PREEMPTION WITHOUT BORDERS: THE MODERN CONFLATION OF TORT AND CONTRACT LIABILITIES

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TABLE OF CONTENTS

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> *"It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."*
>
> Justice Byron White,
> *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)

I. INTRODUCTION

When Joshua Oukrop was a teenager, he suffered a sudden fainting spell and collapsed. His parents took him to the doctor, where they learned that Joshua had inherited a heart condition from his father that caused his heart to occasionally beat irregularly. The doctor recommended that Joshua have a medical device—a cardiac defibrillator—implanted in his chest to detect and correct any abnormalities in his heart rate. Only seventeen years old at the time, Joshua consented to the procedure, and his doctors succeeded in surgically installing the defibrillator. For several years, the device appeared to operate properly and remedied his heart condition. Then one day, while in the midst of a spring break mountain biking trip, Joshua's heart began beating irregularly, causing him to collapse. Moments later, at the age of twenty-one, Joshua Oukrop died. A postmortem examination of his body revealed that Joshua's cardiac defibrillator was defective and that a properly functioning defibrillator would have prevented his death.[1]

The tragic stories of individuals like Joshua Oukrop serve as cautionary tales about modern medical risks, drawing attention to the existence of faulty medical devices and the devastating impacts they can have on the lives of ordinary individuals. Unfortunately, these tragedies are also examples of our legal system failing to provide meaningful redress for individuals who have been harmed by another's wrongful conduct. While consumers were once able to recover damages from the companies

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[1] Kate Scannell, Op-Ed., *Must Consider Burden of Corporate Malfeasance*, CONTRA COSTA TIMES (Walnut Creek, Cal.), Apr. 25, 2010, at 11A; James Walsh, *Cardiologist's Stand for Better Device Safety Spans 40 Years*, STAR TRIB. (Minneapolis) (Apr. 29, 2012), http://www.startribune.com/business/149299585; *When Medical Implants Fail*, CBS NEWS SUNDAY MORNING (Apr. 4, 2012), http://www.cbsnews.com/news/when-medical-imlants-fail/.

that manufactured faulty medical devices,[2] recent judicial decisions have shut the courthouse doors on these individuals.[3] The equitable concerns raised by these decisions are obvious, but no one has recognized the significant way in which these decisions have drastically expanded the scope of regulatory preemption and assaulted fundamental principles of contract law.

This Article develops two novel theses. First, district and appellate courts have construed medical device preemption statutes well beyond their terms and improperly denied individuals the opportunity to pursue valid contractual claims against manufacturers. Second, because these courts have ignored fundamental differences that distinguish tort and contract liability, they have created precedents that undermine foundational contract law principles and threaten the contractual liberties of individuals and states.

Basic federal preemption principles dictate that when a federal law and a state law conflict, the state law is "without effect."[4] Federal preemption occurs either when federal law explicitly states that it was intended to override state law (express preemption) or when continued enforcement of state law would conflict with federal law (implied, obstacle, or impossibility preemption).[5] Whether federal regulatory systems preempt state laws has been one of the most hotly contested legal issues of the

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[2] *See, e.g.*, Christopher Snowbeck, *Guidant Will Pay Fine of $296M: Company Is Guilty of Misleading Federal Regulators*, ST. PAUL PIONEER PRESS, Jan. 13, 2011, at C1 (noting a $240 million settlement secured in 2007 against manufacturer of defective cardiac defibrillators).

[3] *See, e.g.*, *In re* Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1157–66 (D. Minn. 2009) (dismissing all of the plaintiffs' claims against a medical device manufacturer); Heisner v. Genzyme Corp., No. 08-C-593, 2008 WL 2940811, at *9 (N.D. Ill. July 25, 2008) (same); *see also* Malika Kanodia, *The Fate of the Injured Patient in the Wake of* Riegel v. Medtronic: *Should Congress Interject?*, 32 HAMLINE L. REV. 791, 794–95 (2009) (noting that hundreds of suits against manufacturers of medical devices have been dismissed as a result of a Supreme Court holding).

[4] Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992) (quoting Maryland v. Louisiana, 451 U.S. 725, 746 (1981)).

[5] *See* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2485–94 (2013) (Sotomayor, J., dissenting) (rejecting defendants' reliance on impossibility and obstacle preemption); Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 540–53 (2011) (addressing scope of express preemption provision in tobacco legislation); Wyeth v. Levine, 555 U.S. 555, 563–81 (2009) (rejecting defendants' reliance on impossibility and obstacle preemption); Robert J. Blomquist, *Overinterpreting Law*, 116 PENN. ST. L. REV. 1081, 1104–04 (2012) (describing implied preemption as based on conflict between a state law and the policy, legislative history, or congressional purpose of a federal law).

modern era, generating a number of memorable Supreme Court opinions that have split the Justices[6] and inspiring academic commentary in the nation's leading academic publications.[7]

The federal government's decision to actively regulate the medical device market has forced courts to determine whether preemption principles immunize device manufacturers from the common law liabilities that apply to the producers of other commercial goods. Initially, many of the courts that were presented with this issue determined that the federal regulatory system did not preclude individuals from bringing common law claims against manufacturers.[8] In the 1990s and 2000s, however, courts began construing regulatory statutes in ways that expanded their preemptive effects, a trend that culminated in the Supreme Court's decision in *Riegel v. Medtronic, Inc.*[9] Distinguishing earlier precedents, which had found that state law claims against device manufacturers were not preempted, the Court held that the federal regulatory scheme insulated the manufacturers of a subset of Class III devices—the most dangerous category of medical devices—from common law tort liabilities.[10]

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[6] For opinions where the Justices have split, see, for example, *Barlett*, 133 S. Ct. at 2466; *Wyeth*, 555 U.S. at 555; Riegel v. Medtronic, Inc., 552 U.S. 312 (2008); Altria Grp., Inc. v. Good, 555 U.S. 70 (2008); Bates v. Dow Agrosciences L.L.C., 544 U.S. 431 (2005); Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000).

