



JUDICIAL POLITICS AND MEDICAL DEVICE PREEMPTION AFTER *RIEGEL*

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I. INTRODUCTION

Recent Supreme Court rulings on the scope of federal preemption of state tort law have sparked passionate debate in legal circles

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and among lower courts. Tort preemption implicates powerful issues related to federalism, since it suggests that federal agencies are the proper locus for regulation rather than states and state courts. In this Note, I examine lower court cases decided after the Supreme Court's opinion in *Riegel v. Medtronic*,¹ which interpreted the 1976 Medical Device Amendments (MDA), to see whether structural factors and judicial politics influence determinations of preemption. After examination of these extralegal factors, I summarize the substance of surviving tort claims, and attempt to harmonize the findings with well-supported normative theories of judicial behavior. I conclude by critiquing a recent argument favoring further narrowing of medical device claims, and point to broader principles of federalism that best serve both consumers and manufacturers.

This paper seeks to answer a highly salient question about judicial behavior regarding preemption. Legal academics and philosophers have pointed to a number of factors beyond statutes and precedent that influence judges, like locus of the court, ideology, and biographical factors like race and gender. These factors are particularly prominent in the context of preemption, especially the preemption of state tort law. Commentators have suggested that some preemption decisions and the resulting public reaction are motivated by ideology,² and scholars have carefully researched whether federal courts are more likely to find preemption than state courts.³

The Supreme Court's decision in *Riegel* settled the disputed question⁴ about the preemptive extent of the MDA. The Court ruled

¹ 552 U.S. 312 (2008).

² See Richard H. Fallon, Jr., *The "Conservative" Paths of the Rehnquist Court's Federalism Decisions*, 69 U. CHI. L. REV. 429, 462, 471 (2002) (linking the "Supreme Court's preemption cases to its federalism agenda" and mentioning that the "substantive conservatism of Justices O'Connor and Kennedy draws them to view the Commerce Clause as embodying antiregulatory, procompetitive ideals"); Jonathan R. Macey, *Federal Deference to Local Regulators and the Economic Theory of Regulation: Toward a Public-Choice Explanation of Federalism*, 76 VA. L. REV. 265, 265 (1990) (arguing that commentators "extol the virtues of state autonomy whenever deference to the states happens to serve their political needs at a particular moment.").

³ Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J.L. & POL'Y 1013 (2007); Keith N. Hylton, *Preemption and Products Liability: A Positive Theory*, 16 SUP. CT. ECON. REV. 205 (2008).

⁴ Before the opinion in *Riegel*, the D.C. Circuit and Eleventh Circuit had ruled that the MDA did not preempt state tort law, in opposition to every other federal circuit

that the Food and Drug Administration's (FDA) pre-market approval process constitutes "requirements" which manufacturers must meet before the product can be sold.⁵ Those MDA requirements displaced state common law tort claims of negligence and strict liability which are also "requirements."⁶ Only tort claims predicated on a violation of FDA regulations, and therefore "parallel" to the federal requirements, survive preemption.⁷ The Court did not answer whether the complaint brought in *Riegel* was in fact parallel, and reserved that definition for lower courts.⁸

This definition is subtle.⁹ Since preemption denies the plaintiff from recovering for their injuries, and restricts the authority of state courts, ideological and structural dispositions may affect judicial reaction. Lower courts might implement their ideological and personal beliefs into their opinions. The empirical question I seek to answer is whether these factors have influenced judges in defining whether a claim is parallel. I look to certain variables, including the type of court deciding a case, whether the litigants live in the state where the judge sits, the political party of the judge or the person who appointed them, and factors which correlate with ideology like race and gender. I code each case to determine whether the court found a successful parallel claim, and examine whether the independent variable creates variation among the cases. I harmonize these findings with academic theories of judicial decisionmaking.

court of appeals. See Kim M. Schmid & Shane V. Bohnen, *Riegel v. Medtronic: Better Off Without It?*, LAW 360, Aug. 1, 2008, at 2-3, available at <http://www.bowmanandbrooke.com/files/News/b996c4b5-5c7f-46a2-924e-ca8f3d71ea2c/Presentation/NewsAttachment/c91e1930-beb6-482e-8ca2-e067de4c9318/KMSRiegelLaw360Article.PDF>.

⁵ *Riegel*, 552 U.S. at 322-23.

⁶ See *id.* at 325.

⁷ *Id.* at 330.

⁸ *Id.*

⁹ Jim Beck & Mark Herrmann, *The Future is Now*, DRUG AND DEVICE L. BLOG (Apr. 21, 2008 08:51 EST), <http://druganddevicelaw.blogspot.com/2008/04/future-is-now.html> (questioning "the line between privately actionable 'parallel state law requirements' and non-actionable 'fraud on the FDA'"). The Supreme Court had previously ruled that such "fraud on the FDA" claims, where plaintiffs plead that false information provided by the defendants to the FDA led to agency approval, are preempted by the Federal Food, Drug, and Cosmetic Act. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001).

I then examine the substance of surviving claims. As I describe, lower courts have considered three types of claims sufficiently parallel and not preempted. I mention some of the implications of the empirical results. I conclude by explaining and critiquing a recent journal piece which seeks to narrow the available scope of parallel claims, arguing that the piece is inconsistent with Supreme Court precedent and is also deficient in its policy rationale. Courts and legislatures should ensure that some subset of medical device tort claims survive the recent pro-preemption trend of the Supreme Court.

II. MUDDLED PREEMPTION LAW, THE INVITATION FOR JUDICIAL POLITICS, AND *RIEGEL*

The Constitution determines that federal law is supreme to state law.¹⁰ Preemption cases involve a potential conflict between federal and state law, and the examination of whether both the federal and state command address the issue before the court. Despite that simple description, legal doctrine surrounding preemption is often messy and ill-formed, which gives expanded discretion to judges. Preemption also cuts along clear ideological poles. The judicial role traditionally requires judges to set aside personal beliefs and decide cases solely upon neutral legal principles, but the indeterminacy and ideology in preemption law may make that endeavor particularly difficult. While *Riegel* narrowed some judicial discretion, the open spaces left by the issue of parallel claims invite some further decisionmaking.

A. *The Indeterminacy of Preemption Doctrine*

The Supreme Court's precedent on preemption has created a veneer of clarity, but is in fact disputed and unsettled in three important ways. First, preemption cases are about interpretation of state and federal law, which raises fundamental philosophical disputes about the nature of the legal system. Second, the Court's

¹⁰ U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.").

answer to that problem, which categorizes types of preemption cases, is simplistic and often unwieldy and confusing. Third, the Court has inconsistently approved the use of a background canon of interpretation providing for a “presumption against preemption.”

Disputes about statutory interpretation are more than a hundred years old.¹¹ Legal academics and judges have pet normative theories about how courts should view the meaning and application of a statute.¹² Preemption analysis requires examination of not one but two types of law, a federal statute or norm and a state statute or common law right.¹³

The Court developed a tripartite framework that attempts to simplify these questions of interpretation. When Congress clearly declares its intent to preempt state law in the text of a statute, “express” preemption applies.¹⁴ “Impossibility” or “implied” preemption exists if citizens cannot comply with both sets of law, or if the state law acts as an obstacle to federal duties.¹⁵ Finally, federal law

¹¹ See, e.g., *Holy Trinity Church v. United States*, 143 U.S. 457 (1892) (rejecting the plain textual meaning of a statute in favor of its deeper “purpose”).

¹² See generally STEPHEN BREYER, *ACTIVE LIBERTY: INTERPRETING OUR DYNAMIC CONSTITUTION* (2005); Frank H. Easterbrook, *Statutes' Domain*, 50 U. CHI. L. REV. 533 (1983); William N. Eskridge, Jr., *Dynamic Statutory Interpretation*, 135 U. PA. L. REV. 1479 (1987).

¹³ See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 510 (1996) (O'Connor, J., concurring in part and dissenting in part) (arguing that the majority misread the language of a federal statute); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 533–34 (1992) (Blackmun, J., concurring in part and dissenting in part) (arguing that the majority opinion misinterpreted the federal statute to cover a claim for damages at common law); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108–09 (1992) (interpreting an Illinois statute as regulating “occupational safety and health” rather than merely creating a “‘pre-condition’ to employment”).

¹⁴ See, e.g., *Cipollone*, 505 U.S. at 517 (finding that Congress had clearly intended to preempt state tort obligations).

¹⁵ See, e.g., *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963) (defining preemption as occurring “where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce.”); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000) (holding a state law preempted because the “rule of law for which petitioners contend would have stood ‘as an obstacle to the accomplishment and execution of’ the important means-related federal objectives”). An easy example would be if federal law required all widgets to be two inches in diameter, but a state law required each widget to be one inch in diameter.

displaces state law when Congress intended to “occupy the field” of regulation, making any state regulation inapposite.¹⁶ This framework seems to create bright lines between the categories, but commentators have pointed out the differences are blurry.¹⁷ The Court has itself denied that the categories are “rigidly distinct,”¹⁸ and a disagreement about which category applied led to a fractured opinion and lack of a clear majority in a major case.¹⁹

The final doctrinal element which causes uncertainty and confusion in the lower courts and among academics is the intermittent use of the “presumption against preemption.” In *Rice v. Santa Fe Elevator*, Justice Douglas wrote that courts should assume ambiguous federal law does not displace the state enactment, because of the traditional police power delegated to state governments.²⁰ The Supreme Court's decisions in *Cipollone* and *Lohr* discuss the canon and its restraint on expansive findings of preemption at length.²¹ However, in a 2001 case, Chief Justice Rehnquist argued that the presumption should and did not apply to laws that regulate the relationship between the federal government and a private actor.²² The majority opinion in *Riegel* consequently did not mention the presumption.²³ The following year, though, in a case that also touched on the relationship between a federal regulator and a

¹⁶ See, e.g., *Gade*, 505 U.S. at 104–05; *Hines v. Davidowitz*, 312 U.S. 52, 63–64 (1941) (finding that the Constitution and the Congressional statute maintained that only the federal government could regulate in the broad area of immigration).

