of a general presumption against preemption”). The mere presence of federal regulation alone, however, does not necessarily mean the presumption does not apply. See Wyeth v. Levine, 555 U.S. 555, 565 n.3 (2009) (denying defendant’s argument that presumption should not apply, because “[t]he presumption thus accounts for the historical presence of state law but does not solely rely on the absence of federal regulation”); see also Lohr, 518 U.S. at 485 (applying presumption despite presence of federal health and safety law); Farina, 625 F.3d at 116 (reasoning that presence of FCC law in state regulation did not generate conclusion that presumption did not apply).

1. Conflict Preemption

Conflict preemption analysis considers whether concurrent compliance with a federal law and state standard is possible.\textsuperscript{23} Courts first examine the scope of the two laws to determine what each law requires of the party advocating for preemption.\textsuperscript{24} That party must demonstrate that an actual conflict exists, meaning that the two laws conflict and the clash makes it impossible to satisfy both requirements.\textsuperscript{25} Nevertheless, there may be situations where Congress only intended to prescribe minimum federal standards, leaving room for states to set higher standards of care.\textsuperscript{26}

\begin{itemize}
\item \textsuperscript{24} See, e.g., Gade, 505 U.S. at 91–93 (opening opinion by describing scope of both federal and state law and describing where they conflict); Fellner, 539 F.3d at 251 (explaining that defendant offered three theories on why scope of federal law sufficiently conflicted with state regulation); see also Gasaway & Parrish, supra note 23, at 220 (“Courts have increasingly recognized that when federal decision makers make an affirmative judgment in favor of a certain, optimum level of regulation . . . that judgments operates as a negative judgment on state law . . . .” (emphasis in original)).
\item \textsuperscript{25} See Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm’n, 461 U.S. 190, 205–06 (1983) (explaining that despite federal Atomic Energy Act not expressly requiring or prohibiting states from constructing or authorizing constructing nuclear power plants, conflict preemption principles apply because of dichotomous federal and state requirements); Fla. Lime & Avocado Growers, Inc., 373 U.S. at 143 (noting in dicta that conflict preemption requires “impossibility of dual compliance,” where products could not be labeled under state law without violating federal law); N.J. Chamber of Commerce v. Hughey, 774 F.2d 587, 594 (3d Cir. 1985) (explaining that it was impossible to comply with both state right-to-know law and federal OHSA standard). But see Bates, 544 U.S. at 445–46 (rejecting proposition of “implied inducement” argument where state tort judgment would require defendant to adopt remedial measures that put it in conflict with federal regulations).
\item \textsuperscript{26} See Williamson v. Mazda Motor of Am., Inc., 562 U.S. 323, 335 (2011) (reasoning that imposing stricter standards that treated federal standards as maximum standards would render minimum standards clause as meaningless); Freightliner Corp. v. Myrick, 514 U.S. 280, 286 (1995) (noting that federal statute proscribed “minimum standards,” which allowed state to establish their own standards); Hillsborough Cty., 471 U.S. at 722 n.5 (“The federal interest at stake here is to ensure minimum standards not uniform standards.”); Horn v. Thoratec Corp., 376 F.3d 163, 186 (3d Cir. 2004) (noting medical device premarket approval processes set minimum standard but not “ceiling”).
\end{itemize}
Under these circumstances, this type of arrangement is not conflict preempted because compliance is practicable.\textsuperscript{27} Indicative of the need for actual conflict is the Third Circuit’s opinion in \textit{Fellner v. Tri-Union Seafoods, L.L.C.}\textsuperscript{28} There, the plaintiff brought a state failure-to-warn claim against a tuna packager alleging that the tuna’s mercury content injured her.\textsuperscript{29} In its defense, the seafood company argued that the plaintiff’s claim should be conflict preempted because: (1) the FDA had adopted a “pervasive regulatory approach” to regulate mercury content, (2) the FDA chose not to require warning labels on tuna, and (3) any requirement of a warning label would constitute “misbranding” under federal law.\textsuperscript{30} The Third Circuit determined none of the arguments generated an actual conflict between state and federal law because the FDA’s actions on mercury content did not amount to an official “federal legal standard.”\textsuperscript{31} \textit{Fellner}’s holding posits that a court must find an applicable and affirmative federal standard before considering whether dual compliance of state and federal law is impossible.\textsuperscript{32}

2. \textit{Field Preemption}

Field preemption and conflict preemption are considered distinct concepts, despite being subcategories of implied preemption.\textsuperscript{33} Certain federal regulation is so comprehensive that courts have determined federal law occupies the entire field of law, effectively boxing out state regulation in that field.\textsuperscript{34} For example, field preemption arguments are more

\textsuperscript{27} Compare \textit{Sprietsma}, 537 U.S. at 69 (finding that compliance between federal standard and state standard was achievable) and \textit{Silkwood}, 464 U.S. at 258 (reasoning state law claim for punitive damages and federal regulations of nuclear facilities could coexist), \textit{with PLIVA, Inc. v. Mensing}, 564 U.S. 604, 617–18 (2011) (holding that because generic drug manufactures are bound by federal law to replicate name-brand version, state law is preempted where it imposes heightened labeling requirement).

\textsuperscript{28} 539 F.3d 237 (3d Cir. 2008).

\textsuperscript{29} \textit{See id.} at 240–41 (explaining that plaintiff alleged her diet consisted mostly of defendant’s seafood products and she became sick from mercury poison due to defendant’s failure to warn her of chemical content).

\textsuperscript{30} \textit{See id.} at 248–49, 251–54 (addressing defendant’s three theories on why federal labeling law preempted state failure-to-warn claims).