[7] For commentary inspired by the Supreme Court opinions, see, for example, Benjamin I. Sachs, *Despite Preemption: Making Labor Law in Cities and States*, 124 HARV. L. REV. 1153 (2011); Gillian E. Metzger, *Federalism and Federal Agency Reform*, 111 COLUM. L. REV. 1 (2011); Jessica Bulman-Pozen & Heather K. Gerken, *Uncooperative Federalism*, 118 YALE L.J. 1256 (2009); Paul M. Schwartz, *Preemption and Privacy*, 118 YALE L.J. 902 (2009); William W. Buzbee, *Asymmetric Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547 (2007).

[8] *See, e.g.*, Moore v. Kimberly-Clark Corp., 867 F.2d 243, 247 (5th Cir. 1989); Elbert v. Howmedica, Inc., 841 F. Supp. 327, 332 (D. Haw. 1993) (permitting suit against manufacturer of artificial knee); Callan v. G.D. Searle & Co., 709 F. Supp. 662, 667–68 (D. Md. 1989); Mitchell v. Iolab Corp., 700 F. Supp. 877, 879 (E.D. La. 1988); Tetuan v. A.H. Robins Co., 738 P.2d 1210, 1233 (Kan. 1987) (allowing plaintiff to bring action for false labeling under state law).

[9] 522 U.S. 312 (2008); *see* also Marin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C. DAVIS L. REV. 1, 2–5 (2001) (discussing four preemption cases, including two relating to state tort claims, decided by the Court during its 1999–2000 term); Jamelle C. Sharpe, *Legislating Preemption*, 53 WM. & MARY L. REV. 163, 167, 178–79 (2011) (arguing that the Court in *Riegel* adopted a broad reading of a preemption provision and the view that "Congress wanted to prioritize regulatory efficiency concerns over corrective justice concerns and that centralized decision making by the FDA was the appropriate means of addressing those concerns").

[10] *Riegel*, 552 U.S. 312–25 (2008).

While *Riegel* shielded certain device manufacturers from tort liabilities, it did not state whether these companies could be liable to consumers for violating their non-tort obligations to consumers. Following the decision, district and appellate courts have had to determine whether the regulatory scheme preempts individuals' contract and statutory claims. By and large, these courts have adopted expansive views about the scope of federal preemption and have insulated manufacturers from non-tort liabilities. Notably missing in these decisions are discussions of the fundamentally different natures of tort, contract, and statutory liabilities.

While the propriety of the Court's *Riegel* decision has been hotly debated in both academic and mainstream circles,[11] there has been little discussion of the doctrinal expansion that has occurred in the district and appellate courts. Scholars have questioned the validity of the Supreme Court's statutory analysis,[12] argued over the societal impacts that will result from an expansive federal preemption jurisprudence,[13] and speculated about the future

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[11] *See* Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. U. L.J. 453, 453–55 (2011) (addressing the "thousands of patients seriously injured by . . . medical devices" and without remedy as a result of application of the preemption provision of the MDA); Jenéa M. Reed, Note, *In the Shadows of* Lohr*: The Disconnect Within the Supreme Court's Preemption Jurisprudence in Medical Device Liability Cases*, 64 U. MIAMI L. REV. 305, 305–07 (2009) (criticizing preemption jurisprudence as both "unwise and unsupported by the text of the MDA"); Elliot Sheppard Tarloff, Note, *Medical Devices and Preemption: A Defense of Parallel Claims Based on Violations of Non-Device Specific FDA Regulations*, 86 N.Y.U. L. REV. 1196 (2011) (addressing "hurdles of express and implied preemption" facing plaintiffs in a post-*Riegel* world).

[12] *See* David Brennan, *Federal Preemption of All State Law Tort Claims in* Riegel v. Medtronic: *A Need to Undo a Serious Wrong*, 36 W. ST. U. L. REV. 137, 170 (2009); Lisa M. Mottes, Comment, *The Need for Federal Preemption of State Tort Claims in the Context of "New Drugs" and Premarket-Approved Medical Devices*, 41 SETON HALL L. REV. 723, 743–44 (2011) (describing the disparate results reached by the Supreme Court in assessing preemption in *Riegel* and *Wyeth*); Reed, *supra* note 11, at 316–32.

[13] *See* Kanodia, *supra* note 3, at 814–15 (noting that *Riegel* will decrease the amount of lawsuits filed against manufacturers and that "medical tort litigation can lead to substantial negative consequences"); Abigail R. Moncrieff, *The Supreme Court's Assault on Litigation: Why (and How) It Might Be Good for Health Law*, 90 B .U. L. REV. 2323, 2336–37, 2362–72 (2010) (discussing the effect of *Riegel* to shift responsibility of enforcement of quality standards from private individuals to the federal government); Amalea Smirniotopoulos, *Bad Medicine: Prescrption Drugs, Preemption, and the Potential for a No-Fault Fix*, 35 N.Y.U. REV. L. & SOC. CHANGE 793, 796–98 (2011) (cautioning that expanded federal preemption jeopardizes the balance of state tort law and federal regulations and noting that state tort law has "protect[ed] the health and safety of the public" by "compensating for the failures of federal regulations"); Reed, *supra* note 11, at 333–38

evolution of the Court's preemption doctrines.[14] Concern about the detrimental effects that shielding manufacturers might have on the public has not been limited to academic circles. Former Senator Ted Kennedy proposed a bill—the Medical Device Safety Act of 2009—that would have allowed tort suits against device manufacturers, but it died in committee.[15]

This Article approaches the controversies surrounding medical device claim preemption from a novel angle. Rather than recite the now-familiar arguments regarding the merits of the Court's preemption of tort claims, this Article draws attention to the lower court decisions that have expanded the preemptive effect to other types of liability. Not only will it establish that these decisions were wrongly decided, but it will also diagnose the theoretical flaws in these decisions' analyses and expose the danger that these decisions pose to individuals' contractual liberties.