¹⁷ See, e.g., Karen A. Jordan, *The Shifting Preemption Paradigm: Conceptual and Interpretive Issues*, 51 VAND. L. REV. 1149, 1175 (1998); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 262 (2000).

¹⁸ *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 n.5 (1990).

¹⁹ Nelson, *supra* note 17, at 262 (describing *Gade*, 505 U.S. at 109–14).

²⁰ 331 U.S. 218, 230 (1947).

²¹ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992).

²² *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347–48 (2001) (arguing that the state law at issue, which granted monetary damages for fraudulent claims made to the FDA, was not an area traditionally delegated to state authority, so there was no background norm preventing preemption).

²³ See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 334–35 (2008) (Ginsburg, J., dissenting) (explaining the presumption against preemption and stating that “[f]ederal laws containing a preemption clause do not automatically escape the presumption against preemption.”).

private actor, the Court revived the presumption, and relied heavily upon it to deny preemption.²⁴

Preemption doctrine is therefore murky and somewhat obscure. Disputes abound about interpretive methodology, about the judicially created framework, and the lingering role of the presumption against preemption. These disputes create indeterminacy, which allows lower courts to evade existing doctrine by choosing among a number of competing rules and theories. This lack of bright line rules opens the door to uncontrolled judicial decisionmaking.²⁵ We can theorize, therefore, that lower court judges, especially state judges who are not directly monitored by the Supreme Court, will have a greater ability to steer law in preemption decisions than in other areas.

B. Preemption is Particularly Susceptible to Personal and Ideological Judging

Preemption touches on issues of surpassing political salience. When state tort claims are preempted, business interests are shielded from monetary liability. When they are not, plaintiffs' attorneys can successfully recover money damages for their clients. Decisions on preemption therefore benefit a discrete, identifiable interest group.²⁶ Additionally, the proper locus of government power is a politically charged issue, with clearly defined poles.²⁷

²⁴ See *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 n.3 (2009) (finding that the presumption of preemption applies whenever state law has an "historic presence" in the regulated field). This reasoning highlights the failure by the majority in the *Riegel* case to cite to the preemption, since state law indeed has an "historic presence" in regulating products liability. See generally *MacPherson v. Buick Motor Co.*, 111 N.E. 1050 (N.Y. 1916).

²⁵ See, e.g., Antonin Scalia, *The Rule of Law as a Law of Rules*, 56 U. CHI. L. REV. 1175, 1179-80 (1989) (arguing that bright line rules constrain judges regardless of their political preferences).

²⁶ See generally Sandra Zellmer, *Preemption by Stealth*, 45 HOUS. L. REV. 1659, 1662 (2009) (arguing that *Riegel* and other preemption cases provide evidence of the Roberts' Court's pro-business bias).

²⁷ For example, one of the planks in the 2008 Republican Party platform calls for "Empowering the States" by re-invigorating the 10th Amendment. REPUBLICAN NAT'L COMM., 2008 REPUBLICAN PLATFORM 17 (2008), available at <http://www.gop.com/2008Platform/GovernmentReform.htm#3>.

Preemption has invited strongly ideological reactions,²⁸ and has been characterized as a fundamentally political issue.²⁹ Legal realists and modern legal empiricists³⁰ deny that judges make decisions based solely on neutral legal principles, instead pointing to personal factors including ideology as major motivation. Regardless of the normative underpinnings of that practice, the idea that judges are heavily influenced by ideology is extremely popular in media depictions of the Supreme Court.³¹ Empirical work has supported that proposition, in the Supreme Court and in lower courts.³² Researchers have found that ideological measures correlate with Supreme Court findings of preemption.³³ This suggests that ideology should also correlate with findings of preemption in lower courts.³⁴

Preemption implicates other factors specific to individual judges. Preemption undercuts state autonomy. State judges may be unwilling to deny cases derived from their state's deep-seated common law traditions. Federal judges, on the other hand, may feel

²⁸ For example, self-proclaimed "progressive" groups like the Drum Major Institute, which seek to "generat[e] . . . ideas that fuel the progressive movement," (<http://www.drummajorinstitute.org/about.html>) included opposition to preemption as one of the planks in their "Civil Justice Presidential Platform," available at http://www.tortreform.com/archives/2007/11/federal_preemption_1.html. Scholars often denoted as "conservative" or "libertarian," including Richard Epstein and Michael Greve, writing for the "conservative" American Enterprise Institute, have argued for far broader findings of preemption. See Richard A. Epstein & Michael S. Greve, *Federal Preemption: Principles and Politics*, FEDERALIST OUTLOOK, June 2007, available at <http://www.aei.org/outlook/26296>.

²⁹ Fallon, *supra* note 2, at 462.

³⁰ See HAROLD J. SPAETH & JEFFREY A. SEGAL, *THE SUPREME COURT AND THE ATTITUDINAL MODEL REVISITED* (2002).

³¹ See, e.g., Editorial, *The Court's Blow to Democracy*, N.Y. TIMES, Jan. 21, 2010 ("[The] conservative majority has distorted the political system to ensure that Republican candidates will be at an enormous advantage in future elections.").

³² See, e.g., SPAETH & SEGAL, *supra* note 30; Cass R. Sunstein, et al., *Ideological Voting on Federal Courts of Appeals: A Preliminary Investigation*, 90 VA. L. REV. 301, 305 (2004) ("[I]n numerous areas of the law, all three hypotheses [including one that suspects judges rule ideologically] are strongly confirmed.").

³³ Michael S. Greve & Jonathan Klick, *Preemption in the Rehnquist Court: A Preliminary Empirical Assessment*, 14 SUP. CT. ECON. REV. 43 (2006).

³⁴ See James M. Beck & Mark Herrmann, *Device Preemption Bookends*, DRUG & DEVICE L. BLOG (Mar. 12, 2009), <http://druganddevicelaw.blogspot.com/2009/03/device-preemption-bookends.html> ("courts continue to view tort preemption questions through the lenses of their own particular philosophies.").

greater kinship with the federal government, and be more likely to find preemption.³⁵

From a more prosaic perspective, state judges should be more likely to reject preemption because of simple electoral goals. Many state judges are elected by voters.³⁶ Those judges may try to increase their chances of reelection by appealing to certain constituencies with favorable rulings.³⁷ Judges seeking contributions from the business community may protect firms from expensive tort suits, while those seeking the support of trial lawyers would allow more suits to go forward.

Judges deciding preemption cases are therefore likely to be influenced by personal factors like ideology, the court they sit on, and election strategy. The indeterminacy and freedom to apply complex precedent, with the influence of personal factors, gives lower courts motive and opportunity to enshrine their personal preferences in preemption law.

C. Background to Riegel

Congress passed the Medical Device Amendments of 1976 (“MDA”)³⁸ to create a uniform federal regulatory regime regarding medical devices after the notable failure of the Dalkon Shield led to many deaths, injuries, and massive tort judgments.³⁹ The MDA established certain federal oversight rules before allowing medical devices to be widely sold.⁴⁰ Class III devices, considered the most dangerous category, require months of careful testing by the Food and Drug Administration (“FDA”) before widespread sale.⁴¹

³⁵ See generally Burt Neuborne, *The Myth of Parity*, 90 HARV. L. REV. 1105 (1977) (asserting that state courts vindicate fewer federal rights than federal courts); Sharkey, *supra* note 3.

³⁶ Fredreka Schouten, *States Act to Revise Judicial Selection*, USA TODAY, March 31, 2010, at 1A (“Thirty-nine states elect at least some of their judges.”).

³⁷ See, e.g., *Caperton v. A.T. Massey Coal Co.* 129 S. Ct. 2252, 2262–64 (2009) (broadly examining the role fundraising may play in judicial decisionmaking).

³⁸ Pub. L. No. 94-295, 90 Stat. 539.

³⁹ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315–16 (2008).

⁴⁰ *Id.* at 316.

⁴¹ *Id.* at 318 (“The FDA spends an average of 1,200 hours reviewing each application” (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996))).

In 1996, Charles Riegel was found to have a diffusely diseased, heavily calcified right artery, and underwent a coronary angioplasty.⁴² His doctor inserted a balloon catheter into the artery to cause dilation, against the specific warnings on the device's label against use for diffuse or calcified arteries.⁴³ Riegel's doctor inflated the balloon to a pressure of 10 atmospheres, which was also contraindicated by the label, causing the catheter to rupture, and leave Riegel on life support.⁴⁴ Riegel and his wife sued the developer of the balloon catheter, Medtronic, in the Northern District of New York alleging that the catheter was defective in design, warning, and manufacture under New York products liability common law.⁴⁵ The catheter is a Class III device, and passed through the FDA's premarket approval testing process in 1994, with all later changes to the label authorized by the FDA. The District Court ruled against the Riegels on summary judgment, ruling that both FDA premarket approval and state tort law created "requirements" as defined by the MDA,⁴⁶ and therefore the state law must be set aside in favor of federal law.⁴⁷ This opinion was affirmed by the Second Circuit on similar grounds; since both the premarket approval process and state tort law were requirements, state tort law must be trumped by the federal regulatory system.⁴⁸

D. Riegel and the "parallel" claims exception

Justice Scalia affirmed the two lower courts and rejected the Riegels' appeal. Scalia first laid out the FDA's arduous premarket

⁴² *Riegel*, 552 U.S. at 320.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Riegel v. Medtronic, Inc.*, 2003 WL 25556778, at *1 (N.D.N.Y. 2003).

⁴⁶ 21 U.S.C. § 360k(a) (2006) (the express preemption clause of the MDA: "Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act."). Subsection (b) allows the FDA to exempt some state and local requirements from preemption. *See* 21 U.S.C. § 360k(b) (2006).

⁴⁷ *Riegel v. Medtronic, Inc.*, 2002 WL 34234093, at *6, *8 (N.D.N.Y. 2002).

