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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.

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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.*

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"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."[1]

## 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.[2] This tension often materializes in products liability litigation involving goods that have followed a federal administrative agency's

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1. The Federalist No. 33, at 200 (Alexander Hamilton) (Clinton Rossiter ed., 1961).

2. *See* Geier v. Am. Honda Motor Co., 529 U.S 861, 894 (2000) (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." (emphasis in original) (footnote omitted)); Thomas O. McGarity, The Preemption War 17–18, 43 (2008) (describing preemption doctrine as preferred battlefield of tort reform advocates to diminish liability for manufacturers traditionally subject to state tort liability); Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 Wm. & Mary L. Rev. 903, 905 (1996) ("[T]he use of the preemption defense in tort litigation sometimes immunizes defendants from liability irrespective of their conduct."); *see also* Erwin Chemerinsky, *Empowering States When It Matters*, 69 Brook. L. Rev. 1313, 1327 (2004) (criticizing Rehnquist Court for always favoring preemption when it eroded state law claims and benefited businesses avoiding liability); Ernest A. Young, *Two Cheers for Process Federalism*, 46 Vill. L. Rev. 1349, 1377 (2001) (criticizing Rehnquist Court for appearing to favor federalist principles, but when it came to preemption doctrine decisions it promoted federalization of tort law and diminished liability for interstate corporations); Stephen Labaton, *'Silent Tort Reform' Is Overriding States' Powers*, N.Y. Times (Mar. 10, 2006), http://www.nytimes.com/2006/03/10/politics/silent-tort-reform-is-overriding-states-powers.html [https://perma.cc/WAE8-AA9P] ("In the last three decades, the state courts and legislature

premarket approval process that mandates minimum standards and design quality.[3] 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.[4] In *Sikkelee v. Precision Airmotive Corp.*,[5] the Third Circuit addressed this issue by integrating Supreme Court precedent on federal premarket approval regulations to develop a new, synthesized rule.[6] 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.[7]

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.[8] 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 ap-

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have been vital avenues for critics of Washington deregulation. Federal policy makers, having caught onto the game, are now striking back.").

3. *See* Norfolk S. Ry. Co. v. Shanklin, 529 U.S. 344, 360–61 (2000) (Ginsburg, J., dissenting) (arguing that finding preemption in favor of railroad resulted in "double windfall" where government foots safety bill and railroad is exempt from liability); Samuel Issacharoff & Catherine M. Sharkey, *Supreme Court Preemption: The Contested Middle Ground of Products Liability*, *in* FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 194, 195 (Richard A. Epstein & Michael S. Greve eds., 2007) ("Because tort law is so thoroughly a traditional area of state governance, the federalization of this branch of the common law threatens a serious reallocation of power in our delicate system of dual sovereignty."); Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrate State*, 1 J. TORT L. 4, 12–13 (2006) (discussing litigation concerning FDA premarket approval processes).

4. *See* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2485 (2013) (Sotomayor, J., dissenting) (quoting *Sprietsma v. Mercury Marine* to note remedial role states play through tort law); Sprietsma v. Mercury Marine, 537 U.S. 51, 70 (2002) (stating evidence of preemption was too sparse to erode state's role in compensating victim); Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 249 (3d Cir. 2008) ("Federal regulatory programs frequently do not include a compensatory apparatus . . . ." (citing *Spriestsma*, 537 U.S. at 64)); *see also* David G. Owen, *Federal Preemption of Product Liability Claims*, 55 S.C. L. REV. 411, 441 (2003) (arguing that courts should be cautious when constructing federal statutes in ways that override state common law claims designed to compensate victims).

5. 822 F.3d 680 (3d Cir. 2016), *cert. denied*, AVCO Corp. v. Sikkelee, 137 S. Ct. 495 (2016).

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.[9] Part III then turns to the core analysis of *Sikkelee* that identifies how the Third Circuit established its implied preemption framework.[10] Next, because *Sikkelee* crystalizes the Third Circuit's premarket approval preemption framework, Part IV provides recommendations to Third Circuit practitioners on how to incorporate *Sikkelee* into their arguments.[11] Finally, Part V of this Casebrief concludes that *Sikkelee* marks an appropriate preservation of state police powers in the face of an ever expanding federal regulatory system.[12]

## II. 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.[13] Ex-

9. *See infra* notes 13–75 and accompanying text for an examination of rules and cases crucial to understanding *Sikkelee*.