The first three parts of this Article set the stage for these arguments. After Part II describes the history of medical device regulation, Part III outlines the different theoretical bases for holding medical device manufacturers liable for the injuries caused by their products. Part IV provides a detailed review of *Medtronic, Inc. v. Lohr*[16] and *Riegel v. Medtronic, Inc.*,[17] the most recent Supreme Court medical device preemption decisions. Part V establishes the viability of contractual implied warranty claims in two steps. It begins by explaining why the Court's decision in *Riegel* only precludes injured consumers from recovering from device manufacturers via tort-based claims. It then presents three arguments that prove that the federal regulatory scheme should not be interpreted as preempting contract claims. First, regulations promulgated by the federal agency responsible for regulating medical devices indicate that its approval process is not meant to preempt contract-based claims. Second, permitting

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(discussing possible implications of *Riegel* for litigants, medical device manufacturers, physicians, and Congress).

[14] *See* James M. Beck, *Federal Preemption in FDA-Regulated Product-Liability Litigation: Where We Are and Where We Might Be Headed*, 32 HAMLINE L. REV. 657, 678–79 (2009); Christen Linke Young, Comment, *Agency Preemption Inputs in* Riegel v. Medtronic, 118 YALE L.J. POCKET PART 22, 22–26 (2008) (speculating how *Riegel* might impact *Wyeth*, which was then pending argument before the Supreme Court).

[15] S. 540, 111th Cong. (2009); *S. 540 (111th): Medical Device Safety Act of 2009*, GOVTRACK.US, http://www.govtrack.us/congress/bills/111/s540 (last visited May 15, 2014).

[16] 518 U.S. 420 (1996).

[17] 552 U.S. 312 (2008).

contractual claims would be consistent with the Court's broader preemption jurisprudence and would advance the legislative interests that inspired the federal government to regulate medical devices in the first place. Third, holding the sellers of faulty devices liable would allocate the cost of device-related injuries to the parties who have the greatest ability to mitigate the negative impact of losses. The final section of Part V discusses the fundamental differences that distinguish contract and tort liabilities and explains why conflating these claims in the regulatory preemption context poses a threat to important contractual liberties. The Article concludes by discussing an additional type of claim that could provide relief to individuals injured by devices and setting forth some of the broader theoretical implications of the arguments advanced.

II. THE HISTORY OF MEDICAL DEVICE REGULATION IN THE UNITED STATES

The courts were not always so callous to the claims of individuals like Joshua Oukrop. When an individual was injured by a faulty medical device twenty years ago, a court would have been likely to look favorably upon the claims that he (or his estate) brought against the device's manufacturer.[18] Even as late as the mid-2000s, many courts would allow such individuals to use contract and tort claims to obtain recovery.[19] But in 2008, the Supreme Court issued its opinion for *Riegel v. Medtronic, Inc.*,[20] and the outlook for these plaintiffs became quite grim.[21] Things

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[18] *See* Reed, *supra* note 11, at 313–14 (explaining that in 1996 the Supreme Court held that the MDA did not preempt all common-law claims).

[19] *See, e.g.*, *In re* Guidant Corp. Implantable Defibrillators Prods. Liab. Litig., MDL No. 05-1708 (DWF/AJB), 2008 WL 682174, at *3 (D. Minn. Mar. 7, 2008) (discussing the procedural history of a medical device MDL and noting the court's denial of the device manufacturer's requests for summary judgment); Notmeyer v. Stryker Corp., 502 F. Supp. 2d 1051, 1054–60 (N.D. Cal. 2007) (denying a device manufacturer's motion for summary judgment against a consumer's claims); Rattay v. Medtronic, Inc., 482 F. Supp. 2d 746, 763 (N.D. W. Va. 2007) (refusing to grant summary judgment against a consumer's implied warranty claim).

[20] 552 U.S. 312 (2008).

[21] *See In re* Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) ("In the . . . months following *Riegel*, courts across the country have applied Section 360k(a) broadly, preempting all manner of claims . . . ."); Sue Ann Mota, *Federal Preemption After* Medtronic*,* Altria Group*, and* Wyeth, 35 OKLA. CITY U. L. REV.

have only worsened over time, as courts in the majority of jurisdictions have construed *Riegel* liberally and summarily dismissed injured individuals' claims against manufacturers.[22]

Contemporary hostility to these claims can, in part, be understood as the product of a series of legislative and judicial acts. Until the early twentieth century, the law did not differentiate between medical devices and other commercial goods, and it relied on the standard set of tort- and contract-based liabilities to police the behavior of device manufacturers. Devices began to be distinguished from other goods in the 1930s, when the federal government enacted legislation that prohibited the sale of adulterated or misbranded medical devices.[23] The degree to which medical devices constituted a unique category of goods increased in the 1970s, when the federal government drastically expanded its regulation of them.[24] As part of this expansion, the government imposed a slew of new requirements on device manufacturers and prohibited the sale of medical goods that did not comply with federal statutory and regulatory standards.[25]

A brief review of the evolution of medical device regulation provides part of the background necessary to assess the viability of contractual implied warranty claims. Until the middle of the twentieth century, the regulation of medical devices fell within the

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147, 154 (2010) (nothing that all claims in a suit alleging defective defibrillator leads were dismissed in 2009).