⁴⁸ *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006).

approval process.⁴⁹ The FDA spends many hours studying a product before granting PMA status, and only do so when there is “reasonable assurance of the device's safety and effectiveness.”⁵⁰ Once the FDA has approved the device, the manufacturer cannot make changes in specifications, processes, labels, or other attributes absent FDA permission.⁵¹

Justice Scalia determined that this process constituted a “requirement” since it was tailored to individual products and did not apply generally to a wide range of medical devices.⁵² State tort law also imposes requirements, since judges and juries find that the manufacturer “violated a state law obligation” in determining the product was insufficiently safe, which sets some legal standard for the use of the device in the state.⁵³ Since the federal requirement is supreme to the state requirement, state law is preempted. Scalia concluded by rejecting any use of the presumption against preemption⁵⁴ and found that an unclear FDA regulation⁵⁵ was not relevant to the disposition of the case.⁵⁶

Riegel eliminated nearly all state causes of action on medical devices which had passed through premarket approval. The majority did allow that since the MDA only bars state laws “different from or in addition to” federal law, state tort claims predicated on violations of FDA regulations survive the express preemption clause.⁵⁷ The court found, though, that the *Riegels* failed to properly assert any “parallel” claims in their suit.⁵⁸ Therefore, the Supreme Court left the definition of “parallel” to lower courts.⁵⁹

⁴⁹ *Riegel*, 552 U.S. at 317–18.

⁵⁰ *Id.* at 318 (citing 21 U.S.C. § 360e(d)).

⁵¹ *Riegel*, 552 U.S. at 319.

⁵² *Id.* at 322–23. (holding that preemption occurs when FDA issues specific requirements applicable to a specific device (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996))).

⁵³ *See Riegel*, 552 U.S. at 325.

⁵⁴ *See id.* at 326–27.

⁵⁵ 21 C.F.R. § 808.1(d)(1) (2008).

⁵⁶ *Riegel*, 552 U.S. at 329–30.

⁵⁷ *Id.* at 330.

⁵⁸ *Id.*

⁵⁹ On their face, such parallel claims are circumscribed and narrow. In a simplified sense, state law would do no more than offer private enforcement actions to litigants for the failure of manufacturers to follow and apply FDA regulations. The opinion in

E. The reaction to *Riegel*

The Court's decision sparked heated legal commentary. Some academics and popular media sources regarded the *Riegel* decision as fundamentally policy-driven.⁶⁰ Justice Antonin Scalia, who wrote the majority opinion in the case, strongly disputed this characterization.⁶¹ Congress began considering a statutory override to reverse the MDA's preemption language.⁶² Some lower courts also rejected *Riegel*, including Chief Justice Jim Hannah of the Arkansas Supreme Court, who decried the decision in an opinion explicitly calling for Congressional override.⁶³ Hannah's arguments echo resolutions passed by the Conference of Chief Justices zealously guarding federalism and the authority of state courts.⁶⁴ A federal

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), determining that the MDA implicitly preempted claims against manufacturers for defrauding the FDA, provides another limitation. Reading the two cases together, it seems that state tort law can only apply when the FDA approves a device, and the manufacturer violates an FDA regulation through some means besides fraud.

This paper discusses, *supra* Section II.A, that open spaces in Supreme Court doctrine on preemption could increase judicial discretion, but the narrow band provided by the two cases may severely limit the freedom lower courts enjoy in other preemption cases. See discussion *infra* Section V for more.

⁶⁰ E.g., Editorial, *No Recourse for the Injured*, N.Y. TIMES, Feb. 22, 2008, at A22 (suggesting that Justice Scalia's opinion was motivated by his "faith in the F.D.A."). See generally Zellmer, *supra* note 26.

⁶¹ *Scalia Criticizes News Media*, ASSOCIATED PRESS, Mar. 27, 2008, <http://www.breitbart.com/article.php?id=D8VM047O4>. In his criticism, Scalia specifically mentioned the New York Times editorial, *supra* note 60.

⁶² See H.R. 6381, 110th Cong. (2008); S. 3398, 110th Cong. (2008). Congress failed to pass the legislation in that session of Congress. The bill was re-introduced during the 111th Congress, and currently sits in the respective committees of the House and Senate. See H.R. 1346, 111th Cong. (2009); S. 540, 111th Cong. (2009).

⁶³ *Despain v. Bradburn*, 282 S.W.3d 814, 816-17 (2008) (Hannah, C.J., concurring).

⁶⁴ See CONFERENCE OF CHIEF JUSTICES, RESOLUTION 1: IN SUPPORT OF THE EFFORTS BY THE U.S. CONGRESS TO PROMOTE RESPECT FOR PRINCIPLES OF FEDERALISM AND SEPARATION OF POWERS (2008), available at <http://ccj.ncsc.dni.us/FederalismResolutions/resol1RespectPrinciplesOffederalism.html>; CONFERENCE OF CHIEF JUSTICES, RESOLUTION 7: URGING THE UNITED STATES CONGRESS TO CONSIDER STATE POLICIES AND PRINCIPLES OF FEDERALISM WITH REGARD TO REFORMING HEALTH CARE LIABILITY SYSTEMS (2009), available at <http://ccj.ncsc.dni.us/FederalismResolutions/resol7HealthCare.html>.

district court judge in Arkansas also decried the frequent findings of preemption at the expense of state jury decisions.⁶⁵

III. MODEL CONSTRUCTION, HYPOTHESES, RESULTS, AND ANALYSIS

The preceding sections lay out the problem this paper seeks to answer. There is reason to believe that judges decide cases based on factors unrelated to precedent or law in the preemption area. The 75 cases involving medical devices approved for marketing provides a natural experiment for this proposition. I will compare the judicial rulings on preemption using the independent variables to evaluate patterns and thereby reveal the relationships between these variables and judicial outcomes.

A. Independent variables

I examine five independent variables within the 75 cases regarding medical devices between *Riegel* and July 15, 2010. Those variables are: 1) whether the court was federal or state, 2) the political party of the judge or the party of the appointing officer, 3) whether the defendant had a branch office in the state where the trial occurred, 4) whether the plaintiff was a resident of the state where the trial occurred, and 5) the race and gender of the deciding judge.

I distinguish between federal and state courts because of the intuitive power of Burt Neuborne's seminal claim about the disparate results between Article III and state judges reach retains intuitive power.⁶⁶ I will compare the sample of cases decided in federal courts with those in state courts, and see whether a disparity exists in findings of preemption. Neuborne's argument should be heightened when judges sit in cases involving in-state litigants, since state judges will likely consider local reactions to their decisions.

I use two factors to capture ideology. I use variables to stand in for political party, either by using the party of the appointing officer⁶⁷ or the party of the judge in states with partisan elections.⁶⁸ I

⁶⁵ Doug Smith, *State Judges Reproach U.S. Supreme Court*, ARK. TIMES, May 8, 2008, at 10.

⁶⁶ See Neuborne, *supra* note 35.

⁶⁷ For Article III judges and state appointed judges.

also look to the race and gender of the judge, which has a controversial but somewhat recognized effect on some areas of judicial decisionmaking.⁶⁹

B. *Dependent variable*

I define any ruling which maintains a cause of action as “no-preemption.” Judges who dismiss all claims arising from the design, manufacture, and labeling of a medical device are defined as finding “preemption.”⁷⁰ I define the dependent variable in this way despite the fact that many of the cases are dismissed as insufficiently pled. Judges will dismiss most of the plaintiff’s common law claims as preempted, and then determine that the alleged parallel claims are not sufficiently supported. While such a finding is not in fact “preemption,” the narrow reading of the claim demonstrates how the court defines the term parallel. Therefore, for simplicity, and to best highlight surviving parallel claims, I define such a dismissal as “preemption.”

C. *Hypotheses*

The selection of variables compels certain hypotheses about the data. I believe the data will show some disparity between federal

⁶⁸ Where states have only recently instituted non-partisan elections, I code the party affiliation the judge was originally elected under.

⁶⁹ See, e.g., Tajuana Massie, et. al, *The Impact of Gender and Race in the Decisions of Judges on the United States Courts of Appeals*, at *1 (2002), <http://www.cas.sc.edu/poli/psrw/MassieJohnsonGubala.pdf> (determining that “women judges in the courts of appeals tend to vote more conservatively in criminal procedure cases and more liberally in civil right and liberties cases than their male counterparts”); Pat K. Chew & Robert E. Kelley, *Myth of the Color-Blind Judge: an Empirical Analysis of Racial Harassment Cases*, 86 WASH. U. L. REV. 1117 (2009).

⁷⁰ I determine that one case in the sample which maintained causes of action against a device manufacture to nonetheless be “preemption.” *Medtronic, Inc.*, sent three samples of a device to a hospital, one of which turned out to be a different, and inappropriate device, leading to a patient’s death. *William Beaumont Hospital v. Medtronic, Inc.*, 2009 WL 2849546, at *1 (E.D. Mich. 2009). The patient’s estate sued the hospital, which then attempted to receive contribution from Medtronic. *Id.* The court ruled any causes of action arising from the labeling of the product at use to be preempted, *id.* at *7, but allowed a claim of negligence in sending an inappropriate product in the guise of the appropriate product to continue. *Id.* at *6. Since the claims relevant to this empirical study were dismissed, I mark this case as “preemption.”

and state courts, though the general applicability of the theory remains controversial.⁷¹ The disparity thesis is even more potent in the tort preemption context, since state judges would lose their authority to administer a traditional area of state control.⁷² State judges will try to remove some of these limits by expanding the definition of parallel.

As mentioned earlier, preemption is highly ideological. Liberal scholars and commentators seek to increase damages actions while conservatives should favor clear rules for manufacturers. Therefore, I suspect that conservative judges will preempt more often than liberal judges.⁷³ Federal judges appointed by Republican Presidents should find fewer claims to be parallel than those appointed by Democratic Presidents, and the same should hold true for state elected judges.