10. *See infra* notes 76–118 and accompanying text for the facts and a narrative analysis of *Sikkelee*.

11. *See infra* notes 119–41 and accompanying text for critical analysis that integrates previous Third Circuit cases to contextualize *Sikkelee*.

12. *See infra* notes 142–44 for a prediction on the impact of *Sikkelee*.

13. *See* Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 152–53 (1982) ("Preemption may 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, *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, *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.[14] 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, 230 (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). 430 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.[15] Implied preemption operates through either conflict or field preemption—both of which will be explained in Section II(A).[16] Im-

addition to, or different than, those made under" the FMIA. *See id.* at 530 (citing entirety of FMIA). The clause spoke for itself and the conflicting state regulation was displaced. *See id.* ("We therefore conclude [California state law is] pre-empted by federal law."). Even if a litigant convinces the court the federal law allows preemption of state law, the argument must turn to whether the state law falls under the intended scope of preemption. *See* O'REILLY, *supra* note 13, at 60 (citing Catherine L. Fisk, *The Last Article About the Language of ERISA Preemption? A Case Study of the Failures of Textualism*, 33 HARV. J. LEGIS. 35, 45 (1996)) (noting that merely determining federal statute expressly permits preemption is only part of express preemption analysis). This consideration is again one of congressional intent and requires a parsing of the statute to determine what is inside and outside Congress's intended scope. *See, e.g.*, Metro. Life Ins. Co. v. Massachusetts, 471 U.S. 724, 758 (1985) (finding state law outside scope of National Labor Relations Act); *see also* Fisk, *supra*, at 45 (noting that ERISA trumps all relevant state law, thus has wide scope). In the *Jones* example this analysis was relatively straightforward because both statutes regulated the same object—bacon—and the federal law on its face was intended to apply to packaging. *See Jones*, 430 U.S. at 530. An example of a statutory technique that deters a finding of express preemption is a savings clause. *See Geier*, 529 U.S. at 861, 868, 870 (2000) (reasoning saving clause exempts state tort suits from preemption, but not interpreting clause too broadly as to disrupt balance of federal regulation); Morales v. Trans World Airlines, Inc., 504 U.S. 374, 378 (1992) (noting applicability of saving clause); Taj Mahal Travel, Inc. v. Delta Airlines, Inc., 164 F.3d 186, 194 (3d Cir. 1998) (finding existence of savings clause as expressly retaining state law causes of action); *see also* Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 994 (2002) (noting that increased use of saving clauses required courts to take harder looks at congressional intent). A typical savings clause states that the remedy provided by the federal statute *is in addition to* any remedy for the same harm provided by state law. *See, e.g.*, Williamson v. Mazda Motor of Am., Inc., 562 U.S. 323, 329 (2011) (quoting saving clause); Sprietsma v. Mercury Marine, 537 U.S. 51, 59 (2009) ("Compliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person of liability under State law." (quoting 46 U.S.C. § 4311(g))). *But see* Roth v. Norfalco LLC, 651 F.3d 367, 378–79 (3d Cir. 2011) (noting absence of savings clause leaves little room for non-federal regulation). Inelegantly, the presence of a savings clause instructs courts on whether to use the Supremacy Clause because it specifically contemplates the existences of concurrent regulation, as opposed to exclusive federal dominance. *See Geier*, 529 U.S. at 868 (finding existence of saving clause as assumption that there are common-law claims to save); *see also* Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2091 (2000) (casting saving clauses as congressional demarcations of boundaries that indicate where scope of preemption ends).

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 unclear.").