\textsuperscript{31} \textit{See id.} at 256 (“Fellner’s lawsuit does not conflict with the FDA’s ‘regulatory scheme’ for the risks posed by mercury in fish or the warnings appropriate for that risk because the FDA simply has not regulated the matter.”).

\textsuperscript{32} \textit{See id.} (explaining that because FDA only issued consumer advisory regarding dangers of mercury, but did not create any substantive policy or rules on issue, no conflict could exist).

\textsuperscript{33} \textit{See Goodspeed Airport LLC v. E. Haddam Inland Wetlands & Watercourses Comm’n}, 634 F.3d 306, 209 n.4 (2d Cir. 2011) (noting that while conflict and field preemption are both subsets of implied preemption and conflict could be thought to be subset of field preemption, courts conceptualize two forms of implied preemption separately and apply different rules to analyze each (citing \textit{English v. Gen. Elec. Co.}, 496 U.S. 72, 79 n.5 (1990))).

\textsuperscript{34} \textit{See City of Burbank v. Lockheed Air Terminal, Inc.}, 411 U.S. 624, 633 (1973) (“[T]he Act of Congress may touch a field in which the federal interest is so
likely to succeed in areas where federal interests have been historically paramount, such as maritime, environmental, immigration, and commercial aviation.35 State regulation need not conflict with federal law in areas with a dominant federal interest, because if Congress chooses to “occupy the field,” all state regulations must acquiesce.36 Finding field preemption requires parsing federal statutory, regulatory, and legislative history to conclude that Congress intended to completely control a specific area of regulation.37

In *Abdullah v. American Airlines*,38 the Third Circuit found Federal Aviation Administration (FAA) regulations field preempted a state negligence claim brought following injuries sustained when a commercial flight

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37. See *Starr*, supra note 13, at 19 (quoting *Fla. Lime & Avocado Growers, Inc.*, 373 U.S. at 142) (noting that field preemption consists of two prongs: “(1) whether Congress has pervasively regulated with such global breadth as to leave no room for competing centers of regulatory power, and (2) whether ‘the nature of the regulated subject matter permits no other conclusion.’ . . . .”).

38. 181 F.3d 363 (3d Cir. 1999).
encountered unexpected turbulence. The plaintiffs alleged the airline attendants breached their duty of care by failing to give a verbal warning after the captain turned on the “fasten seatbelt” sign. The Third Circuit analyzed FAA in-flight regulations and determined that federal law governed in-flight safety standards so pervasively that any state law claim over aviation safety must be field preempted. The Third Circuit was persuaded by the fact that a specific FAA regulation established a comprehensive standard of care for airline personnel that stated “[n]o person may operate an aircraft in a careless or reckless manner so as to endanger the life or property of another.” The Abdullah court found a supplemental, state-law based duty of care was unnecessary because the FAA identified an appropriate safety standard that governed airline personnel uniformly.

B. Remove Your Belt, Shoes, and Sense of Personal Space: Structure of Premarket Approval Schemes

Federal premarket approval programs are a type of licensing scheme that requires manufacturers in certain industries to prove to the federal government that their product will work safely as advertised. Defendants in products liability suits commonly put forth a “government standards defense” that absolves the defendant of liability if they complied with federal regulations and the regulation preempts state law. The Supreme

39. See id. at 365 (explaining background and facts of case).
40. See id. at 365–66 (noting cause of action brought against defendant and explaining that district court instructed jury on state law duty of care).
41. See id. at 365 (“Our finding on [implied field] preemption is based on our determination that the FAA and relevant federal regulations establish complete and thorough safety standards . . . .”).
42. See 14 C.F.R. § 91.13(a) (2017) (laying out general standard of care for those operating aircrafts); see also Abdullah, 181 F.3d at 371 (discussing federal regulation).
43. See Abdullah, 181 F.3d at 365 (“FAA and relevant federal regulations establish complete and thorough safety standards for interstate and international air transportation and . . . these standards are not subject to supplementation . . . .”).
44. See Wyeth v. Levine, 555 U.S. 555, 566 (2009) (describing premarket approval process as “most substantial” portion of Federal Food, Drug, and Cosmetics Act); Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 344–45 (2001) (explaining premarket approval process within Medical Device Act); see also McGarity, supra note 2, at 23 (dichotomizing federal regulatory functions into “standard setting and licensing,” wherein companies “must first obtain a permit or a license from a regulatory agency” before taking their product to market); Nagareda, supra note 3, at 8–12 (explaining “the regulatory framework” employed by FDA to approve medical devices).
45. See McGarity, supra note 2, at 60 (“On the judicial front, federal preemption became the favored defense for regulated companies seeking to avoid liability and accountability for harm caused by their products and activities.”); Grey, supra note 17, at 562 (positing that issue of whether to sustain preemption defense could mean difference between liability and absolution); Keith N. Hylton, Preemption and Products Liability: A Positive Theory, 16 Sup. Ct. Econ. Rev. 205, 210–11 (2008) (noting one author that has advocated that regulatory compliance defense could be beneficial for society in certain industries); Noah, supra note 2, at 967–68 (develop-
Court, however, has not accepted a blanket argument that premarket approval regulations broadly field preempt state duties of care; rather, the Court looks for express congressional intent or conflict preemption to find preemption.46 FDA and DOT regulations are examples that demonstrate how, in most instances, premarket approval regulations fail to stretch as broadly as businesses facing liability would like.47

1. Food and Drug Administration Regulations

The FDA requires comprehensive approval processes before a company can bring a medical device or new pharmaceutical drug to market.48 These requirements include testing the product’s safety and effectiveness, as well as labeling specifications.49 Once a company receives FDA approval it is prohibited from making further changes to the product without the Administration’s approval.50 FDA medical device regulations

46. See infra notes 52–69 and accompanying text for an explanation of cases litigating preemptive effect of federal premarket approval programs.