Judges will likely respond to local conditions. Though federal judges are removed from direct democratic accountability, they usually reside in their judicial district. State judges are reliant on local democracy, either by direct election or appointment by state officials. Therefore, if one of the litigants resides in-state, I expect both federal and state judges to favor that litigant. I examine the relationship when both plaintiffs and defendants reside in-state, and also isolate the “hometown advantage effect” by looking at cases when only one litigant resides in the state. I suspect there will be a relationship between residency of the litigants and decisions on preemption.

⁷¹ See Erwin Chemerinsky, *Parity Reconsidered: Defining a Role for the Federal Judiciary*, 36 UCLA L. REV. 233 (1988) (closely examining and comparing studies about parity and concluding that the debate is unresolvable as constructed).

⁷² This is buffeted by the third judicial opinion written in the aftermath of *Riegel, Despain v. Bradburn*, 282 S.W.3d 814, 816–17 (Ark. 2008) (Hannah, C.J., concurring). Chief Justice Hannah's concurrence criticized *Riegel* for trampling on the structure of federalism by arrogating enormous powers to the federal government without regards to state courts. Despite his criticism, Hannah found preemption in that case, saying his hands were tied by the Supreme Court.

⁷³ It is possible that Republican appointed judges will be more likely to rule against a parallel claim because they believe that they are correctly applying *Riegel*, rather than acting from predispositions towards one of the litigants. Republican appointed judges may also be more likely to share the *Riegel* majority's theory of statutory interpretation. For our purposes, motives are irrelevant; the relevant inquiry is determining whether partisan appointments have a consistent effect.

I believe the data will also show some connection between race and gender and findings of preemption. However, the data set is not large enough to isolate the effect of race or gender from that of political party or ideology. Presidents Clinton and Carter appointed minorities to 21.7% and 24.3% of the total vacancies to the federal bench, while George W. Bush appointed the most minority judges of any Republican, 17.6% of his appointments as of 2007.⁷⁴ As a result, 58.0% of the minority judges appointed between 1969 and 2007 were Democratic appointees, making it challenging to distinguish race and gender from political party.

D. Results

Between February 20, 2008, the date the Riegel case was decided, and July 15, 2010, American courts have ruled on 75 cases involving devices the FDA preapproved for the market under § 360k of the Medical Device Amendments.⁷⁵ In those 75 cases, the court found “preemption” 58 times, and found “no preemption” 17 times.⁷⁶ Preemption was therefore found in 77.3% of the cases. Some of these cases were decided by appellate panels, so 105 judges heard those 75 cases, and 21, 20.0% of the judges, found “no preemption.” The following describes the results broken down by independent variable.

1. FEDERAL VS. STATE COURTS

Of the 75 cases, 21 were decided by state judges, 51 by Article III federal judges, and three by federal magistrate judges. The state courts found “preemption” 17 times, and allowed plaintiffs’ claims to continue four times, 19.0% of the cases. Those 21 cases were heard by 47 judges, meaning that 12.8% of the state judges allowed claims to survive. The 51 cases before Article III judges found “no

⁷⁴ See Chew & Kelley, *supra* note 69, at 1128.

⁷⁵ See Jim Beck & Mark Herrmann, (New) Medical Device Preemption Scorecard, DRUG & DEVICE L. BLOG, (Aug. 21, 2008), <http://druganddevicelaw.blogspot.com/2008/08/new-medical-device-preemption-scorecard.html>. I removed the case *Kavalir v. Medtronic*, 2008 WL 4087950 (N.D. Ill. 2008) from the sample, since the judge in that case dismissed the defendant’s motion for summary judgment because of insufficient evidence that the product actually passed through the FDA’s premarket approval process, an issue afield of this paper.

⁷⁶ For a compilation of the data used, see *infra* Appendix.

preemption" 12 times, stopping plaintiffs' claims 39 times, in 76.4% of the cases. 42 of the 55 federal judges who sat on the cases found preemption, 76.3% of the total. The magistrate judges allowed plaintiffs' claims to continue once in three opportunities.⁷⁷

2. PARTY BREAKDOWN

Twenty-eight of the federal district court cases were decided by Republican appointees, and 21 by Democrat-appointed judges. One case was decided by a mixed appellate panel, one by a panel of judges appointed entirely by Republicans. Eight of the decisions by "Democratic" district judges found "no preemption" while 3 decided by "Republican" judges found "no preemption," meaning that 38.1% of the "Democratic" cases, and 10.7% of the "Republican" cases found "no preemption." One Republican judge and one Democratic judge found no preemption over the objection of a Republican appointee in the appellate case decided by the Sixth Circuit Court of Appeals, and all three judges upheld a claim as preempted in the Eight Circuit. Federal magistrate judges, whose results were mentioned earlier, are not appointed by the President, and are considered non-partisan in this study. In state courts, one case was decided by a single state judge elected as a Democrat. That judge found "no preemption." Nine cases were decided by single Republican judges, and one found "no preemption," 11.1% of the cases. One case, which featured a judge originally elected in a non-partisan election, found "no preemption." Ten cases were decided by appellate panels. One of those cases, which found "preemption," was comprised entirely of non-partisan judges. Eight found preemption with no dissenting judges: thirteen Democratic judges, eight Republican judges, and nine judges whose partisan affiliation is unclear. One appellate panel, with one Democrat and two Republicans, reversed a lower court finding of full preemption.

⁷⁷ Magistrate judges do not have the power to make final dispositions on issues of law. In the first device case decided after *Riegel*, Magistrate Judge David R. Homer ruled that preemption decisions could not be made in the context of administering discovery, but did determine that the plaintiff's claims "appear[] to remain viable after *Riegel*." *Strini v. Edward Lifesciences Corp.*, No. 05-CV-440, 2008 WL 820192, at *2 (N.D.N.Y. Mar. 26, 2008). The district court has yet to rule on the defendant's motion for summary judgment asserting that the plaintiff's claim is preempted.

Therefore, in sum, of the fifteen state court judges appointed or elected as Democrats who decided a preemption case, two found “no preemption.” Of the 19 Republican state court judges, three found “no preemption.” Of the nine state court judges marked as non-partisan, one found “no preemption.” Overall, 37 judges marked as “Democratic” found “no preemption” 11 times, 29.7% of the sample. 52 “Republican” judges found “no preemption” 7 times, 13.5% of the time. The other 16 judges, marked as non-partisan or with unclear partisan affiliations, including federal magistrate and state judges, found “no preemption” twice.

3. RESIDENCE OF LITIGANTS

In the 75 cases examined, the plaintiffs were clearly residents of the state the court sat in 50 times. In those 50 cases, judges found that 14 claims survived, 28.0%.⁷⁸ Two of the 13 cases where the plaintiff was clearly not a resident found a surviving claim, 15.4%. Ten cases are unclear about the residence of the plaintiff, and each resulted in preemption. One case in federal court was a “mass action” product liability action,⁷⁹ and two were appeals,⁸⁰ making plaintiffs’ residence less relevant.

Of the 21 cases decided by state judges, the plaintiff was not a resident in three. One did not result in preemption. Seven cases are unclear about the residence of the plaintiffs, and all found preemption. In the 11 cases where the plaintiff was clearly a resident, judges found “no preemption” three times. Of the 48 relevant cases decided by Article III district judges, nine were decided where the plaintiff was not a resident of the state, and eight of those resulted in “preemption.” No judge where the residency of the plaintiff was unclear found “no preemption,” while 10 of the 36 federal judges hearing cases with local plaintiff found “no preemption,” 27.8% of the sample.

⁷⁸ There is no publicly available information about the residence of the plaintiff in three of the cases. However, I have compiled information that strongly suggests that the litigants were residents of the state wherein the court sat.

⁷⁹ *Adams v. I-Flow Corp.*, No. CV09-09550, 2010 WL 1339948, at *1 (C.D. Cal. Mar. 30, 2010).

⁸⁰ *Howard v. Sulzer Orthopedics, Inc.*, No. 09-3406, 2010 WL 2545586, at *5 (6th Cir. June 16, 2010); *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir. 2010)

For simplicity I determine that a defendant manufacturer is a resident of any state when the defendant or its parent has an office in the state.⁸¹ In 45 cases in the sample, the defendant does not have an office in the state the court sits. The judges found “no preemption” in 10 of those, 23.8%. In the remaining 28 cases⁸² where defendants have an office in-state, judges found “no preemption” six times, 21.4% of the cases.

In 11 of the 21 state cases, defendants have an office in-state. Two of those cases, find “no preemption.” In the ten other state cases where defendants do not have an office in-state, two judges found “no preemption.” 32 of the 49 relevant federal cases were decided with out of-state defendants, and judges found that preemption did not exist in 21.8%, seven of the cases. In the remaining 17 federal cases with in-state defendants, judges found “no preemption” four times, 23.5%.

There are 43 cases where one litigant resides in-state and the other out of state. The judge ruled in favor of the in-state litigant in 16 of those cases, 37.2%. Ten were decided in state court, with four finding in favor of the in-state litigant. Thirty were decided by Article III judges, who ruled in favor of the in-state litigant 11 times, 36.7%.

4. RACE AND GENDER

American courts are not particularly diverse. Thirty-six minority or female judges heard the question in the sample.⁸³ Five found “no preemption,” 13.9%. 15 of the 69 white male judges found “no preemption,” 21.7%.

⁸¹ I presume that the incentives on the judge to favor the hometown defendant holds true whenever local citizens have an economic interest in the corporation, which would hold true for satellite offices as well as manufacturers incorporated or with their principle place of business in-state.

⁸² Excluding the cases decided in the federal courts of appeal.

⁸³ Given the small representation in the sample, I decided to combine minority and female judges in this independent variable, since both function as minority groups on the federal bench.