16. *See* STARR, *supra* note 13, 18–30 (dividing implied preemption into multiple categories, most important of which are conflict and field preemption). See

plied preemption is a tool a defendant can use to convince a court that Congress did not intend for the state to impose a standard of care in a particular area of regulation.[17] Section II(B) will examine premarket approval regulations of the Food and Drug Administration (FDA) and Department of Transportation (DOT) to develop context for the interaction between federal regulations and implied preemption.[18]

### 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.[19] To overcome this presumption, the preemption advocate must demonstrate Congress's "clear and manifest" intent to preempt.[20] In some cases "where there has been a history of significant

generally *id.* at 31–34 for background information and case citations regarding obstacle preemption, a spinoff of conflict preemption that this Casebrief does not address. *See also generally* Kenneth W. Starr, *Reflections on Hines v. Davidowtiz: 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). *But see* Issacharoff & Sharkey, *supra* note 3, at 201 (explaining how federal interest in preemption is typically weaker in products liability claims than, for example, in foreign relations).

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

19. *See* Hillman v. Maretta, 133 S. Ct. 1943, 1950 (2013) (beginning analysis by citing presumption against preemption, particularly because case involved family law); Farina v. Nokia Inc., 625 F.3d 97, 116 (3d Cir. 2010) ("The presumption applies with particular force in fields within the police power of the state, but does not apply where state regulation has traditionally been absent." (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) and Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347 (2001))); *see also* O'REILLY, *supra* note 13, at 7 (describing that when subject matter is traditionally regulated by states, then courts will rely more heavily on rule, which requires preemption advocates to submit proof of specific intent to preempt). *But see* Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist., 541 U.S. 246, 256 (2004) (Souter, J., dissenting) (criticizing majority for not invoking presumption against preemption); Riegel v. Medtronic, Inc., 552 U.S. 312, 334–35 (2008) (Ginsburg, J., dissenting) ("Federal laws containing a preemption clause do not automatically escape the presumption against preemption." (citing Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005))).

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]

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(same); Abdullah v. Am. Airlines, Inc., 181 F.3d 363, 366 (3d Cir. 1999) (same); Bass River Assoc. v. Mayor, Twp. Comm'r, Planning Bd. of Bass River, 743 F.2d 159, 162 (3d Cir. 1984) (same); Nat'l State Bank, Elizabeth N.J. v. Long, 630 F.2d 981, 985 (3d Cir. 1980) (same); Amalgamated Transit Union, Div. 819 v. Byrne, 586 F.2d 1025, 1039 (3d Cir. 1977) (same). This presumption serves as a reminder that the federal government's ability to regulate must be derived from an express constitutional power and if such delegation is lacking, the power of regulation should be left with the states. *See* Maryland v. Louisiana, 451 U.S. 725, 746 (1981) ("Consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." (citing *Rice*, 331 U.S at 230)); *see also Bates*, 544 U.S. at 449 ("[W]e have long presumed that Congress does not cavalierly pre-empt state-law causes of action." (citing *Lohr*, 518 U.S. at 485)); N.Y. State Dept. of Soc. Serv. v. Dublino, 413 U.S. 405, 413 (1973) (noting need to preserve balance of federal and as such preemption should not be "lightly assumed"); *Roth*, 651 F.3d at 375 (citing *Bates* for same proposition); *Farina*, 625 F.3d at 116 (same); Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc., 617 F.3d 207, 224 (3d Cir. 2010) (citing *Lohr* for same proposition); Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 248 (3d Cir. 2008) (same).

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 presence, 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).

22. *See* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2485 (2013) ("[C]ommon-law claims 'necessarily preform an important remedial role in compensating accident victims.'" (quoting Sprietsma v. Mercury Marine, 537 U.S. 51, 64 (2002))); Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 256 (1984) (explaining despite federal regulation of nuclear facilities, Congress did not intend to preempt states' role in compensating victims of nuclear accidents); *Fellner*, 539 F.3d at 249 n.7 ("Federal regulatory programs frequently do not include a compensatory apparatus . . . ." (citing *Spriestsma*, 537 U.S. at 64)); *see also* Owen, *supra* note 4, at 441 (arguing that courts should be cautious when constructing federal statutes in ways that override state common law claims designed to compensate victims).