49. See McGarity, supra note 2, at 79–80 (explaining how 1979 Medical Device Amendment to Food, Drug, and Cosmetics Act gave FDA ability to oversee sale and production of medical devices through approval schemes); Nagareda, supra note 3, at 8–10 (discussing regulatory framework employed by FDA).

50. See Riegel v. Medtronic, Inc., 552 U.S. 312, 319 (2008) (noting that FDA will send “approvable letter” when device could be approved with more information or agreed upon restrictions and that FDA is able to set device modification limits (citing 21 C.F.R. § 814.44e (2016))); see also Michael D. Green & William B. Schultz, Tort Law Defe nce to FDA Regulation of Medical Devices, 88 Geo. L.J. 2119, 2136–37 (2000) (explaining that to meet premarket approval standards, pharmaceutical manufacturers must produce two controlled clinical studies, while medical device companies must submit two independent studies). See generally 21 U.S.C. § 360c (describing premarket approval process for medical devices); Premarket Ap
contain an express preemption clause that specifically prohibits states from requiring manufacturers to comply with alternate specifications that deviate from federal law.\textsuperscript{51}

The Third Circuit encountered FDA pharmaceutical labeling regulations in \textit{Colacicco v. Apotex, Inc.},\textsuperscript{52} wherein the plaintiff alleged a state failure-to-warn claim based on a drug label’s exclusion of particular side effects.\textsuperscript{53} \textit{Colacicco} applied conflict preemption principles to analyze the issue due to “the lack of a Congressional directive expressly approving or rejecting preemption in the context of drug labeling . . . .”\textsuperscript{54} FDA pharmaceutical labeling regulations require that before a drug is put on the market, the FDA must approve the labeling and any subsequent changes to the label based on new risks.\textsuperscript{55} The Third Circuit determined that the practical effect of these regulations made it impossible for pharmaceutical companies to comply with both state and federal law if a state required any labeling requirements in addition to FDA rules.\textsuperscript{56} Thus, the \textit{Colacicco} court determined that state failure-to-warn claims challenging labeling veracity were conflict preempted.\textsuperscript{57}

\textit{Colacicco} was ultimately vacated by the Supreme Court’s decision in \textit{Wyeth v. Levine},\textsuperscript{58} The Court in \textit{Wyeth} held state failure-to-warn claims could survive a preemption challenge when the drug company had the ability to make unilateral labeling changes outside the FDA’s approval process.\textsuperscript{59} In form, \textit{Colacicco} was correct because the \textit{Wyeth} Court also applied

\textsuperscript{51}See 21 U.S.C. § 360k(a) (2012) (noting that generally no state shall impose requirements on medical devices that depart from federal requirements); \textit{see also} \textit{Riegel}, 552 U.S. at 321–22 (noting express preemption clause and considering whether plaintiff’s claims are preempted by statute).


\textsuperscript{53}See \textit{Colacicco}, 521 F.3d at 256–57 (explaining background facts of case).

\textsuperscript{54}See id. at 266 (“It follows that in this case, which is also one of conflict preemption, the lack of a Congressional directive expressly approving or rejecting preemption in the context of drug labeling regulations is not determinative. Rather, the conflict preemption analysis is designed to determine the propriety of preemption where Congress has not explicitly stated its intent.”).

\textsuperscript{55}See id. at 268 (discussing FDA regulations dealing with pharmaceutical labeling).

\textsuperscript{56}See id. at 268–69, 271 (indicating that being forced to comply with extraneous state regulations would trigger “misbranding” violation under federal law).

\textsuperscript{57}See id. at 271, 276 (acquiescing to FDA’s analysis of situation and finding state law sufficiently conflict preempted).


\textsuperscript{59}See \textit{Wyeth}, 555 U.S. at 571–73 (explaining that it was in fact possible for pharmaceutical company to change labeling without clearance from FDA, particu-
conflict preemption principles to reach its outcome; however, the Third Circuit’s holding in Colacicco was overturned based on its substantive outcome. 60 Conversely, in both Mutual Pharmaceutical Co. v. Bartlett 61 and PLIVA, Inc. v. Mensing 62 the Court determined that when FDA regulations do not permit labeling exceptions to generic drugs, any heightened state standard is preempted because it is impossible to depart from FDA regulations without violating federal law. 63 Thus, the Supreme Court considers actual impossibility a dispositive indicator of conflict preemption in the pharmaceutical labeling arena. 64

The Supreme Court has also determined that federal law does not trigger field preemption in the medical device context. 65 In Medtronic, Inc. v. Lohr, 66 the Court determined that a state law imposing requirements on medical devices is only preempted “where a particular state requirement threatens to interfere with a specific federal interest.” 67 The Court in Riegel v. Medtronic, Inc. 68 subsequently drew on Lohr to hold that states are not prohibited from implementing “parallel” requirements to federal law as long as the state requirements do not directly conflict in a way that makes compliance impossible. 69 Both cases demonstrate that

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60. See infra notes 130–32 and accompanying text for an explanation of how the Third Circuit in Colacicco applied the right rules to decide its case but was overturned based on its outcome.


63. See id. at 624 (reasoning that because generic drug manufacturers must request permission from FDA to alter chemistry of their drug, pharmaceutical company could not concurrently comply with heightened state standard without also violating federal law); see also Mut. Pharm. Co., 133 S. Ct. at 2476–78 (finding that because it is impossible for pharmaceutical manufacturer to comply with both state and federal law, state law must be preempted and generally drawing on PLIVA).