[22] *See, e.g.*, Duggan v. Medtronic, Inc., 840 F. Supp. 2d 466, 471–73 (D. Mass. 2012) (holding that premarket approval of device preempted the plaintiffs' state law claims); Llado-Carreno v. Guidant Corp., No. 09-20971-CIV, 2011 WL 6223409 at *4–6 (S.D. Fla. May 16, 2011) (summarizing *Riegel* and dismissing the plaintiff's negligence and strict liability claims); Lewkut v. Stryker Corp, 724 F. Supp. 2d 648, 660 (S.D. Tex. 2010) ("The court recognizes and deeply regrets all that plaintiff has suffered in this case. Were it not faced with such uniform and consistent legal precedent, this Court would have reasoned that those claims should be allowed to proceed. . . .").

[23] Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399 (2012)); *see also* Efthimios Parasidis, *Patients Over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WIS. L. REV. 929, 937–41 (discussing the evolution of statutory authority for post-market review of medical devices).

[24] Medtronic, Inc. v. Lohr, 518 U.S. 470, 476–78 (1996) (detailing the changes stemming from the 1976 Amendment).

[25] Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 360–360n (2012)); *see also Riegel*, 552 U.S. at 341–42 (Ginsberg, J., dissenting) (glossing the impact of Congress's premarket approval requirements for drugs between 1938 and 1976); Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD & DRUG L.J. 511, 512–14 (1988) (providing a detailed break down of the MDA's provisions).

umbrella of public health and safety concerns that the federal government felt were best left to state governments.[26] Given the primitive state of medical goods during this period, there was little need for states to develop laws differentiating them from other commercial goods.[27] Producers of medical goods, like any other commercial entity, had to satisfy the standards set forth in each state's statutes and common law to avoid being held liable to their consumers.[28]

Federal involvement in the regulation of health care goods began with the passage of the Pure Food and Drug Act of 1906.[29] The Act prohibited the interstate transport of food and drugs that had been adulterated or misbranded.[30] The Bureau of Chemistry within the United States Department of Agriculture (USDA) was tasked with enforcing the Act's provisions.[31]

Although nothing in the original act applied to the sale of medical devices (as opposed to consumable products), its scope was expanded in 1938.[32] The post-amendment act—the Food, Drug, and Cosmetic Act (FDCA)—prohibited interstate commerce involving the sale of adulterated or misbranded medical devices but did not authorize the federal government to assert control over the market entry of new medical devices.[33] Several years prior to the amendment's enactment, the federal government reorganized the Bureau of Chemistry of the USDA, transforming its regulatory branch into a separate administrative entity—the Food and Drug

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[26] *See Lohr*, 518 U.S. at 475 (explaining the increasing role of the federal government in this area).

[27] S. REP. NO. 94-33, 2-3 (1975).

[28] *See, e.g.*, Sears, Roebuck & Co. v. Marhenke, 121 F.2d 598, 599–600 (9th Cir. 1941) (applying California law against seller of hot water bag); Harmon v. Plapao Labs., 218 S.W. 701, 701 (Mo. Ct. App. 1920) (applying Missouri law to an action regarding a device for treating hernias).

[29] Ch. 3915, 34 Stat. 768. *See generally* C.C. Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 LAW & CONTEMP. PROBS. 3 (1933) (outlining the early history of food and drug regulation); Wallace F. Janssen, *The Story of the Laws Behind the Labels,* FDA CONSUMER MAG., June 1981, *available at* http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm (same).

[30] § 1, 34 Stat. at 768; *Lohr*, 518 U.S. at 475.

[31] *See* Janssen, *supra* note 29 ("The Bureau of Chemistry enforced the 1906 law until 1927. . . .").

[32] Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399f (2012)).

[33] *Id. See generally* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROBS. 2 (1939) (discussing the history and substance of the FDCA).

Administration.[34] The FDA was responsible for enforcing the 1938 version of the Act.[35] Even though the revised version of the FDCA introduced federal regulatory involvement to medical device markets, the Act's limited scope—the prohibition of adulterated or mislabeled devices—meant that the majority of safety and efficacy issues remained under the purview of state law.[36]

This regime remained largely intact until the 1970s. Toward the end of this period, significant advancements in technology led to an increasing number of complex medical devices becoming available in the market.[37] While the inventions introduced in this period—e.g., pacemakers, kidney dialysis units, and artificial blood vessels—were widely viewed as having the potential to revolutionize medical care, they also raised public concerns about their use.[38] The rapid rate at which these devices were integrated into medical care, the technological complexity of many devices, and well-publicized incidents of patients being injured by malfunctioning devices generated societal anxiety about the dangers posed by these items.[39]

In response to these concerns, a number of state legislatures passed statutes regulating the sale and use of medical devices.[40] In 1975, California enacted the most comprehensive of these regulatory schemes when it passed the Sherman Food, Drug, and Cosmetic Act.[41] The Sherman Act authorized the California State

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[34] Michelle Meadows, *A Century of Ensuring Safe Foods and Cosmetics*, FDA CONSUMER MAG., Jan.–Feb. 2006, *available at* http://www.fda.gov/AboutFDA/WhatWeDo/History/FOrgsHistory/CFSAN/ucm083863.htm.

[35] *See id.* ("[In] 1938 . . . the FDA received authority . . . to issue food standards. . . .").