1. *Conflict Preemption*

Conflict preemption analysis considers whether concurrent compliance with a federal law and state standard is possible.[23] Courts first examine the scope of the two laws to determine what each law requires of the party advocating for preemption.[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.[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.[26]

23. *See* Boggs v. Boggs, 520 U.S. 833, 844 (1997) (noting that conflict preemption arises from direct clash between state and federal law and "[c]onventional conflict pre-emption principles require pre-emption 'where compliance with both federal and state regulations is a physical impossibility, . . . or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" (quoting Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992))); Simon v. FIA Card Serv., 732 F.3d 259, 275 (3d Cir. 2013) (citing *Gade* for same proposition); *cf.* Robert R. Gasaway & Ashley C. Parish, *The Problem of Federal Preemption: Toward a Formal Solution*, *in* FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS 219, 221 (Richard A. Epstein & Michael S. Greve eds., 2007) (countering scholars such as Gardbaum and Chemerinsky and arguing for "robust" implied preemption doctrine that protects federal prerogatives).

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)).

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).

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").

Under these circumstances, this type of arrangement is not conflict preempted because compliance is practicable.[27]

Indicative of the need for actual conflict is the Third Circuit's opinion in *Fellner v. Tri-Union Seafoods, L.L.C.*[28] There, the plaintiff brought a state failure-to-warn claim against a tuna packager alleging that the tuna's mercury content injured her.[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.[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."[31] *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.[32]

2. *Field Preemption*

Field preemption and conflict preemption are considered distinct concepts, despite being subcategories of implied preemption.[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.[34] For example, field preemption arguments are more

27. *Compare Sprietsma*, 537 U.S. at 69 (finding that compliance between federal standard and state standard was achievable) *and Silkwood*, 464 U.S. at 258 (reasoning state law claim for punitive damages and federal regulations of nuclear facilities could coexist), *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).

28. 539 F.3d 237 (3d Cir. 2008).

29. *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).

30. *See id.* at 248–49, 251–54 (addressing defendant's three theories on why federal labeling law preempted state failure-to-warn claims).

31. *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.").

32. *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).

33. *See* Goodspeed Airport LLC v. E. Haddam Inland Wetlands & Watercourses Comm'n, 634 F.3d 206, 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 English v. Gen. Elec. Co., 496 U.S. 72, 79 n.5 (1990))).

34. *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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dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947))). Even if state regulation arguably does not conflict with the operation of federal law in a given area, field preemption will still invalidate it. *See* LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW § 6-27, at 497 (2d. ed. 1988). Two factors play into whether Congress intended to preempt an entire field, namely "(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.'" *See* STARR, *supra* note 13, at 19 (quoting *Fla. Lime & Avocado Growers, Inc.*, 373 U.S. at 142). Dean Chemerinsky distilled four considerations to determine whether federal law preempts the field.

> First, is it an area where the federal government traditionally has played a unique role? . . . Second, has Congress expressed an intent in the text of the law or in the legislative history to have federal law be exclusive in the area? . . . Third, would allowing state and local regulations in the area risk interfering with comprehensive federal regulatory efforts? . . . Fourth, is there an important traditional state or local interest served by the law?

CHEMERINSKY, CONSTITUTIONAL LAW, *supra* note 13, at § 5.2.3, at 430–31.

35. *See, e.g.*, Arizona v. United States, 567 U.S. 387, 402–03, 406–07, 409–11, 415–16 (2012) (holding that federal immigration law preempts state-made law on immigration); United State v. Locke, 529 U.S. 89, 108–09 (2000) (finding federal dominance over maritime law means it field preempts any topical state law); Int'l Paper Co. v. Ouellette, 479 U.S. 481, 490–91 (1987) (noting that federal Clean Water Act contemplated minimal state role in policing interstate waterways); *City of Burbank*, 411 U.S. at 633 (holding that FAA has full control over air craft noise).

36. *See* Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000) ("When Congress intends federal law to 'occupy the field,' state law in that area is preempted." (quoting California v. ARC Amer. Corp., 490 U.S. 93, 100 (1989)) (subsequent citation omitted)); Holk v. Snapple Beverage Corp., 575 F.3d 329, 336 (3d Cir. 2009) ("Field preemption occurs when state law occupies a 'field reserved for federal regulation' . . . ." (quoting *Locke*, 529 U.S. at 111)); Abdullah v. Am. Airlines, Inc., 181 F.3d 363, 376 (3d Cir. 1999) (noting that Congress may "occupy a given field to the exclusion of state law" (quoting Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 300 (1988))).