64. Compare Mut. Pharm. Co., 133 S. Ct. at 2476–78 (finding actual impossibility), with Wyeth, 555 U.S. at 570–71 (finding dual compliance was possible).

65. See, e.g., Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (holding that “[s]tate requirements are pre-empted under the [Medical Device Act] only to the extent they are ‘different from, or in addition to’ the requirements imposed by federal law” (citation omitted)); Medtronic, Inc. v. Lohr, 518 U.S. 470, 508 (1996) (lacking evidence to find Congress or FDA intended to “occupy entire field” of medical device regulation).


67. See id. at 500 (“Although we do not believe [§ 360(k)] necessarily precludes ‘general’ federal requirements from ever pre-empting state requirements . . . it is impossible to ignore its overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest.”).

68. 552 U.S. 312 (2008).

69. See id. at 330 (“Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” (citations omitted)). See generally Elliot Sheppard Tarloff, Note, Medical Devices and Pre-
conflict preemption can only result when the two laws are directly at odds.\textsuperscript{70}

2. Department of Transportation Premarket Approval

During the 1980s and 1990s, the DOT permitted car manufacturers to employ a variety of passive restraint devices to induce both manufacturers and consumers to adopt air bags over time.\textsuperscript{71} A number of states, however, found that their common law tort doctrine mandated air bags be installed in cars for the manufacturer to fulfill its duty of care.\textsuperscript{72} The Supreme Court in \textit{Geier v. American Honda Motor Co.}\textsuperscript{73} determined that the stricter state law requirement sufficiently conflicted and presented a policy obstacle to the achievement of federal objectives.\textsuperscript{74} It was this direct conflict between both standards of care and policy goals that made it impossible for the car manufacturer to comply with both state and federal law.\textsuperscript{75}

III. No Room in the Overhead Compartment: The Third Circuit Finds State Products Liability Claims Are Not Impliedly Preempted by FAA Regulations

\textit{Sikkelee} presented the Third Circuit with the issue of whether the FAA premarket approval process broadly preempted state products liability

\textsuperscript{70} See \textit{Riegel}, 552 U.S. at 334–35 (Ginsburg, J., dissenting) (explaining that when Congress is not specific about preemption in its statutory text, then courts should opt for readings that disfavor preemption or find preemption narrowly); see also Issacharoff & Sharkey, supra note 3, at 203–04 (noting that \textit{Lohr} declined to find broad field preemption and hesitated to completely displace tort law).


\textsuperscript{72} See \textit{Geier}, 529 U.S. at 866 (noting cases from New York, Ohio, Arizona, Indiana, and New Hampshire required car manufacturers to comply with stricter duty than federal law permitted, but noting First, Tenth, and Eleventh Circuit Courts of Appeal found preemption of state law).

\textsuperscript{73} 529 U.S. 861 (2000).

\textsuperscript{74} See id. at 869, 873, 881, 886 (explaining that first, presence of savings clause took statute out of express preemption consideration and then applying implied preemption principles to find state law requirements of air bags were preempted).

\textsuperscript{75} See id. at 881 (classifying analysis as obstacle preemption, because disagreement was at policy level, rather than outright impossibility of dual compliance); see also \textit{Sprietsma v. Mercury Marine}, 537 U.S. 51, 63–64 (2002) (deciding similar case to \textit{Geier} involving premarket regulations of watercraft and finding that absent express preemption, conflict preemption principles should apply (citing \textit{Geier}, 529 U.S. at 869)).
The Sikkelee court answered this question in the negative and applied a standardized framework to navigate premarket approval preemption questions. Section III(A) will present the facts of Sikkelee and its path to the Third Circuit. Section III(B) will then describe the Third Circuit’s application of its preemption framework through a narrative analysis.

A. Please Check Your Bag: Facts and Procedure

In Sikkelee, a widow brought a products liability claim following her husband’s tragic death in an airplane crash. Her complaint alleged that the Textron Lycoming engine installed in the small aircraft piloted by her husband allowed raw fuel to leak from the carburetor into the engine, causing the plane to lose power and crash shortly after takeoff. Every airplane part is subject to an extensive FAA approval process where the manufacturer must submit various design plans and preform airworthiness tests to receive a “type certificate,” which is official FAA approval to sell the part. In defense to Sikkelee’s claims, Precision Airmotive (Precision) ar-
gued that *Abdullah* preempted the entire field of aviation regulation and, moreover, because it complied with the FAA’s type certificate program the company was not liable. On a motion for summary judgment, the United States District Court for the Middle District of Pennsylvania agreed that *Abdullah* should be interpreted broadly and that a federal standard of care should apply to aviation products liability claims; however, the district court also pointed out the impossibility of fashioning jury instructions based on FAA regulations because they “were never intended to create federal standards of care.”

Stuck between two contradictory conclusions, the district court certified the issue of whether FAA regulations preempt state product liability law for appeal.

B. *Fees, Fees, and More Fees: The Third Circuit Holds Premarket Approval Regulations Are Subject to Traditional Conflict Preemption Principles*

On appeal, Precision raised three express and field preemption arguments, each of which argued that the FAA has expansive power over state law. First, Precision argued *Abdullah* was controlling because the Third Circuit previously found the FAA to have broad field preemption power.
over state law. Second, it argued the enabling FAA statute and its premarket approval regulations expressly preempted state products liability claims. Finally, Precision argued, even if FAA rules do not explicitly preempt state law, they nonetheless are so pervasive that field preemption is the logical result. The Third Circuit rejected all of Precision’s arguments, holding that state products liability claims are not preempted by premarket approval processes, unless (a) Congress expressly intended preemption, or (b) “traditional conflict preemption principles” led to the conclusion that it is impossible to concurrently comply with both state and federal obligations.