[36] 52 Stat. at 1040; *see also* Cavers, *supra* note 33, at 23 (discussing the scope of the Act).

[37] *See* S. REP. NO. 94-33, at 5 (1975); Medtronic, Inc. v. Lohr, 518 U.S. 470, 475–76 (1996).

[38] H.R. REP. NO. 94-853, at 5–12 (1976); S. REP. NO. 94-33, at 5.

[39] *See* S. REP. NO. 94-33, at 5 ("Although many lives have been saved or improved by the new discoveries, the potential for harm to consumers has been heightened . . . ."); *Lohr*, 518 U.S. at 475–76 (noting that the MDA was, in part, a response to "mounting consumer and regulatory concern" over potentially dangerous medical technology, such as the infamous Dalkon Shield contraceptive); Bruce Alan Finck, *The Effectiveness of FDA Medical Device Regulation*, 7 U.C. DAVIS L. REV. 293, 297–301 (1974) (discussing changes in the medical device field since 1938 and the judicial seizure of two potentially dangerous medical devices).

[40] Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After* Medtronic, 64 TENN. L. REV. 691, 703 n.66 (1997) (listing the statutes passed by thirteen states).

[41] Sherman Food, Drug and Cosmetic Act, ch. 1573, 1970 Cal. Stat. 3237 (codified as amended at CAL. HEALTH & SAFETY CODE §§ 26000–26851 (West. Supp. 1971)); H.R. Rep. No. 94-853, at 45.

Department of Health to control the sale of new devices within the state and promulgate regulations containing the design, manufacture, and advertising requirements for devices.[42]

The federal government greatly expanded its medical device regulatory system when it passed the Medical Device Amendments of 1976 (MDA).[43] Congress's stated intent for passing the MDA was "to provide for the safety and effectiveness of medical devices intended for human use."[44] The timing of the MDA's enactment indicated that the expansion of the federal government's program was intended to be, at least in part, a response to the proliferation of state regulatory schemes.[45] This conclusion also finds support in the MDA's legislative history and Congress's inclusion of a provision that expressly declared that state regulatory rules that conflicted with the federal scheme were invalid.[46]

Still in effect today, the MDA categorizes all medical devices into one of three regulatory groups. Products posing a low risk of causing illness or injury—for instance, tongue depressors, bandages, and operating tables—are labeled "Class I" devices.[47] Class I devices are subject to minimal regulation.[48] Examples of requirements that the manufacturers of these devices must comply with are regulations that set forth good manufacturing practices, prohibit adulteration and misbranding, and require accurate recordkeeping and registration with the FDA.[49] Products presenting slightly greater risk profiles—for example, portable oxygen tanks, hypodermic needles, and condoms—are considered

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[42] *See* CAL. HEALTH & SAFETY CODE §§ 26600–26692.

[43] Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 360–360n (2012)); *see also* Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008); Adler, *supra* note 25, at 512–14 (providing a detailed-break down of the MDA's provisions).

[44] 90 Stat. at 539.

[45] *Riegel*, 552 U.S. at 315–16.

[46] 21 U.S.C. § 360k (2012); *see also Riegel*, 552 U.S. at 342 (Ginsberg, J., dissenting) (finding support in a House report that "state premarket regulation of medical devices accounts for Congress's inclusion of a preemption clause in the MDA"); Medtronic, Inc. v. Lohr, 518 U.S. 470, 489–91 (1996) (discussing the preemption provision).

[47] Mary Mahon, Note, *Food and Drug Administration—Medical Devices Amendments to the Food, Drug, and Cosmetic Act Gives the FDA the Power to Regulate the Manufacture and Use of Medical Devices Through Recommendations by Expert Panels—21 U.S.C.A. §§ 360c–360j (West Supp. 1977)*, 50 TEMP. L.Q. 1105, 1107 n.14 (1977).

[48] *Lohr*, 518 U.S. at 476–77.

[49] Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 913 n.88 (1995); Mahon, *supra* note 47, at 1007.

Class II devices.[50] Class II devices must comply with all of the requirements that apply to Class I devices and satisfy the performance standard that the FDA has promulgated for the relevant type of device.[51]

The most significant expansion of federal power over the medical device market involved Class III devices. The MDA defines Class III devices as those used "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" and those that "present[ ] a potential unreasonable risk of illness or injury."[52] Pacemakers,[53] metal hip implants,[54] penile implants,[55] contraceptive intrauterine devices,[56] and silicone breast implants[57] are examples of goods that have been classified as Class III devices.[58]

While new Class I or II devices are permitted to enter the market ninety days after the seller has sent the proper notification to the FDA,[59] Class III devices cannot be sold prior to obtaining the FDA's approval.[60] The only exception to this rule is when the MDA grants devices that were legally in commercial distribution prior to the MDA's enactment "preamendment status" and exempts them from the approval requirement.[61] Manufacturers of devices that are ineligible for preamendment status can pursue the FDA's approval through two different avenues. They can put their product through the FDA's premarket approval (PMA) process, or they can demonstrate that the device is "substantially equivalent" to a preamendment device.[62]

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[50] Mahon, *supra* note 47, at 1109 n.21.

[51] *See* 21 U.S.C. § 360c(a)(1)(B) (providing guidelines for classifying medical devices as Class II); Mahon, *supra* note 47, at 1108–09 (discussing requirements placed on Class II devices).

[52] 21 U.S.C. § 360c(a)(1)(C).

[53] 21 C.F.R. § 870.3610 (2013).

[54] *Id.* § 888.3410.

[55] *Id.* § 876.3350.

[56] *Id.* § 884.5360.

[57] *Id.* § 878.3530.

[58] *See* Mahon, *supra* note 47, at 1110 n.34 (listing other Class III devices).