E. Analysis of the data

In this section, I compare the data with earlier hypotheses, and engage with normative theories to try to explain the results. Since there have only been 75 cases since *Riegel*, these conclusions will be somewhat speculative. The small sample sizes, and need to divide the sample using the independent variables, mean that small changes can dramatically alter the conclusions. Nonetheless, it is helpful to reflect upon the data as it comes, since litigation strategies and descriptions of states of the law are shaped by recent developments, and often depend upon small sample sizes.

1. DISPARITY

I hypothesized that there would be a clear disparity between state and federal courts, because of the powerful federalism ramifications of the *Riegel* decision.⁸⁴ Instead, there is broad parity between state and federal courts on preemption and parallel claims, with in fact more state judges finding preemption than federal judges. I believe there are two main explanations for this parity. First, the theory that disparity exists remains highly controversial from both an empirical and normative perspective.⁸⁵ Some empirical research supports the contention that the two systems are in parity, but those studies may be irretrievably flawed.⁸⁶ Parity may exist because state courts almost always mimic federal courts.⁸⁷ Another explanation is that the exception created by the “parallel” requirements language of *Riegel* is so narrow that lower courts have very little discretion and will closely follow the commands of the Supreme Court in interpreting medical device claims.

2. POLITICAL PARTY

The data here shows that political party correlates closely with preemption. Federal judges exhibited the greatest disparity, with

⁸⁴ *Despain v. Bradburn*, 282 S.W.3d 814, 816–17 (Ark. 2008).

⁸⁵ See Chemerinsky, *supra* note 71.

⁸⁶ See *id.* at 262–64 for an examination of the flaws in a highly cited study (Michael E. Solimine & James L. Walker, *Constitutional Litigation in Federal and State Courts: An Empirical Analysis of Judicial Parity*, 10 HASTINGS CONST. L.Q. 213 (1983)).

⁸⁷ *But see* Hylton, *supra* note 3, at 229.

Democratic-appointed judges more than 3 times as likely to find “no preemption” as Republican-appointed judges. The data is somewhat less clear with respect to state judges. Looking at all the data, which may moot imperfections within the sample, “Democratic” judges were more than twice as likely to find “no preemption” than “Republican” judges. This conforms to my hypothesis, and is consistent with sophisticated empirical research about ideology and preemption decisions.⁸⁸

3. RESIDENCE OF LITIGANTS

The data suggests that litigants are better off when the case is decided in the state where they reside or have an office. When the plaintiff sues in a different state than their residence, they won just a single time. Plaintiffs won 27.2% of the cases where they sued in their home state court. Article III judges were far more likely to find a claim to be parallel when the plaintiff was a resident: the likelihood of winning moved from 11% to nearly 28%. Defendants on the other hand saw basic parity, regardless of whether they had a branch in the state of decision. In state court, defendants faced approximately the same chances, falling from 22.2% to 20% if they had a branch in-state. In federal court, defendants' chances were also not materially affected by residence.

4. RACE AND GENDER

The data suggests that minority and female judges are less likely to find preemption, though the sample size for minority judging is quite small.

IV. A GUIDE TO POTENTIAL ISSUES IN LITIGATION: THE SUBSTANTIVE SCOPE OF PARALLEL CLAIMS AND THE ROLE OF FORUM SHOPPING

This section analyzes the substance of parallel claims and discusses some issues of federal-state forum shopping in medical device litigation. The three main types of parallel claims are described

⁸⁸ See, e.g., David B. Spence & Paula Murray, *The Law, Economics, and Politics of Federal Preemption Jurisprudence: A Quantitative Analysis*, 87 CAL L. REV. 1125, 1130 (1999) (finding some role for ideology in the preemption decisions examined).

in close detail. I also offer some examples of attempted forum shopping and one important development increasing the stakes for forum selection.

A. *The Scope of Parallel Claims*

Seventeen cases in the empirical dataset compiled found at least part of the plaintiffs' claims to survive.⁸⁹ The judicial reasoning varies greatly among these cases. The cases that include detailed legal reasoning generally allow three types of claims to move forward: complaints arising from injuries suffered because of a design change without FDA approval; claims that the manufacturer made express warranties to the consumer; and claims of manufacturing defect. Other courts, however, have explicitly rejected the reasoning behind each of these claims. Additionally, many potentially successful parallel claims are dismissed as insufficiently pled at the complaint stage.

One court has held that plaintiffs can recover when injured by a device that the manufacturer changed without FDA approval. The decision in *Riegel* explicitly denoted that where a state law claim merely "parallels" a federal requirement, it is not "different from, or in addition to" the federal law, and is not preempted.⁹⁰ This requires that plaintiffs allege that the state tort law under which they sue imposes no additional requirements on manufacturers, and is solely predicated upon a violation of relevant FDA regulations or statutory law.⁹¹ The Medical Device Amendments ("MDA") bar any changes to medical devices after the FDA approves the design,

⁸⁹ As mentioned earlier, I coded any cases which do not preempt or dismiss all claims as "non-preemption." Any claim that proceeds gives the litigants an opportunity to settle, and the plaintiff the chance to recover some money. The medical device industry is highly competitive, and manufacturers guard trade secrets closely. That increases the incentives for the defendants in the sample to settle cases rather than proceed with discovery. *See, e.g.,* *Cordis Corp. v. O'Shea*, 988 So. 2d 1163 (Fla. Dist. Ct. App. 2008) (determining the scope of discovery amid defendant's concerns about trade secrets after the rejection of a motion to dismiss). Some defendants have settled claims rather than pay continuing litigation fees. *See* *Stipulation and Order of Dismissal*, *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009) (No. 1:08-CV-0855-SEB-TAB).

⁹⁰ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (citing 21 U.S.C.A. § 360k(a)(1) (2008)).

⁹¹ *Riegel*, 552 U.S. at 330.

unless the manufacturer confers with the FDA regarding the alterations.⁹² If plaintiffs sufficiently plead that the device which injured them was adulterated without approval, one court has allowed a tort claim to proceed.⁹³ These claims may differ from the FDA regulations, but are parallel so long as they do not “impose requirements different from those arising under federal law.”⁹⁴ This is an infrequent factual occurrence,⁹⁵ and provides little relief for later plaintiffs. Other courts have explicitly rejected this claim.⁹⁶

A larger number of cases have allowed claims alleging violation of express warranties to move forward. The Supreme Court did not answer this question in *Riegel* since it was not properly appealed.⁹⁷ Some lower courts allow express warranty claims since they are predicated on the idea that “the device [at issue] should fit the description on [the FDA approved] label.”⁹⁸ Warranty theories of recovery are contractual, not tortious, and focus upon communications between the consumer and manufacturer.⁹⁹ A jury finding that the manufacturer violated an express warranty would not find that the product was “unsafe” according to state law, but would find that the product did not conform to the manufacturer’s representations.¹⁰⁰ If the manufacturer made any statements not

⁹² 21 U.S.C. § 351(f) (2006).

⁹³ *Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-1777-M, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008) (decided by a federal judge appointed by then-President Clinton).

⁹⁴ *Id.* at *3.

⁹⁵ No other plaintiff has successfully alleged such facts since *Riegel*.

⁹⁶ See *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (holding that the MDA does not allow any private right of action to enforce FDA regulations); see also Mark Herrmann et al., *The Meaning of the Parallel Requirements Exception under Lohr and Riegel*, 65 N.Y.U. ANN. SURV. AM. L. 545, 563-65 (2010) (reiterating that the MDA does not create a private right of action for enforcement). But see *infra* Section V (arguing that such claims should not be implicitly preempted without further Congressional intent).

⁹⁷ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 n.2 (2008).

⁹⁸ *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 839 (S.D. Ind. 2009).

⁹⁹ *O’Shea v. Cordis Corp.*, No. 50 2006 CA 013019 AA, 2008 WL 3139428, at *4 (Fla. Cir. Ct. May 19, 2008) (citing *Mitchell v. Collagen Corp.*, 126 F.3d 902, 916 (7th Cir. 1997)).

¹⁰⁰ See *Huber v. Howmedica Osteonics Corp.*, No. 07-2400, 2008 WL 5451072, at *3 (D.N.J. Dec. 31, 2008) (holding *Michael v. Shiley*, 46 F.3d 1316 (3d Cir. 1995) to be binding in the Third Circuit, despite noting that other courts found the same claims

authorized by the FDA, plaintiffs can argue that the product did not live up to the manufacturer's representations.¹⁰¹ Other courts have rejected the express warranty theory, determining that violation of a warranty requires that the product be deemed unsafe under state law, and any such finding conflicted with the FDA's conclusion that the device was "safe" for sale on the market.¹⁰²

The broadest claim some courts have found not to be preempted after *Riegel* involve injuries arising from manufacturing defect.¹⁰³ Plaintiffs assert that the device used in their medical procedure was defective in failing to meet the standards crafted by the manufacturer and approved by the FDA.¹⁰⁴ Courts that allow the claim determine that the device at issue was not manufactured in conformance with the FDA's Current Good Manufacturing Practice and Quality System Regulation.¹⁰⁵ State law claims that award monetary relief can then succeed, since they are predicated only on a violation of an FDA regulation.¹⁰⁶ These manufacturing claims provide

preempted after *Riegel*); *O'Shea v. Cordis Corp.*, No. 50 2006 CA 013019 AA, 2008 WL 3139428, at *3 (Fla. Cir. Ct. May 19, 2008).

¹⁰¹ *Cornett v. Johnson & Johnson*, 414 N.J. Super. 365, 404 (App. Div. 2010).

¹⁰² *See, e.g., Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1304 (D. Colo. 2008) (arguing that since the FDA evaluates safety with respect to the labeling, express warranty based on the representations made by the label "would contradict the FDA's determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements."); *Miller v. DePuy Spine, Inc.*, 638 F. Supp. 2d 1226, 1230 (D. Nev. 2009); *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1164 (D. Minn. 2009) (citing *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006)).

¹⁰³ I use the term "arising from" because the *Hofts* case, while examining the defective manufacture of a specific product, uses the language of a negligence claim, looking at "unreasonable[ness]" and "duty of care." I interpret this as allowing liability for negligence per se claims predicated on deviations from the manufacturing requirements created by the FDA. *Hofts*, 597 F. Supp. 2d at 836-38. (S.D. Ind. 2009).