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.[39] 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.[40] 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.[41] 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."[42] 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.[43]

### 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.[44] 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.[45] 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

ing theory of "government standards defense" that has not traditionally protected companies from liability, but is increasingly immunizing them); *see also* Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2053–54 (2000) (positing that if state courts begin to accept argument of adherence to federal regulations, then compliance defense could become more widely recognized). *See generally* W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1475, 1478 (1994) (arguing that requirements to meet FDA premarket approval process are so comprehensive that state tort litigation is wasteful and federal regulations are sufficient to protect consumers). This defense also gained congressional traction but was never signed into law. *See* Common Sense Product Liability Reform Act of 1996, H.R. 956, 104th Cong. §§ 204–05 (1996) (vetoed by President May 2, 1996) (providing for "FDA defense"); Product Liability Fairness Act, S. 640, 102d Cong. § 303(c)(1) (1991) (providing punitive damages would not be awarded in cases involving drugs given premarket approval by FDA).

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

47. *See, e.g.*, Colacicco v. Apotex, Inc., 521 F.3d 253, 265–66 (3d Cir. 2008), *cert. granted and judgment vacated*, 556 U.S. 1101 (2009) (remanding for further consideration in light of Wyeth v. Levine, 555 U.S. 555 (2009)); *see infra* notes 48–75 and accompanying text for background on premarket approval regulations and cases that interpret them.

48. *See generally* 21 U.S.C. § 360c (2012) (detailing "Class I," "Class II," and "Class III" medical devices); 21 U.S.C. § 360k (2012) (codifying 1976 medical device amendment to Food, Drug, and Cosmetics Act).

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 Deference 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. § 360e (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.[51]

The Third Circuit encountered FDA pharmaceutical labeling regulations in *Colacicco v. Apotex, Inc.*,[52] wherein the plaintiff alleged a state failure-to-warn claim based on a drug label's exclusion of particular side effects.[53] *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 . . . ."[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.[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.[56] Thus, the *Colacicco* court determined that state failure-to-warn claims challenging labeling veracity were conflict preempted.[57]

*Colacicco* was ultimately vacated by the Supreme Court's decision in *Wyeth v. Levine*.[58] The Court in *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.[59] In form, *Colacicco* was correct because the *Wyeth* Court also applied

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*proval (PMA)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/ [https://perma.cc/N9SB-NT8Z] (last visited Feb. 25, 2017) (same).

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); *see also Riegel*, 552 U.S. at 321–22 (noting express preemption clause and considering whether plaintiff's claims are preempted by statute).

52. 521 F.3d 253 (3d Cir. 2008), *cert. granted and judgment vacated*, 556 U.S. 1101 (2009) (remanding for further consideration in light of Wyeth v. Levine, 555 U.S. 555 (2009)).

53. *See Colacicco*, 521 F.3d at 256–57 (explaining background facts of case).

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 proprietary of preemption where Congress has not explicitly stated its intent.").

55. *See id.* at 268 (discussing FDA regulations dealing with pharmaceutical labeling).

56. *See id.* at 268–69, 271 (indicating that being forced to comply with extraneous state regulations would trigger "misbranding" violation under federal law).

57. *See id.* at 271, 276 (acquiescing to FDA's analysis of situation and finding state law sufficiently conflict preempted).

58. *See* Colacicco v. Apotex, Inc., 556 U.S. 1101 (2009) (vacating judgment and remanding for further consideration in light of Wyeth v. Levine, 555 U.S. 555 (2009)).

59. *See 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

larly when updating labeling to reflect changes in safety information would be reasonable).

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.

61. 133 S. Ct. 2466 (2013).

62. 564 U.S. 604 (2011).

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).

66. 518 U.S. 470 (1996).