[59] *See* 21 U.S.C. § 360k (2012) (reporting requirement).

[60] *Id.* § 360c(a)(1)(C); *see also* Riegel v. Medtronic, Inc., 552 U.S. 312, 317–20 (2008).

[61] 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1).

[62] 21 U.S.C. § 360e(a)(6)(1)(B); 21 C.F.R. § 814.1(c)(1)–(2); Medtronic, Inc. v. Lohr, 518 U.S. 470, 477–78 (1996).

A minority of the medical devices entering the market utilize the FDA's premarket approval process.[63] Described by the Supreme Court as "rigorous,"[64] the PMA process requires the manufacturer of a device to submit an immense amount of information to the FDA: copies of all reports and investigations done regarding the device's safety and efficacy; statements of device components, ingredients, and properties; descriptions of manufacturing locations and procedures; proposed labeling; and more.[65] In order to receive approval, the manufacturer's submissions must be sufficient to give the FDA "reasonable assurance" that the product is safe and effective.[66] When considering whether to approve a product, the FDA may impose restrictions on the sale or distribution of the product or promulgate regulations that impose device-specific requirements.[67] The FDA estimates that it spends approximately 1,200 hours evaluating each device that is submitted for premarket approval.[68]

Once a device is given FDA approval through the PMA process, device manufacturers are required to take several additional steps to remain in compliance with the FDA's regulations. They must file annual reports to the FDA,[69] as well as collect and report data on certain types of adverse events caused by the device.[70] Further, they must submit supplemental applications and obtain the FDA's approval before making any changes to a device (or a device's label) that might affect its safety or effectiveness.[71] The FDA retains the right to withdraw market approval for any product that does not satisfy its safety and effectiveness standards.[72] The

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[63] *See Lohr*, 518 U.S. at 477–80 (noting that nearly "1,000 out of approximately 1,100 Class III devices were admitted as 'substantial equivalents' and without any PMA review"); Susan M. Mesner, *Medical Device Technology: Does Federal Regulation of This New Frontier Preempt the Consumer's State Common Law Claims Arising from Injuries Related to Defective Medical Devices?*, 7 J.L. & HEALTH 253, 287 (1993) ("Few devices currently being marketed have been subjected to the scrutiny of the premarket approval process.").

[64] *Riegel*, 552 U.S. at 317; *Lohr*, 518 U.S. at 478.

[65] 21 U.S.C. § 360(c)(1).

[66] 21 C.F.R. 814.20(b)(3)(vi).

[67] 21 U.S.C. §§ 360e(d)(1)(B)(ii), 360j(e)(1); 21 C.F.R.. § 814.82(a)(1).

[68] *Riegel*, 552 U.S. at 318.

[69] 21 U.S.C. § 360(b).

[70] 21 C.F.R. § 814.84.

[71] 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39(a). Device manufacturers are permitted, however, to modify their devices (or labels) prior to receiving approval if doing so would enhance safety. 21 C.F.R. § 814.39(a), (d)(1).

[72] 21 C.F.R. § 814.46.

FDA also possesses the authority to order a device recall for devices that pose a reasonably probable risk of causing serious adverse health consequences or death.[73]

The vast majority of medical devices on the market have not gone through the PMA process, but rather have obtained FDA approval through what is known as the 510(k) process.[74] The 510(k) process requires device manufacturers to send the FDA a "premarket notification," which demonstrates that their product is "substantially equivalent" to a product that has preamendment status.[75] While 510(k) submissions must include information describing the device and supporting the manufacturer's claim of substantial equivalence, the amount of documentation required to satisfy these requirements is not nearly as onerous as that required in a PMA application.[76] Because the FDA's primary concern is determining whether the new device is equivalent to a device with preamendment status and the agency never conducts an inquiry into the new device's safety and efficacy, the turnaround time on 510(k) submissions is significantly faster than that of the PMA process.[77] In sharp contrast to the amount of time the agency commits to each PMA review, the average 510(k) review lasts only twenty hours.[78]

The introduction of this complex federal regulatory structure to an area that had previously fallen squarely within the province of the states raised questions about what role, if any, remained for state-based regulation of medical devices. The MDA addresses this issue in Section 360k, which states:

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[73] *See id.* § 810.1–.18 (describing the procedures for recall).

[74] *See* Robert Higgs, *Wrecking Ball: FDA Regulation of Medical Devices*, CATO POL'Y ANALYSIS, no. 235 (Aug. 7, 1995), *available at* http://www.cato.org/pubs/pas/pa-235.html ("[M]any devices have entered the market through an abbreviated premarket notification process under section 510 of the [Safe Medical Devices] Act."); D. Kessler, S. Pape & D. Sundwall, *The Federal Regulation of Medical Devices*, 317 NEW ENG. J. MED. 357, 359 (1987) (noting "that the great majority, about 98 percent, of products being introduced to the market arrive[ ] via the 510(k) route" and that "[t]he 510(k) process is no longer simply notification, but an approval process"); Mesner, *supra* note 63, at 287 (noting that as of the 1990s, 98% of marketed medical devices entered the market through the 510k process).

[75] 21 C.F.R. § 807.81; Medtronic, Inc. v. Lohr, 518 U.S. 470, 478–79 (1996).

[76] *Compare* 21 C.F.R. § 807.87 (listing the "information required in a premarket notification submission" for a device submitted through 510(k) process), *with* 21 U.S.C. § 360e (listing requirements for premarket approval).

[77] *Lohr*, 518 U.S. at 478–80; *see also* Higgs, *supra* note 74 (comparing the PMA process and the 510(k) process).