1. In-Flight Versus on the Ground: Distinguishing Abdullah

The Sikkelee court distinguished Abdullah by finding that its applicability was limited only to “in-flight” operations by “drawing a line between what happens during the flight and what happens upon disembarking.” FAA regulations regarding in-flight protocol were comprehensive enough to establish a federal duty of care that left no room for supplemental state standards. Those same provisions employed in Abdullah, however, were not tailored to apply to a products liability claim over an airplane part.

87. See id. at 688–89 (noting that defendant argued Abdullah is controlling due to its broad scope and held FAA regulations broadly preempt all state law that touches on aviation safety); see also infra notes 91–93 and accompanying text for the Third Circuit’s analysis of why Abdullah is distinguishable from Sikkelee.

88. See Sikkelee, 822 F.3d at 691–95 (countering defendant’s argument that FAA’s statutory framework and its corresponding regulations constituted “clear and manifest” congressional intent to preempt state laws touching on aviation safety); see also infra notes 94–101 and accompanying text for a further explanation of why the Third Circuit found the defendant overvalued the text of the FAA statute and regulation to ultimately find no such congressional intent was present.

89. See Sikkelee, 822 F.3d at 698–706 (explaining defendant’s argument that FAA premarket approval regulations field preempt state law misunderstands Supreme Court precedent that applies conflict preemption principles to premarket approval schemes); see also infra notes 102–18 and accompanying text for an explanation of Sikkelee’s logic that holds if broad express preemption argument fails, then the challenger must move to a narrower conflict preemption argument.

90. See Sikkelee, 822 F.3d at 695 (“[A]bsent clear evidence that Congress intended the mere issuance of a type certificate to foreclose all design defect claims, state tort suits using state standards of care may proceed subject only to traditional conflict preemption principles.”); see also infra notes 102–18 and accompanying text for the Third Circuit’s reasoning that its rule is consistent with Supreme Court cases on premarket approval.

91. See Sikkelee, 822 F.3d at 688–89 (noting that while Abdullah broadly preempted “the ‘field of aviation safety’” that decision was limited to “in-air operations” (quoting Abdullah v. Amer. Airlines, 181 F.3d 363, 371 (3d Cir. 1999))).

92. See id. at 689 (explaining that in-air regulations provided “catch-all standard of care”); supra notes 42–43 and accompanying text for the standard of care the Abdullah court applied and derived from federal regulations.

93. See Sikkelee, 822 F.3d at 689, 693 (pointing out that regulations addressed in Abdullah are completely different from type certificate regulations at issue in Sikkelee). Compare 14 C.F.R. § 91.13(a) (2017) (laying out general standard of care
2. Show Your Ticket at the Gate: Part One of Sikkelee’s Framework Considers Express Preemption

After distinguishing Abdullah, the Sikkelee court applied part one of its premarket approval preemption framework and considered whether Congress or the FAA expressly intended preemption. Precision failed to convince the Third Circuit that either the FAA enabling statute or the type certificate regulations demonstrated “a clear and manifest” express intent to preempt. The overarching FAA statute declares that the FAA is tasked with setting “minimum standards” for the construction of airplane components and also contains a savings clause, which states that any remedy in the statute is in addition to relief provided by state law. Statutory language containing a “minimum standards” and a savings clause have previously been found to be “insufficient on [their] own to support a finding of clear and manifest intent to preemption.”

Additionally, the language of the FAA’s type certificate program lacked the utility to be used as a comprehensive standard of care. The Third Circuit found the regulations “devoid” of express intent to preempt because the regulations merely embodied “procedures for manufacturers to obtain certain approvals” and were no more than benchmarks to meet the requirements to receive a type certificate. In contrast, the regulations in Abdullah were comprehensive enough to find field preemption because they established a general standard of behavior of airline personnel that could easily be applied to a variety of similar cases, whereas type certificate procedures establish discrete, minimum standards for airplane

for those operating aircrafts), with 14 C.F.R. § 21.31 (2016) (explaining requirements of type design).

94. See Sikkelee, 822 F.3d at 689–90 (beginning analysis by applying presumption against preemption by identifying that state law has governed aviation torts since at least 1914); supra notes 19–20 and accompanying text for a background explanation of the presumption against preemption.

95. See Sikkelee, 822 F.3d at 687 (explaining that because of states’ historical role in governing tort law, “clear and manifest” intent must be shown that Congress intended preemption of federal aviation torts (citing Wyeth v. Levine, 555 U.S. 555, 565 (2009))); infra notes 97–101 and accompanying text for a further explanation of the Third Circuit’s rejection of Precision’s express preemption argument.

96. See Sikkelee, 822 F.3d at 692–93 (“While the inclusion of the savings clause ‘is not inconsistent’ with a requirement that courts apply federal standards of care when adjudicating state law claims, it belies Appellees’ argument that Congress demonstrated a clear and manifest intent to preempt state law products liability claims altogether.” (citing Abdullah, 181 F.3d at 374–75)); see also supra note 14 and accompanying text for background explanation of savings clauses.


98. See id. at 693 (reasoning that one primary difference between Sikkelee and Abdullah was that regulations governing flight personnel presented workable standard of care that applied reasonable person test).