¹⁰⁴ The methods by which a medical device is manufactured are also closely regulated by the FDA. 21 C.F.R. § 820.1(a)(1) (2010). The plaintiffs will allege that the device was not manufactured in conformance with those methods. *See, e.g., Complaint* at 17, *Hofts*, 597 F. Supp. 2d 830 (No. 1:08-CV-0855-DFH-TAB).

¹⁰⁵ 21 C.F.R. § 820 (2010). For more information on the legislative history of the CGMP, see 61 Fed. Reg. 52, 602, 52,603 (Oct. 7, 1996).

¹⁰⁶ *See, e.g., Hofts*, 597 F. Supp. 2d at 836-37 ("Similarly, on *Hofts*' strict liability claim, a jury could find that Howmedica's deviation from the FDA's manufacturing requirements was unreasonably dangerous without imposing different or additional requirements."); *O'Shea v. Cordis Corp.*, No. 50 2006 CA 013019 AA, 2008 WL

the largest number of unpreempted parallel cases.¹⁰⁷ The first federal court of appeals to rule on this question agreed that manufacturing defects were not preempted by *Riegel*.¹⁰⁸

Other courts have rejected this interpretation by dismissing these claims. Those courts argue that the FDA Current Good Manufacturing Practice and Quality System Regulations are too flexible and general to provide requirements of law that could be violated.¹⁰⁹ The regulations are so general that any jury finding against the defendant would be interpreting the federal “umbrella quality system”¹¹⁰ and implicitly crafting specific requirements for the manufacturer. That jury verdict would create a requirement not present in federal law, meaning it was “additional” and barred by *Riegel*.¹¹¹ This reliance on general FDA requirements also led the

3139428, at *3 (Fla. Cir. Ct. May 19, 2008) (“Plaintiff alleges specific failures to comply with ‘Current Good Manufacturing Standards’ in the production of the Coronary Stents. Such claims parallel federal requirements and assert a deviation from specific FDA guidelines. These claims, therefore, are not preempted”); *Cornett*, 414 N.J. Super. at 398 (“A state claim with [the effect of vindicating FDA regulations] is therefore parallel under *Riegel*’s construction of *Lohr* and not preempted.”).

¹⁰⁷ See *Prudhel v. Endologix, Inc.*, No. CIV. S-09-0661, 2009 WL 2045559, at *8 (E.D. Cal. July 9, 2009) (allowing the claim to move forward because the plaintiff’s “manufacturing defect claim alleges that the manufacturing was not in compliance with the requirements imposed by 21 C.F.R. § 820, resulting in a defect”); *Shertzer v. Howmedica Osteonics Corp.*, No. 1:08-cv-0856, 2009 WL 535997, at *1 (S.D. Ind. Mar. 3, 2009) (citing *Hofts*, decided by the same judge on the same reasoning); *Means v. Howmedica Osteonics Corp.*, No. 1:08-cv-0334, 2009 WL 347407, at *1 (S.D. Ind. Feb. 11, 2009) (citing *Hofts*, decided by the same judge, on the same day, with the same reasoning); *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 801 (W.D. La. 2008) (maintaining a non-preempted claim since “one can infer that [plaintiff] intends to adduce evidence that the problem with the [device at issue] . . . was that the anchor of the [device] used in her procedure did not deploy properly . . . due to its not being packaged and/or manufactured in accordance with FDA specifications”); *Mitaro v. Medtronic, Inc.*, 886 N.Y.S.2d 71 (N.Y. Sup. Ct. 2009) (allowing a manufacturing defect claim to continue because plaintiff alleged “that the facilities and controls used by Medtronic in the manufacture of the leads are not in conformity with the applicable federal requirements”).

¹⁰⁸ *Howard v. Sulzer Orthopedics, Inc.*, No. 09-3406, 2010 WL 2545586, at *5 (6th Cir. June 16, 2010) (determining that the FDA’s Good Manufacturing Practice created an actual duty which manufacturers must conform to, making a manufacturing defect claim parallel to that duty).

¹⁰⁹ *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009).

¹¹⁰ *Id.* at 1157.

¹¹¹ *Id.* at 1156.

Eight Circuit federal Court of Appeals to uphold a finding of preemption.¹¹²

Finally, even where plaintiffs have a cognizable parallel claim, they may not be able to recover because they did not provide sufficient factual material to survive a motion to dismiss. The Supreme Court clarified the standard for pleading the year before *Riegel* was decided, in *Bell Atlantic v. Twombly*.¹¹³ Federal courts must now determine whether a complaint alleges a plausible claim for relief.¹¹⁴ In the medical device context, plaintiffs cannot simply recite the legal standard for a parallel claim or assert conclusory allegations, but must include specific facts supporting their complaint that provide the “‘grounds’ on which the claim rests.”¹¹⁵ One judge dismissed plaintiff’s failure to warn and defective design claims with prejudice on preemption grounds,¹¹⁶ and determined that any remaining claims were insufficiently pled, since “mere promises of future factual allegations are not sufficient to meet [the *Twombly*] standard.”¹¹⁷ That court strongly disagreed with a judge who had rejected the dismissal of a complaint with similar factual allegations,¹¹⁸ replying that “on the contrary, requiring amplification as to how the defendants’ alleged federal violations relate to the plaintiff’s claims is exactly what *Twombly* contemplates, especially where such a connection is implausible.”¹¹⁹ A judge in New Jersey federal district court also applied *Twombly* to dismiss as insufficiently pled an express warranty claim, which is not preempted in the Third

¹¹² *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1208 (8th Cir. 2010), *aff’d* 592 F. Supp. 2d 1147 (D. Minn. 2009).

¹¹³ 550 U.S. 544 (2007).

¹¹⁴ *Id.* at 557; *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009).

¹¹⁵ *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1299 n.1 (D. Colo. 2008) (citing *Robbins v. Oklahoma*, 519 F.3d 1242, 1247–48 (10th Cir. 2008)).

¹¹⁶ No court in the sample allowed such a defective design claim to move forward, since such a claim would “challenge[] the FDA’s findings concerning the safety of the Trident System’s design.” *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009).

¹¹⁷ *Id.* at 280.

¹¹⁸ See *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 838 (S.D. Ind. 2009) (holding that dismissal would be an “unusually stringent application of *Twombly*”).

¹¹⁹ See *Horowitz*, 613 F. Supp. 2d at 283 n.5.

Circuit.¹²⁰ The Eighth Circuit concurred in affirming a lower court dismissal because *Twombly* required further facts than the plaintiff had shown to allege a manufacturing defect.¹²¹

B. The Extent and Implications of Forum Shopping

The data analyzed here and previous empirical studies suggest that judges deciding preemption cases are influenced by extralegal factors like the court they sit on, their ideology, and the residence of the litigants. This creates powerful incentives for plaintiffs and defendants to seek judges predisposed towards their argument. Some of the cases in the dataset show strategic forum selection. The Supreme Court's opinions in *Twombly* and *Iqbal* may have increased forum shopping, since they highlight a disparity in applicable law between many states and the federal system.

Litigants seek advantages in the courtroom, including through steering the matter to judges or courts more favorable to their interests. A number of the cases demonstrate obvious forum selection tactics.¹²² For example, a number of the cases were originally filed in state court, with defendants filing removal motions to move the cases to federal court suggesting that the defendants believed the federal system was more favorable.¹²³ Indeed, in one case the parties spent five months and submitted four motions debating whether the plaintiff had "fraudulently joined" one defendant for

¹²⁰ *Delaney v. Stryker Orthopaedics*, No.08-03210, 2009 WL 564243, at *5 (D.N.J. Mar. 5, 2009). See *supra* note 100 for *Huber*, which allowed a well-pled express warranty complaint to move forward.

¹²¹ *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1208 (8th Cir. 2010), *aff'g* 592 F. Supp. 2d 1147 (D. Minn. 2009).

¹²² The empirical data does not show a significant disparity between state and federal courts, but forum shopping will exist whenever the parties *believe* that state and federal courts will come to different outcomes.

¹²³ See, e.g., Complaint at ¶¶ 55, 56, *Hofts*, 597 F. Supp. 2d 830 (S.D. Ind. 2009) (No. 1:08-cv-0855) (the Westlaw citation shows that the case was originally filed in Marion County Courts of Indiana); Amended Complaint, *Dorsey v. Allergan, Inc.*, No. 3:08-0731 (M.D. Tenn. Mar. 11, 2009) (No. 2008-CV-560) (the Westlaw citation shows that the case was originally filed in Circuit Court in Tennessee); Notice of Removal, *Link v. Zimmer Holdings, Inc.*, 604 F. Supp. 2d 1174 (N.D. Ill. 2008) (No. 06-C-05438).

the sole purpose of breaking complete diversity and keeping the case in state court.¹²⁴

Similar inefficiencies are more likely because of *Twombly*, since federal courts have dismissed many potentially parallel claims as insufficiently pled under the new pleading rules. Many states continue to apply the less stringent “notice” pleading standard, meaning complaints are less likely to be dismissed in state court. Plaintiffs have great incentives to keep the case in state court, where they have a better chance of surviving a motion to dismiss. For example, a judge on the New York State Supreme Court found that a complaint without “specific” information was still sufficient under New York’s pleading standard.¹²⁵ Nearly identical complaints were repeatedly rejected in federal court as lacking the necessary facts to demonstrate plausibility.¹²⁶ This disparate treatment of similar complaint based solely on the court where it is heard raises serious fairness questions¹²⁷ and increases the likelihood of wasteful forum selection strategies.