[78] *Lohr*, 518 U.S. at 478–79; *see also* Higgs, *supra* note 74 (noting review times).

> Section 360k. State and local requirements respecting devices
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> (a) General Rule – . . . [N]o State . . . may establish . . . with respect to a device intended for human use any requirement—
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (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 chapter.[79]

This provision indicates that Congress wanted to clearly state that, going forward, the existing state regulatory systems would be subordinate to the federal system and that the MDA expressly preempts attempts by the states to seize control from the federal system. While some state regulations were preserved as exceptions to this general rule,[80] the core provisions of the most expansive state regulatory regimes were curtailed. For instance, shortly after the MDA was enacted, the administrative review mechanisms created by California's Sherman Food, Drug, and Cosmetic Act were severely curtailed.[81]

The text of Section 360k, however, did not comprehensively address all of the issues that could arise concerning the enforceability of state laws. While it was obvious that state statutes and regulations imposing specific requirements on medical devices were forbidden, it remained unclear whether the MDA immunized medical device manufacturers from *all* potential state law liabilities.[82] Nothing in the MDA addressed whether

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[79] 21 U.S.C. § 360k.

[80] *See* 21 C.F.R. §§ 808.53–.101.

[81] *Compare* Sherman Food, Drug, and Cosmetic Act, ch. 980, § 1-6, 1977 Cal. Stat. 2954, *with* Sherman Food, Drug and Cosmetic Act, ch. 1573, 1970 Cal. Stat. (codified as amended at CAL. HEALTH & SAFETY CODE §§ 26000–26851 (West. Supp. 1971)).

[82] Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 FOOD & DRUG L.J. 245, 254–58 (2004) (discussing the "judicial schism over the proper interpretation and application of [S]ection [360k]"); AM. L. OF PRODUCTS LIABILITY § 91.15, at 38 (3d ed. Supp. 2008) ("The issues presented as a result of differing interpretations of 21 U.S.C. § 360k(a) of the MDA have been vigorously contested in the federal courts. Both circuit and district courts have

suits from injured patients based on state contract, tort, or statutory law would continue to be viable after its enactment or whether the liabilities that could be imposed on manufacturers in such suits would constitute conflicting—and thus, preempted—requirements.

Further complicating the scope of preemption analysis is the fact that Section 360k(b) of the MDA grants the FDA the authority to exempt state requirements from being preempted by the general rule.[83] Pursuant to this provision, the FDA has promulgated regulations that describe the mechanism the agency uses when deciding whether to grant exemptions and listing the different exemptions it has granted.[84] While many of the FDA's exemptions are focused on specific state statutory requirements,[85] others describe larger categories of claims and requirements that are not precluded by the MDA.[86] Courts have struggled when they have had to determine what impact these regulations should have on their interpretation of Section 360k.[87]

Since the MDA's enactment in 1976, the basic framework for the regulation of medical devices has remained largely unchanged. While Congress has passed several bills that have modified minor aspects of the scheme,[88] entities seeking to sell Class III medical

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wrestled with the congressional language employed and the accompanying FDA regulations without reaching any clear consensus.").

[83] *See* 21 U.S.C. § 360k(b) ("[T]he Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from [preemption a state requirement] applicable to a device intended for human use. . . .").

[84] 21 C.F.R. §§ 808.1–.101.

[85] *Id*. §§ 808.53–.101.

[86] *See id.* § 808.1 (prescribing procedures by which some state requirements may qualify for an exemption to preemption).

[87] *See, e.g.*, Rattay v. Medtronic, Inc., 482 F. Supp. 2d 746, 759–60 (N.D. W. Va. 2007) (noting differing views of the Justices in *Lohr* and concluding that if the state law claims were successful, they would "impose state requirements that could be preempted by § 360k(a)"); Mulligan v. Pfizer, Inc., 850 F. Supp. 633, 635 (S.D. Ohio 1994) (finding state law causes of action at issue not preempted pursuant to 21 C.F.R. § 808.1(d)(1)); Oliver v. Johnson & Johnson, Inc., 863 F. Supp. 251, 255 (W.D. Pa. 1994) (finding claims under Pennsylvania's Uniform Commercial Code not preempted pursuant to 21 C.F.R. § 808.1(d)(1)); Burgstahler v. AcroMed Corp., 670 A.2d 658, 663–65 (Pa. Super. Ct. 1995) (comparing recent court decisions on the preemption ability of Section 360k and applying "general principles of preemption to each of the [state law] claims"); Worthy v. Collagen Corp., 921 S.W.2d 711, 715–16 (Tex. Ct. App. 1995) (finding that the state law at issue was preempted because the MDA has a broader scope than as interpreted by the FDA)

[88] For an overview of legislative modifications to the MDA's regulatory scheme, see Richard A. Merrill, *Regulation of Drugs and Devices: An Evolution*, 13 HEALTH AFF., NO. 3, 1994, at 63–64 and Higgs, *supra* note 74.

devices are still required to obtain PMA or 510(k) approval from the FDA. State-imposed device requirements remain subject to the preemption rules set forth in Section 360k, but Congress has not modified the MDA to clarify whether injured patients can sue the creators of defective medical devices for violating state common law, nor has a federal cause of action for such claims been created.[89] Additionally, the FDA has not modified its regulations concerning exceptions to 360k(a)'s general rule. As will be discussed in the following parts of this Article, congressional inaction has meant that the task of determining the scope of preemption has fallen on the judiciary.