99. See id. at 694 (determining that none of regulatory language at issue indicated that it was intended to supply general duty of care).
part design. 100 Thus, part one of Sikkelee’s test was not met because neither Congress nor the FAA intended to expressly preempt state products liability claims. 101

3. Holding Pattern on the Tarmac: The Third Circuit Applies Traditional Conflict Preemption Principles

Precision then argued that, nevertheless, the premarket approval regulations implicitly field preempt state standards of care. 102 The Third Circuit disagreed with this premise, stating “absent clear evidence that Congress intended the mere issuance of a type certificate to foreclose all design defect claims, state tort suits using state standards of care may proceed subject only to traditional conflict preemption principles.” 103 To test part two of its framework, the Third Circuit considered “analogous statutory regimes” and similar premarket approval processes. 104

Sikkelee found that DOT premarket approval regulations were sufficiently similar to the relevant FAA procedures. 105 In Geier, the Court noted that the relevant statute authorized the agency to promulgate minimum standards and it contained a savings clause—just like the Federal Aviation Act. 106 Similarly, the Geier Court steered away from conducting a field preemption analysis and instead applied conflict preemption principles because it was apparent that the structure of each statute envisioned...
concurrent regulation unless the two standards—state and federal—made compliance impossible.107

The Third Circuit additionally compared its rule to the Supreme Court’s cases on medical devices and pharmaceutical labeling.108 The Court found that both Bartlett and PLIVA suggest that a premarket approval program only preempts state law when compliance with the two standards is impossible because complying with one would violate the other.109 Consequently, state law will likely be conflict preempted when the relevant federal regulations do not provide a design exception; whereas state and federal law can coexist when federal law provides the manufacturer with some design flexibility.110

A comparison to Riegel and Lohr confirmed Sikkelee’s application of conflict principles to premarket approval schemes.111 In Riegel, the Supreme Court found preemption primarily because of an express preemption clause that displaced state law—an aspect missing from the Federal Aviation Act.112 When read together, both Riegel and Lohr find that the “overarching concern” of the [premarket approval scheme] was ensuring “that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest.”113 The preemptory role of premarket approval regulations is narrow and is only invoked when compliance with state and federal standards is impossible.114 Lohr made

107. See id. at 700–01 (citing Geier v. Am. Honda Motor Co., 529 U.S. 861, 875 (2000) (explaining that Geier stands for proposition that when dealing with premarket approval regulations courts should apply traditional conflict preemption principles, not field); supra notes 71–75 and accompanying text for a discussion of Geier.

108. See Sikkelee, 822 F.3d at 701–05 (comparing its rule, in detail, to Supreme Court cases on pharmaceutical labeling and medical device regulations).

109. See id. at 703 (citing Mut. Pharm. Co., Inc. v. Bartlett, 133 S. Ct. 2466, 2473 (2013) and PLIVA, Inc. v. Mensing, 564 U.S. 604, 624 (2011)) (comparing cases dealing with generic versus brand-name drug labeling); see also supra notes 61–64 and accompanying text discussing Bartlett and PLIVA.


111. See id. 704–05 (explaining that when both cases are read together, they “[c]ut against a finding of field preemption” (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 497, 500–01 (1997) and Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008))); see also supra notes 65–70 and accompanying text for background explanation of Lohr and Riegel.

112. See Sikkelee, 822 F.3d at 704 (distinguishing FAA’s statutory scheme from FAA’s statutory scheme).

113. See id. (explaining that this ‘overarching concern’ was to preserve state common law requirements that are equal to or identical to federal standards (citing Lohr, 518 U.S. at 497, 500–01)).

114. See id. (emphasizing through comparison of Lohr and Riegel that conflict preemption should only be found when dual compliance is truly impossible).
this clear by preserving state duties that run “parallel” to federal requirements.\textsuperscript{115}

Precision failed to make a conflict preemption argument, opting for an expansive field preemption theory.\textsuperscript{116} This restricted Precision doctrinally because it ignored both the Supreme Court’s and Third Circuit’s applications of conflict principles to premarket approval regulations.\textsuperscript{117} Thus, the Third Circuit limited its holding to the conclusion that FAA regulations do not establish a standard of care for tort actions and the type certificate is only subject to traditional conflict preemption principles.\textsuperscript{118}

IV. FIRST CLASS UPGRADE: CONSIDERING SIKKELEE’S COMPATIBILITY WITH THIRD CIRCUIT PRECEDENT AND ITS VALUE FOR LITIGATORS

The Sikkelee court based the root of its framework in Supreme Court cases addressing premarket approval preemption; however, the methodology of Sikkelee’s rule was articulated ostensibly through Fellner and Colacicco.\textsuperscript{119} The following analysis will demonstrate how Sikkelee’s approach resulted in a unification of the Third Circuit’s prior premarket approval preemption cases.\textsuperscript{120} Then, this section will offer advice to Third Circuit litigators on how to employ Sikkelee’s framework.\textsuperscript{121}

\begin{enumerate}
\item \textsuperscript{115} See id. at 704–05 (explaining that Lohr and Riegel’s “parallel” requirement rule was sufficient and Third Circuit saw “no justification for going further than the Supreme Court” on conflict preemption principles); see also supra note 69 and accompanying text for a background explanation of the “parallel” exception.

\item \textsuperscript{116} See Sikkelee, 822 F.3d at 702 (explaining that because defendant did not raise conflict preemption argument in its brief, Third Circuit’s holding could only go as far as reversing district court’s summary judgment motion and remanding for further litigation on conflict preemption); see also infra note 123 and accompanying text for an explanation of why the FAA in its amicus brief was the one who actually raised the conflict preemption argument.

\item \textsuperscript{117} See Sikkelee, 822 F.3d at 702 (noting that scope of issues raised by plaintiff and defendant did not require Third Circuit to “demarcate boundaries” of conflict preemption regarding premarket approval processes).

\item \textsuperscript{118} See id. (“[W]e hold only that, consistent with the FAA’s view, type certification does not itself establish or satisfy the relevant standard of care for tort actions, nor does it evince congressional intent to preempt the field of products liability; rather, because the type certification process results in the FAA’s preapproval of particular specifications from which a manufacturer may not normally deviate without violating federal law, the type certificate bears on ordinary conflict preemption principles.” (citation omitted)).