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.[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.[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.[72] The Supreme Court in *Geier v. American Honda Motor Co.*[73] determined that the stricter state law requirement sufficiently conflicted and presented a policy obstacle to the achievement of federal objectives.[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.[75]

## III. NO ROOM IN THE OVERHEAD COMPARTMENT: THE THIRD CIRCUIT FINDS STATE PRODUCTS LIABILITY CLAIMS ARE NOT IMPLIEDLY PREEMPTED BY FAA REGULATIONS

*Sikkelee* presented the Third Circuit with the issue of whether the FAA premarket approval process broadly preempted state products liability

*emption: A Defense of Parallel Claims Based on Violations of Non-Device Specific Regulations*, 86 N.Y.U. L. REV. 1196, 1210 (2011) (explaining implied preemption arguments applying "parallel" rule set forth in *Riegel*).

70. *See 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 *Lohr* declined to find broad field preemption and hesitated to completely displace tort law).

71. *See* Geier v. Am. Honda Motor Co., 529 U.S. 861, 864–65 (2000) (discussing background of DOT regulations); *see also* MCGARITY, *supra* note 2, at 61–65 (discussing Federal Motor Vehicle Safety Act that empowered federal National Highway Traffic Safety Administration to promulgate vehicle design standards). *See generally* 49 U.S.C. § 30101 (2012) (enumerating provisions of Motor Vehicle Safety Act); O'REILLY, *supra* note 13, at 196 (providing background of regulations that triggered *Geier*).

72. *See 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).

73. 529 U.S. 861 (2000).

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).

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* Sprietsma v. Mercury Marine, 537 U.S. 51, 63–64 (2002) (deciding similar case to *Geier* involving premarket regulations of watercraft and finding that absent express preemption, conflict preemption principles should apply (citing *Geier*, 529 U.S. at 869)).

claims.[76] The *Sikkelee* court answered this question in the negative and applied a standardized framework to navigate premarket approval preemption questions.[77] Section III(A) will present the facts of *Sikkelee* and its path to the Third Circuit.[78] Section III(B) will then describe the Third Circuit's application of its preemption framework through a narrative analysis.[79]

### 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.[80] 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.[81] 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.[82] In defense to Sikkelee's claims, Precision Airmotive (Precision) ar-

76. *See* Sikkelee v. Precision Airmotive Corp., 822 F.3d 680, 685–87 (3d Cir. 2016) (citing Abdullah v. Am. Airlines, Inc., 181 F.3d 363 (3d Cir. 1999) (stating that district court found federal standard of care based on FAA premarket approval regulations, but that finding engendered novel questions regarding how far *Abdullah* extended over state products liability claims), *cert. denied*, AVCO Corp. v. Sikkelee, 137 S. Ct. 495 (2016).

77. *See id.* at 709 ("[T]he District Court erred in granting summary judgment on Sikkelee's design defect claims on the basis of field preemption."); *see also infra* notes 86–118 and accompanying text for a narrative analysis of how the Third Circuit arrived at its framework that state products liability claims should be tested against express and conflict preemption, not field preemption.

78. For a further discussion of the facts and procedure of *Sikkelee*, see *infra* notes 80–85 and accompanying text.

79. *See infra* notes 91–118 and accompanying text for the three main portions of the court's analysis in *Sikkelee*, which first defines the scope of *Abdullah*, then applies express preemption to the FAA premarket regulations, and finally considers whether the second part of that analysis should be conducted with conflict or field preemption principles.

80. *See Sikkelee*, 822 F.3d at 685 (explaining accident that gave rise to claim).

81. *See id.* ("Plaintiff-Appellant in this case, alleges that the aircraft lost power and crashed as a result of a malfunction or defect in the engine's carburetor . . . . '[D]ue to the faulty design of the lock tab washers as well as gasket set,' vibrations from the engine loosened screwed holding the carburetor's throttle body to its float bowl. When properly functioning, a carburetor regulates the mixture of fuel and air that enters the engine's cylinders." (citation omitted)).

82. *See* 49 U.S.C. § 44701(a)(1) (2012) ("The Administrator of the Federal Aviation Administration shall . . . [proscribe] minimum standards required in the interest of safety for appliances and for the design, material . . . of aircraft, aircraft engines, and propellers.").