V. LIMITS ON IMPLIED PREEMPTION OF PARALLEL CLAIMS

The scope of “parallel” claims after *Riegel* is therefore somewhat unclear and disputed. While most courts have refused to allow allegedly parallel causes of action to proceed, some have authorized further litigation. In a recent journal article, three medical tort practitioners, Mark Herrmann, David Booth Alden and Bradley W. Harrison, argue that courts should close the door on nearly every tort

¹²⁴ Notice of Removal, *Williams v. Endologix*, No. 08-CI-00918 (Ky. Cir. Ct. Oct. 29, 2009); Motion for Remand to Pike Circuit Court, *Williams v. Endologix*, No. 7:08-cv-00157 (E.D. Ky. Sept. 2, 2008); Boston Scientific Corp.’s Opposition to Plaintiff’s Motion to Remand, *Williams v. Endologix*, No. 7:08-cv-00157 (E.D. Ky. Oct. 21, 2008); Reply to Opposition to Motion to Remand, *Williams v. Endologix*, No. 7:08-cv-00157 (E.D. Ky. Nov. 20, 2008).

¹²⁵ *Mitaro v. Medtronic, Inc.*, 2009 WL 1272398, at *4 (N.Y. Sup. Ct. Apr. 9, 2009) (“At this juncture, on a motion to dismiss (as opposed to a motion for summary judgment where the plaintiff has not or cannot identify specific representations which exceed the scope of FDA-approved statements), this claim remains viable.”).

¹²⁶ See, e.g., *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *16 (M.D.N.C. Aug. 5, 2009); *Delaney v. Stryker Orthopaedics*, No. 08-03210, 2009 WL 564243, at ** 5–6 (D.N.J. Mar. 5, 2009); *Heisner v. Genzyme Corp.*, No. 08-C-593, 2008 WL 2940811, at ** 8–9 (N.D. Ill. Jul. 25, 2008).

¹²⁷ See, e.g., *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938).

claim related to premarket approved devices, based upon Supreme Court precedent and policy concerns. Herrmann, Alden and Harrison would limit parallel claims to “include only instances where there is a prior, final determination that a violation [of FDA regulations] actually occurred.”¹²⁸ The authors argue that allowing any other claim allows plaintiffs to litigate whether the manufacturer violated FDA regulations, contrary to the Supreme Court’s determination that the FDCA provides no private right of action,¹²⁹ and therefore implicitly preempted by the Medical Device Amendments.¹³⁰ This argument is wrong, since it is inconsistent with the empirical conclusions presented in this Note, conflicts with language in three relevant Supreme Court decisions through the controversial doctrine of implied preemption, and fails to engage with sophisticated theories of federalism and administrative law. Courts should continue to reject this expansive argument, and permit well-pleaded parallel claims to proceed.¹³¹

The authors of the piece make four assertions in support of their argument. First, they assert that only the federal government can file suit for violations of the MDA, since otherwise the plaintiffs’ suits would “inevitably conflict with the FDA’s responsibility to police manufacturers.”¹³² Second, they argue that private litigants lack the FDA’s expertise in interpreting its own regulations.¹³³

¹²⁸ Herrmann et al., *supra* note 96, at 569.

¹²⁹ See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352 (2001) (holding that 21 U.S.C. § 337(a) bars private enforcement of the MDA).

¹³⁰ Herrmann et al., *supra* note 96, at 569. This argument echoes that of the federal district court in Minnesota. See *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1161-64 (D. Minn. 2009) (determining that “when Sections 337(a) and 360k(a)—as construed in *Buckman* and *Riegel*, respectively—are read together, nearly all types of claims concerning FDA-approved medical devices are preempted”).

¹³¹ If the Supreme Court were to agree with the authors, and foreclose nearly all medical device claims, Congress should make clear that there is no implicit preemption through a statutory override. Congressional legislation to override *Riegel* itself has stalled in committee since 2008, despite re-submission in the 111th Congress last year. See Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (2009); Medical Device Safety Act of 2009, S. 540, 111th Cong. (2009). A statute which protected the right of plaintiffs to bring parallel suits would provide narrower relief than a complete override of *Riegel*, and may therefore have a better chance of passage.

¹³² Herrmann et al., *supra* note 96, at 567.

¹³³ *Id.*

Third, juries are biased against manufacturers, and see only the injuries suffered by the plaintiff, without weighing the positive benefits created by the medical device.¹³⁴ Finally, the authors argue that jury verdicts may be inconsistent with each other, and will create uncertainty through a patchwork of different regulation across the United States.¹³⁵

These arguments are not sufficient to dismiss almost all litigation involving FDA premarket approved medical devices. First, the data in this article suggests that state courts are generally trustworthy in carefully applying preemption, and dismiss claims at similar rates as federal courts.¹³⁶ That consistency rebuts the concern¹³⁷ that state courts will create disparity and uncertainty throughout the United States.¹³⁸ It also demonstrates that state courts take preemption quite seriously, and will not simply disregard Supreme Court precedent to protect local interest groups. That undermines the assertion that further federal preemption is needed to successfully constrain state courts.

Second, the article would greatly narrow dicta the Supreme Court has referenced in three separate cases,¹³⁹ using the non-textual and controversial theory of implied preemption. The Court's recent opinions regarding implied preemption have sparked a backlash among federal judges and legal scholars. Implied preemption raises serious theoretical concerns, since the Court must evaluate

¹³⁴ *Id.* at 568.

¹³⁵ *Id.* at 569.

¹³⁶ This is particularly potent in a common law area like torts, since state courts are free to develop the law to avoid any conflict with *Riegel*. The fact that state judges have not done so belies the distrust the authors have in state courts.

¹³⁷ Herrmann, et. al, *supra* note 96, at 569. While the authors focus on jury verdicts, the extent of a parallel claim is a pure question of law, and should only be interpreted by a state judge.

¹³⁸ I discuss this issue in greater detail *infra* pp. 38–40.

¹³⁹ *Riegel v. Medtronic*, 552 U.S. 312, 330 (2008) (“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.”); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353 (2001) (“*Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements”); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (“Nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.”).

“the purpose of Congress,”¹⁴⁰ absent any clear textual command. A number of scholars believe that courts are not empowered with such an institutional role.¹⁴¹ Justice Thomas wrote a strongly worded concurrence in a preemption case the year following *Riegel* which warned against the growing use of implied preemption to “invalidate[] state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law.”¹⁴² Other federal judges have begun to question some of the assumptions¹⁴³ behind the theory of implied preemption.¹⁴⁴ Some legal commentators have noted decreased use of implied preemption,¹⁴⁵

¹⁴⁰ *Lohr*, 518 U.S. at 485 (stating that purpose is the “touchstone in every preemption case”).

¹⁴¹ Professor Thomas Merrill, for example, would define that activity as “common law,” and therefore presumptively illegitimate. Thomas W. Merrill, *The Common Law Powers of the Federal Courts*, 52 U. CHI. L. REV. 1, 5 (1985) (defining federal common law as “any federal rule of decision that is not mandated on the face of some authoritative federal text—whether or not that rule can be described as the product of ‘interpretation’ in either a conventional or an unconventional sense.”). See also Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 NW. U. L. REV. 695, 707 (2008) (“the default legislative expectation ... is no preemption. That same assumption should carry over to the agency setting: if Congress does not intend preemption, Congress should be held not to intend agency preemption.”); Nelson, *supra* note 17, at 277 (when engaging in its implied preemption analysis “the Court appears to be conducting an exercise in ‘imaginative reconstruction’”); Easterbrook, *supra* note 12, at 539 (“[T]he court has no authority to [help litigants fill in legislative blanks].”).

¹⁴² *Wyeth v. Levine*, 129 S. Ct. 1187, 1205 (2009) (Thomas, J., concurring).

¹⁴³ The most important assumption is that some “intent” or “purpose” of Congress can ever be determined absent a textual requirement. Since implied preemption suggests or requires that the court look to legislative history and purpose, and since that text does not expressly compel preemption, judges will have strong incentives to warp legislative history to their political vision of the case before them. Patricia M. Wald, *Some Observations on the use of Legislative History in the 1981 Supreme Court Term*, 68 IOWA L. REV. 195, 214 (1983) (“It sometimes seems that citing legislative history is still, as my late colleague Harold Leventhal once observed, akin to ‘looking over a crowd and picking out your friends.’”).

¹⁴⁴ See, e.g., *City of Joliet, Ill. v. New West, L.P.*, 562 F.3d 830, 835, 837 (7th Cir. 2009) (discussing the majority opinion and Justice Thomas’ concurrence in *Wyeth*, as well as arguing that *Wyeth* reiterated that “a conflict between a local law and legislative aspirations does not displace another jurisdiction’s law”); *Begay v. Pub. Serv. Co. N.M.*, 710 F. Supp. 2d 1161, 1193–94 (looking closely to Justice Thomas’ concurrence as evidence of the current status of implied preemption at the Supreme Court).

¹⁴⁵ Though both present only anecdotal evidence, two practitioners with experience in the preemption area have argued that judges are looking more skeptically on

while others have expanded their criticism of the doctrine.¹⁴⁶ From a purely realist perspective, two active and one retired Supreme Court Justices have stated their disagreements with some element of the causal chain crafted in Herrmann, Alden, and Harrison's argument.¹⁴⁷ With a weakening doctrinal framework, and with little empirical demonstration that state courts need to be further restrained, the Supreme Court or another appellate court should not agree to implicitly preempt nearly all remaining device tort claims.

The authors' third argument, that juries will be biased in favor of local plaintiffs, fails to address the problem of regulatory capture. Medical device regulation is an area particularly prone to capture.¹⁴⁸ There is recent evidence that the FDA in fact has been captured by industry, and more generally, that regulators have failed

claims of implied preemption. See Allison M. Zieve, *Thoughts on the Rise and Decline of the Implied Preemption Theory for State Law Damages Claims*, 65 N.Y.U. ANN. SURV. AM. L. 661, 676 (2010); David Walk, *The Pendulum Swings too Far against Preemption*, DRUG AND DEVICE L. BLOG, (June 1, 2010, 14:37 EST), <http://druganddevicelaw.blogspot.com/2010/06/pendulum-swings-too-far-against.html> (decrying the "overreact[ion]" to *Wyeth* by the lower courts and their newly found anti-implied preemption stance).