\item \textsuperscript{119} See supra notes 28–32, 52–57 and accompanying text for background discussion of Fellner and Colacicco; see also infra 127–135 and accompanying text for critical analysis of how principles developed in Fellner and Colacicco translate into understanding Sikkelee.

\item \textsuperscript{120} See infra notes 122–33 and accompanying text for a synthesis of Third Circuit case law on premarket approval preemption.

\item \textsuperscript{121} See infra notes 134–41 and accompanying text for an analysis of how practitioners can integrate Sikkelee into their arguments.
\end{enumerate}
A. More Leg Room, Less Problems: Sikkelee’s Methodology Synthesizes Previous Third Circuit Premarket Approval Preemption Cases

In addition to considering Precision’s expansive field preemption argument, the Sikkelee court also considered the FAA’s amicus brief.\(^\text{122}\) The FAA argued that the preemption analysis should be considered in two, intertwined layers: the first layer is that the FAA broadly field preempts state law in aviation safety, and the second is “to the extent that a plaintiff challenges an aspect of an aircraft’s design that was expressly approved by the FAA . . . a plaintiff’s tort suit” would be conflict preempted.\(^\text{123}\) The Third Circuit observed that on one end of the implied preemption spectrum was Precision’s argument—broad field preemption if a federal regulation is generally on point—while the FAA’s layered approach formed the other end of the spectrum.\(^\text{124}\) However, Sikkelee’s premarket approval preemption framework explains that the proper analysis should be between the two ends of this spectrum because conflict principles—not field preemption—should only be applied in premarket approval analyses.\(^\text{125}\) The outcome in Sikkelee and analyses in Fellner and Colacicco demonstrate that the Third Circuit takes a narrow approach to implied preemption by viewing conflict and field preemption as distinct concepts.\(^\text{126}\)

\(^{122}\) See Sikkelee, 822 F.3d at 702 (quoting FAA amicus brief); see also id. (explaining that FAA raised conflict preemption argument before either named party did).

\(^{123}\) See id. (quoting Letter Brief for FAA at 10–11, Sikkelee v. Precision Airmotive Corp., 822 F.3d 860 (3d Cir. 2016) (No. 14-4193)).

\(^{124}\) See id. at 705 n.22 (citing English v. Gen. Elec. Co. 496 U.S. 72, 79 n.5 (1990) (discussing whether field and conflict preemption are distinct sets of rules). The FAA pointed to the English footnote for the justification of their layered approach, which posits that conflict preemption is necessarily contained in field preemption. See FAA Letter Brief at 6, 10–11, 822 F.3d 860 (3d Cir. 2016) (No. 14-4193). The FAA’s layered approach could potentially be justified by the peculiar wording in the footnote in English; however, the Third Circuit explicitly disagrees with this characterization and views conflict and field preemption as distinct concepts, despite being subsets of implied preemption. See Sikkelee, 822 F.3d at 705 n.22 (explaining that in practice, courts view conflict and field preemption as separate because different rules govern their application).

\(^{125}\) See id. at 704–05 (explaining that based on its reading of Supreme Court precedent, premarket approval regulations should be subject to traditional conflict preemption principles, absent express preemption clause); see also supra note 114 and accompanying text for a discussion of how Sikkelee interprets conflict preemption as a narrow outcome compared to the broader field preemption; supra notes 23–27 & 33–37 and accompanying text for background explanation of how the Supreme Court and the Third Circuit have traditionally applied separate rules and cases to analyze conflict and field preemption.

\(^{126}\) See infra notes 127–33 and accompanying text for further analysis of how Sikkelee’s narrow view of conflict preemption reduces the instances of preemption in the premarket approval context.
The substantive basis for Sikkelee’s framework is found in Fellner.\textsuperscript{127} Fellner demonstrated that the Third Circuit found it imperative that first, the federal government had officially regulated in the issue area and second, that any conflict between state and federal law is real.\textsuperscript{128} Sikkelee embodies this reasoning because its analysis was targeted at whether the FAA truly spoke to a purposeful preemption of state products liability claims.\textsuperscript{129}

The structure of Sikkelee’s premarket approval preemption framework is echoed in Colacicco.\textsuperscript{130} The Colacicco court’s mode of analysis was completely on point because it applied conflict preemption principles after a determination that FDA regulations did not expressly preempt state law.\textsuperscript{131} In that way, Sikkelee is a vindication of Colacicco whose analytical rule was nullified based on its substantive outcome.\textsuperscript{132} Sikkelee brings together the reasoning of Fellner and Colacicco to construct a premarket approval preemption framework that is both doctrinally rigid, because it obeys Supreme Court precedent, and sufficiently flexible to give Third Circuit courts and litigators an analytical framework to apply to preemption cases.\textsuperscript{133}

\textsuperscript{127} See Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 248–49 (3d Cir. 2008) (explaining that applying conflict preemption principles was only logical analytical method in premarket approval context cases).

\textsuperscript{128} See id. at 256 (reasoning that evidence federal government chose not to regulate in certain area was not grounds for inference that it intended conflict preemption to result); see also Gasaway & Parrish, supra note 23, at 220 (“Courts have increasingly recognized that when federal decision makers make an affirmative judgment in favor of a certain, optimum level of regulation . . . that judgments operates as a negative judgment on state law . . . .” (emphasis in original)); supra notes 31–32 and accompanying text for an explanation of the Third Circuit’s application of conflict preemption principles in Fellner.

\textsuperscript{129} See Sikkelee, 822 F.3d at 693–95, 702–04 (identifying that core of analysis revolved around fact that neither Congress nor FAA intended for its type certificate program to preempt state products liability claims and demonstrating that holding through application of both express and conflict preemption).