> Aircraft engine manufactures must obtain (1) a *type certificate*, which certifies that a new design for an aircraft or aircraft part performs properly and meets the safety standards defined in aviation regulations, and (2) a *production certificate*, which certifies that a duplicate part produced for a particular plane will conform to the design in the type certificate . . .

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.[83] 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."[84] Stuck between two contradictory conclusions, the district court certified the issue of whether FAA regulations preempt state product liability law for appeal.[85]

### 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.[86] First, Precision argued *Abdullah* was controlling because the Third Circuit previously found the FAA to have broad field preemption power

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> [and] (3) an *airworthiness certificate*, which certifies that the plane and its component parts conform to its type certificate and are in condition for safe operation.

*Sikkelee*, 822 F.3d at 684 (emphasis in original) (citing 49 U.S.C. § 44704(a), (c), (d) (2012)). Obtaining a type certificate could require "300,000 drawings, 2,000 engineering reports . . . approximately 80 ground tests and 1,600 hours of flight tests." *See id.* at 684 (citing United Sates v. S.A. Empresa de Ciacao Aerea Rio Grandense (Varig Airlines), 467 U.S. 797, 808 n.7 (1984)). The extent of the FAA's review of these submissions must ensure the product "is properly designed and manufactured, performs properly, and meets the regulations and minimum standards prescribed under § 44701(a)" of the Act. *See* 49 U.S.C. § 44704(a)(1); *see also* 14 C.F.R. § 21.31 (2016) (explaining requirements of type design); 14 C.F.R. § 21.137 (2016) (explaining requirements of quality system). After complying with this arduous premarket approval process, an airplane part manufacturer can produce its product and bring it to market. *See* 49 U.S.C. § 44704(a).

83. *See Sikkelee*, 822 F.3d at 683 (explaining that on motion for summary judgment, defendant argued that *Abdullah* was controlling).

84. *See* Sikkelee v. Precision Airmotive Corp., 45 F. Supp.3d 431, 447–48, 437 n.4 (M.D. Pa. 2014) (noting that *Abdullah* should be applied because of its transitive applicability, but lamenting general difficulty of fashioning regulations into legal standard of care (quoting Pease v. Lycoming Engines, No. 4:10-CV-00843, 2011 WL 6339833, at *22 (M.D. Pa. Dec. 19, 2011), *overruled by*, 822 F.3d 608 (3d Cir. 2016))).

85. *See Sikkelee*, 822 F.3d at 686–87 ("Faced with this conundrum, the District Court ordered Sikkelee to submit additional briefing . . . and invited Lycoming to file a motion for summary judgment.").

86. *See id.* at 688, 691, 698 (arguing that (1) *Abdullah* controlled and FAA regulations field preempted state law, (2) FAA statute and regulations expressly preempted state law, and (3) FAA regulations field preempted state law); *see also id.* at 707–08 (noting that parties both raised various policy arguments but that court merely addressed them for completeness rather than for their dispositive nature).

over state law.[87] Second, it argued the enabling FAA statute and its premarket approval regulations expressly preempted state products liability claims.[88] 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.[89] 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.[90]

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."[91] FAA regulations regarding in-flight protocol were comprehensive enough to establish a federal duty of care that left no room for supplemental state standards.[92] Those same provisions employed in *Abdullah*, however, were not tailored to apply to a products liability claim over an airplane part.[93]

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.[94] 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.[95] 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.[96] 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."[97]

Additionally, the language of the FAA's type certificate program lacked the utility to be used as a comprehensive standard of care.[98] 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.[99] 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.

97. *See Sikkelee*, 822 F.3d at 692 (citing Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 145 (1963)).

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

100. *Compare* 14 C.F.R. § 91.13(a) (2017) (laying out general standard of care for those operating aircrafts), *with* 14 C.F.R. § 21.137 (2016) (laying out specific requirements that each applicant for type certificate must meet).