¹⁴⁶ See, e.g., Kevin O. Leske & Dan Schweitzer, *Frustrated with Preemption: Why Courts Should Rarely Displace State Law Under the Doctrine of Frustration Preemption*, 65 N.Y.U. ANN. SURV. AM. L. 585 (2010) (criticizing implied preemption on separation of powers and federalism grounds); Robert S. Peck, *A Separation-of-Powers Defense of the "Presumption against Preemption"*, 84 TUL. L. REV. 1185, 1192 (2010) (describing a "deepening academic criticism of the Court's approach to implied preemption"). But see *Wyeth*, 129 S. Ct. at 1217 (Alito, J., dissenting) (defending implied preemption on both stare decisis and doctrinal grounds); Alan Untereiner, *The Defense of Preemption: A View from the Trenches*, 84 TUL. L. REV. 1257, 1263 (2010) (defending the value of implied preemption).

¹⁴⁷ See *supra* text accompanying note 142; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 333-45 (2008) (Ginsburg, J., dissenting); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353-55 (2001) (Stevens, J., concurring) (disagreeing with the broad reading of implied preemption in the Court's holding).

¹⁴⁸ In the famed model created by James Q. Wilson, medical device regulation fits best as a form of "client politics," where the beneficiaries of a lax regulatory system are a narrow, concentrated band of individuals with large incentives to organize. The costs of lax regulation or enforcement fall broadly upon the general public in the form of serious injuries. See JAMES Q. WILSON, *THE POLITICS OF REGULATION* 369 (1980). The complicated scientific data needed to assess medical device safety provides additional roadblocks to public engagement and understanding of the issue, making public organizing to protest or end this client politics relationship ever more difficult.

to craft regulations supported by scientific findings.¹⁴⁹ Narrowly defined parallel claims, like those created in the lower courts since *Riegel*, provide private rights of action solely to enforce FDA regulations and carves a middle path between overriding expansive tort liability and immunizing medical device manufacturers. It ensures that even if the FDA enforcement division is captured by manufacturers, enforcement proceedings will continue in trial courts. The data in this Note and the lack of disparity between state and federal findings of preemption suggests that state courts have not been captured by local pro-liability interests, so the threat of capture weighs more heavily against preemption.¹⁵⁰ A novel solution to competing concerns over agency capture lies in Professor Catherine Sharkey's agency reference model, which suggests that courts give agency amicus briefs and other regulatory statements some deference in interpreting the scope of regulations in tort actions.¹⁵¹ In granting some deference¹⁵² to FDA opinions, the courts would assuage Herrmann, Alden and Harrison's concern that litigation will commence without FDA expertise.

The authors' third and fourth arguments are both addressed by the theory of mobility based federalism. Herrmann, Alden and Harrison believe that states and juries see only the injuries caused by

¹⁴⁹ See, e.g., Elizabeth J. Cabraser, *Due Process Preempted: Stealth Preemption as a Consequence of Agency Capture*, 65 N.Y.U. ANN. SURV. AM. L. 449, 460–61 (2010); Gardiner Harris & David M. Halbfinger, *F.D.A. Reveals It Fell to a Push by Lawmakers*, N.Y. TIMES, Sept. 24, 2009, www.nytimes.com/2009/09/25/health/policy/25knee.html; Alicia Mundy & Jared A. Favole, *FDA Scientists Ask Obama to Restructure Drug Agency*, WALL ST. J., Jan. 8, 2009, online.wsj.com/article/SB123142562104564381.html (describing some FDA scientists' concerns that the agency is "fundamentally broken," and specifically mentioning "the agency's scientific review process for medical devices").

¹⁵⁰ Whether state courts or the FDA are captured more by certain interests is an empirical question which can be best addressed with more data. Regardless, it is a question that Herrmann and his coauthors simply ignore. See generally Herrmann et al., *supra* note 96.

¹⁵¹ Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 477 (2008).

¹⁵² Sharkey proposes that courts grant lesser *Skidmore* deference to agency amicus briefs and other documents, which means that the court would look to see if the agency interpretation is thoroughly reasoned, valid, and consistent with other agency interpretations. *Id.* at 491. Those factors will help the court determine whether the agency has been captured, and if not, how much deference to give their opinion.

medical devices, and that different jury verdicts will create a patchwork of standards. These claims reduce to the idea that states which award money damages for breaching FDA requirements inflict negative externalities on other states.¹⁵³ They believe that medical device manufacturers and the FDA provide a national, non-excludable good in high-functioning, regulated medical devices. When states allow damage remedies before the FDA has determined the device violates regulations, they reap the reward of monetary damages to their citizens, while suffering only a small price increase since that change is shared nationally. Juries see the harm the device caused to the plaintiff, and the positive value of granting damages to their neighbors, but see only small decreases in utility for higher prices or less access to devices. Unscrupulous and ignorant jurors who seek to maximize personal and local utility will then consistently rule against device manufacturers.

This description is wrong because manufacturers can and will impose costs on localities with unfavorable tort regimes. Manufacturers can restrict the flow of information and valuable jobs to states and jurisdictions with liberal damages mechanisms to decrease the likelihood that they will be haled into court there.¹⁵⁴ Manufacturers can target advertising,¹⁵⁵ samples and medical information to certain doctors and branch offices, and avoid others.¹⁵⁶ Further, device manufacturers have offices and industrial plants throughout the

¹⁵³ See Herrmann et al., *supra* note 96, at 568 ("Thus, juries may see only the injured plaintiffs before them, not the systemic costs that may result from finding that the FDCA prohibits conduct. For that reason, juries may find violations *based on conduct that the FDA would permit because that conduct is beneficial from a larger societal perspective.*" (emphasis added)).

¹⁵⁴ If a manufacturer gave less information to a state's citizens, they would likely purchase fewer of those devices. It may also decrease the likelihood the state would retain personal jurisdiction over the manufacturer.

¹⁵⁵ The authors believe that advertising to consumers is a socially useful activity. Herrmann, et. al, *supra* note 96, at 568.

¹⁵⁶ See, e.g., Melody Petersen, *Campaign for Medical Device Bypasses Doctors*, N.Y. TIMES, Oct. 30, 2003, www.nytimes.com/2003/10/30/business/the-media-business-advertising-campaign-for-medical-device-bypasses-doctors.html (mentioning efforts by medical device manufacturers to target advertising to certain regions and individuals); Gardiner Harris, *Institute of Medicine Calls for Doctors to Stop Taking Gifts From Drug Makers*, N.Y. TIMES, Apr. 28, 2009, www.nytimes.com/2009/04/29/health/policy/29drug.html (discussing gifts to doctors by drug makers).

nation.¹⁵⁷ They can move offices and plants to more favorable tort regimes. Device manufacturers may already be tailoring information and jobs to avoid states with high damage rules. When companies target advertising, samples, and information to certain regions on the basis of tort law, they remove a benefit from other states, which leads each state to internalize the costs of their tort system.¹⁵⁸ Manufacturers can create costs for states with pro-plaintiff damages rules, which would change the calculus of unscrupulous jurors, making both the costs and benefits of a lax tort system obvious. Rather than creating a worrisome patchwork of laws, continued variation and competition between states for mobile citizens and industry, using public goods like information and tort rules, would likely increase overall national utility.¹⁵⁹ Parallel claims, which allow for variable tort rules, allow mobile actors to “vote with their feet” by moving to their most preferable mixture of tort law and information.¹⁶⁰

Empirical data, Congressional text, doctrine, and policy do not compel broad implied preemption of parallel medical device claims, since state courts are already highly constrained under existing precedent, implied preemption rests on shaky grounds after a recent doctrinal backlash, there is a serious worry of regulatory capture at the FDA, and state variation in tort law increases social welfare through mobility of goods, information, and citizens. Therefore, Herrmann, Alden and Harrison should be unsuccessful in their attempt to convince appellate courts to

¹⁵⁷ See, e.g., *Stryker Locations Around the Globe*, STRYKER, <http://www.stryker.com/en-us/corporate/ContactUs/index.htm> (listing 12 American locations, in 6 different states, of a major device manufacturer); *Locations*, MEDTRONIC, <http://www.medtronic.com/about-medtronic/locations/index.htm> (listing 8 American business units, and 26 key facilities, in 12 states).

¹⁵⁸ While actual differential pricing of medical devices throughout the United States is likely impossible because of the mobility of goods and the internet, targeted advertising and movement of key facilities and jobs can create great expenses on a jurisdiction, which is entirely localized to that region.

¹⁵⁹ See generally Charles Tiebout, *A Pure Theory of Local Expenditures*, 64 J. POL. ECON. 416 (1956); Ken Kollman et al., *Political Institutions and Sorting in a Tiebout Model*, 87 AM. ECON. REV. 977 (1997).

¹⁶⁰ The Tiebout model obviously is a challenge to preemption more broadly, since citizens can also properly sort themselves with respect to all tort rules. Given recent Supreme Court precedent, the broader challenge may be irrelevant. The lessons of Tiebout, though, also serve as a narrower rebuttal to the arguments made by Herrmann and his coauthors.

dismiss most surviving parallel claims under *Riegel*. When a suit alleging manufacturing defect caused by unauthorized changes to the device, express warranty, or a failure to conform with FDA regulations includes sufficient factual detail to meet the jurisdiction's pleading standard, the court should allow the claim to move forward.

VI. CONCLUSION

This Note describes how judges are influenced by structure and politics when deciding which state tort claims related to medical devices survive preemption after *Riegel v. Medtronic*. Despite the limited scope of this research due to sample size, the data suggests that some of the associated factors do influence judicial decision-making, a finding consistent with prior normative and empirical research. Certain types of well-pleaded complaints have survived preemption analysis. These narrow parallel claims are legitimate under existing precedent and correct as a policy matter. As cases are appealed to higher courts, judges and policymakers should take steps to ensure that such claims remain protected.