\textsuperscript{131} See Colacicco, 521 F.3d at 265 (“It follows that in this case, which is one of conflict preemption, the lack of Congressional directive expressly approving or rejecting preemption in the context of drug labeling regulations is not determinative. Rather, the conflict preemption analysis is designed to determine the propriety of preemption where Congress has not explicitly stated its intent.”).

\textsuperscript{132} See supra notes 58–60 and accompanying text explaining that Colacicco was overturned based on its outcome, which held FDA labeling regulations preempted state law when the Supreme Court held otherwise, but that the Supreme Court duplicated its application of conflict preemption rules.

\textsuperscript{133} See supra notes 7 & 90 and accompanying text explaining the premarket approval preemption framework that Sikkelee crafted; cf. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005) (“[W]e have long presumed that Congress does not cavalierly pre-empt state-law causes of action.”).
B. Read the Safety Manual Before Departure: Advice to Third Circuit Counsel Arguing for Preemption

Sikkelee’s framework states federal premarket approval regulations will only carry a preemptive effect if there is an express preemption provision in the relevant statute or regulation, or compliance with both federal and state regulations is impossible.134 Counsel arguing in favor of preemption should avoid making broad field preemption arguments when dealing with premarket approval processes because regulations are highly technical and too specific to form a general standard of care.135 Rather, litigators should make a textual, express preemption argument followed by a conflict preemption argument that proves dual compliance is impossible.136 Bartlett, PLIVA, and Fellner demonstrate the granular level at which conflict preemption arguments can successfully be made.137

C. Place Your Seat in Its Upright Position: Advice to Third Circuit Counsel Countering Preemption

Sikkelee is a favorable case to plaintiffs attempting to state a claim of products liability because it establishes that federal premarket approval processes narrowly preempt state law.138 Any counterargument to federal preemption in such cases should emphasize that federal and state law must be in actual conflict, not just hypothetically conflicting or through broad policy differences.139 Counsel arguing against preemption should also stress the parallel state and federal regulation exception developed in

134. See Sikkelee, 822 F.3d at 695 (explaining premise of premarket approval preemption framework); see also supra notes 94–118 and accompanying text for an explanation of how Sikkelee applied its framework and how the Third Circuit justified it doctrinally.

135. Compare Sikkelee, 822 F.3d at 694 (discussing how FAA type certificate regulations are highly specific and technical), with Abdullah v. Am. Airlines, 181 F.3d 363, 371 (3d Cir. 1999) (explaining that FAA regulation governing airline personnel was akin to reasonable person standard).

136. See Sikkelee, 822 F.3d at 692–93 (beginning analysis by looking to text of statute to determine whether Congress evinced express intent to preempt state products liability law).

137. See supra notes 28–32 & 61–64 and accompanying text for an explanation of how in each case the respective courts reasoned that conflict preemption could only be successful when compliance with both federal and state standards was practically impossible.

138. See Sikkelee, 822 F.3d at 709 (overturning district court’s grant of summary judgment and remanding for review of plaintiff’s products liability claim against airplane part manufacturer). See generally McGarity, supra note 2, at 30–34 (arguing that state common law claims are proper way to hold companies who manufacturer defective products accountable).

Riegel and Lohr, which was emphasized in Sikkelee,\textsuperscript{140} The more an argument demonstrates ability of dual compliance through symmetrical standards the less likely a court is to find conflict preemption.\textsuperscript{141}

V. CLEARED FOR TAKEOFF: SIKKELEE’S IMPACT ON PRODUCTS LIABILITY CLAIMS

Sikkelee is a victory for states’ rights advocates and opponents of national tort liability standards because the opinion developed a clear line of delineation between the scope of federal premarket approval processes and the states’ historic role in compensating injured citizens.\textsuperscript{142} Moreover, the Third Circuit’s synthesis of case law on premarket approval regulations produced a cogent framework that standardizes implied preemption analysis for both courts and litigators.\textsuperscript{143} Sikkelee’s reassertion of state police power marks a commitment to federalist principles to the benefit of aggrieved plaintiffs.\textsuperscript{144}

\textsuperscript{140} See Sikkelee, 822 F.3d at 705 (explaining that “parallel” exception means that states are permitted to regulate concurrently to federal law).

\textsuperscript{141} See id. (noting that Supreme Court tolerates parallel regimes). Compare Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (explaining that when manufacturer can independently make changes to product, then it is possible to comply with both federal and state law), with PLIVA, Inc. v. Mensing, 564 U.S. 604, 620 (2011) (finding state law is preempted where party cannot “independently do under federal law what state law requires of it”).

\textsuperscript{142} See supra note 118 and accompanying text for a quote of the Sikkelee holding that overturns the dismissal of the plaintiff’s products liability complaint. See generally McGarity, supra note 2, at 21–22 (explaining preemption in premarket approval context is vacillation between avoiding liability and holding companies responsible for defective products). But see Rabin, supra note 45, at 2053–54 (advocating for government standards defense).

\textsuperscript{143} See supra notes 7, 90, & 102–18 and accompanying text for the Third Circuit’s justification in Sikkelee for its premarket approval preemption framework; see also supra notes 134–41 and accompanying text for a discussion of how Third Circuit practitioners can employ Sikkelee when handling preemption issues.

\textsuperscript{144} See Geier, 529 U.S at 894 (Stevens, J., dissenting) (“[T]he Supremacy Clause does not give unelected federal judges carte blanche to use federal law as a means of imposing their own idea of tort reform on the States.”); Chemerinsky, supra note 2, at 1327 (explaining that expansive preemption doctrine overrides federalism principles and state sovereignty).