101. *See Sikkelee*, 822 F.3d at 695 (finding that FAA type certificate regulations were never intended by their promulgators to ever provide general standard of care for tort claims). The Third Circuit tested this conclusion by comparing the FAA to the General Aviation Revitalization Act of 1994 (GARA). *See id.* (explaining Third Circuit's comparison of FAA to GARA). GARA created a statute of repose that bars suits against aviation manufacturers more than eighteen years following an accident. *See id.* By enacting a statute of repose, Congress necessarily intended to allow claims to be brought against manufacturers within that eighteen-year window. *See id.* GARA would be rendered "superfluous" if preemption was found. *See id.*

102. *See id.* at 699 (noting that Precision put forth three arguments that Congress intended for FAA regulations to broadly field preempt state products liability law based on analogous statutory regimes, Supreme Court's premarket approval cases, and other Appeals Courts that have found field preemption in aviation safety).

103. *See id.* at 695 (emphasis added) (outlining Third Circuit's disagreement).

104. *See id.* at 699, 701–02 (comparing FAA regulations to FDA and DOT regulations and drawing comparison between Supreme Court's previous premarket approval cases); *see also infra* notes 105–18 and accompanying text for a detailed analysis of the comparisons.

105. *See Sikkelee*, 822 F.3d at 699 (noting statutory similarities between transportation and aviation regulations).

106. *See id.* (noting that National Traffic and Motor Safety Act of 1966 possessed similarities to FAA Act); *see also id.* at 699–701 (citing Sprietsma v. Mercury Marine, 537 U.S. 51, 57, 63 (2002)) (comparing FAA to Federal Boat Safety Act).

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*.

110. *See Sikkelee*, 822 F.3d at 703–04 (explaining that impossibility results when "a party cannot 'independently do under federal law what state law requires of it'" (citing *PLIVA*, 564 U.S. at 604 and Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1973))).

111. *See id.* 704–05 (explaining that when both cases are read together, they "[cut] 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 FDA'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.[115]

Precision failed to make a conflict preemption argument, opting for an expansive field preemption theory.[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.[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.[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*.[119] The following analysis will demonstrate how *Sikkelee*'s approach resulted in a unification of the Third Circuit's prior premarket approval preemption cases.[120] Then, this section will offer advice to Third Circuit litigators on how to employ *Sikkelee*'s framework.[121]

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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.

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.

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).

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)).

119. *See supra* notes 28–32, 52–57 and accompanying text for background discussion of *Fellner* and *Colacicco*; *see also infra* 127–133 and accompanying text for critical analysis of how principles developed in *Fellner* and *Colacicco* translate into understanding *Sikkelee*.

120. *See infra* notes 122–33 and accompanying text for a synthesis of Third Circuit case law on premarket approval preemption.

121. *See infra* notes 134–41 and accompanying text for an analysis of how practitioners can integrate *Sikkelee* into their arguments.

### 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.[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.[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.[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.[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.[126]

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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*.[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.[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.[129]

The structure of *Sikkelee*'s premarket approval preemption framework is echoed in *Colacicco*.[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.[131] In that way, *Sikkelee* is a vindication of *Colacicco* whose analytical rule was nullified based on its substantive outcome.[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.[133]

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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).

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*.

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).

130. *See* Colacicco v. Apotex, Inc., 521 F.3d 253, 265 (3d Cir. 2008) (analyzing pharmaceutical labeling issue by first applying express preemption principles, but then determining case involved application of conflict preemption), *cert. granted and judgment vacated*, 556 U.S. 1101 (2009) (vacating judgment and remanding for further consideration in light of Wyeth v. Levine, 555 U.S. 555 (2009)).

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.").

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.

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).

139. *See Sikkelee*, 822 F.3d at 688 (noting that conflict preemption requires actual impossibility of dual compliance); *see also* Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861, 884 (2000) (citing English v. Gen. Elec. Co., 496 U.S. 72, 78–79 (1990) (explaining that conflict preemption requires actual conflict, not just generalized intent to preempt).

*Riegel* and *Lohr*, which was emphasized in *Sikkelee*.[140] The more an argument demonstrates ability of dual compliance through symmetrical standards the less likely a court is to find conflict preemption.[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.[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.[143] *Sikkelee*'s reassertion of state police power marks a commitment to federalist principles to the benefit of aggrieved plaintiffs.[144]

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140. *See Sikkelee*, 822 F.3d at 705 (explaining that "parallel" exception means that states are permitted to regulate concurrently to federal law).

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").

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).

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.

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).