III. BASES FOR MEDICAL DEVICE MANUFACTURER LIABILITY

While the evolution of the regulatory relationship between the federal government and the medical device market has played a crucial role in the development of the courts' preemption doctrines, it only provides one part of the story. In order to grasp the significance of recent rulings, it is equally important to review the rights that state legal systems have provided to consumers of medical devices. Discussing the different grounds for manufacturer liability provides the theoretical foundation necessary for critiquing the lower courts' holdings and diagnosing the dangerous implications that current rulings have for contractual liberties.

Setting aside all considerations of federal preemption, there are three different types of claims that a plaintiff who has been injured by a medical device could use to impose liability on a device manufacturer. Assuming favorable facts, he could allege that the manufacturer's conduct violated tort, contract, and statutory duties. Each of these general bases for liability, as well as specific claims within these broader categories, are reviewed below. For each claim, particular attention is given to describing (1) the basic theoretical justification for imposing liability on the device manufacturer, (2) what a plaintiff would have to prove in

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[89] In 2009, a bill was introduced—The Medical Device Safety Act—that would have resolved this issue by adding the following text to Section 360k: "Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State." H.R. 1346, 111th Cong. (2009); S. 540, 111th Cong. (2009). Both the Senate and House versions of the bill died in committee and have not been reintroduced.

order to establish liability, and (3) the precedential impact that a successful claim would have for future suits involving the same product.

A. TORT CLAIMS

Tort law, with its focus on deterring accidents and compensating individuals for injuries they suffer due to third parties' intentional or negligent conduct, provides the most obvious legal mechanism for dealing with the problems created by faulty medical goods. Two characteristics of tort law are particularly relevant in this context: the general nature of tort standards and the public origin of tort duties. First, a manufacturer's liability in tort will depend on a determination as to whether it satisfied a general standard—e.g., did it take reasonable precautions, is its product reasonably safe, or does the utility created by a product outweigh its potential harms. Because the same standard will be applied in every suit involving a particular product, a single successful tort suit against a manufacturer will often establish the manufacturer's liability to all of its other customers. For instance, a judicial determination that a manufacturer's failure to disclose a risk of injury to a specific consumer on a product's label constituted negligence will typically establish the manufacturer's liability to every person who purchased its product and suffered a similar injury.[90] Second, a manufacturer's tort duties are imposed by the state and typically cannot be modified by agreement. This is important because it means that manufacturers cannot control the standard of care their conduct must satisfy.[91]

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[90] *See* Michael A. Perino, *Class Action Chaos? The Theory of the Core and an Analysis of Opt-Out Rights in Mass Tort Class Actions*, 46 EMORY L.J. 85, 88–94 (1997) (discussing the efficiency advantages of mass tort class actions due in part to "overlapping issues"); *see, e.g.*, Johnson v. Geico Cas. Co., 673 F. Supp. 2d 255, 272–76 (D. Del. 2009) (discussing whether plaintiffs satisfied commonalty requirements to qualify as a class in various contract claims asserted against automobile insurers); Stanich v. Travelers Indem. Co., 249 F.R.D. 506, 523 (N.D. Ohio 2008) ("A claim is typical if it arises from the same event or practice, or course of conduct, that gives rise to the claims of other class members, and if his or her claims are based on the same legal theory." (internal quotation marks omitted)).

[91] *See, e.g.*, Burten v. Milton Bradley Co., 763 F.2d 461, 465 (1st Cir. 1985) ("Under Massachusetts law, parties cannot easily contract out of liability for tortious behavior."); Comind, Companhia de Seguros v. Sikorsky Aircraft Div. of United Techs. Corp., 116 F.R.D. 397, 419–20 (D. Conn. 1987) (noting that negligence disclaimers in contracts are strongly disfavored under Connecticut law); *see also* PROSSER & KEETON, ON THE LAW OF TORTS § 92, at 656 (5th ed. 1984) ("[T]ort obligations . . . are imposed apart from and independent of

There are three general tort claims that injured individuals can assert against the seller of a device: negligence claims, strict liability claims, and breach of implied warranty claims.

1. Negligence. A plaintiff could try to hold a device manufacturer liable for negligence—attempting to show that the company failed to exercise reasonable care when designing, manufacturing, marketing, or selling its product. In order for his claim to be successful, the plaintiff would have to show that the manufacturer owed a legal duty to the plaintiff, that it breached its duty, and that he suffered an injury due to the breach.[92] It is generally accepted that the producers of medical devices have a duty to properly warn consumers of the known dangers associated with use of their devices and to exercise reasonable care when designing and manufacturing their products.[93] Because of the uniformity of the commercial transactions involving devices sales, a finding that the manufacturer failed to satisfy these duties in one instance would likely expose the seller to liability to anyone who purchased the same product and suffered injuries that could be connected to the breach.

2. Strict Liability. Depending on the jurisdiction, a plaintiff might be able to use a strict liability claim to recover from a device manufacturer. In order to prevail on such claims, a plaintiff generally needs to show that the product was, upon leaving the control of the manufacturer, unreasonably dangerous and that the product caused the plaintiff's injury.[94] Courts have found that problems with a commercial good's design, manufacture, or labeling can support strict liability claims.[95] Again, once one court

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promises made and therefore apart from any manifested intention of parties to a contract or other bargaining transaction.").

[92] *See, e.g.*, Armstrong v. Optical Radiation Corp., 57 Cal. Rptr. 2d 763, 771–72 (Cal. Ct. App. 1996) (discussing negligence claim related to the use of a surgical aid in an eye surgery). *See generally* 65 C.J.S. *Negligence* § 20 (2013).

[93] *See, e.g.*, Pritchett v. I-Flow Corp., 2012 WL 1340384, at *2 (D. Colo. Apr. 18, 2012) ("[A]s a medical device manufacturer, Defendant had a duty to properly warn Plaintiff of the known dangers . . . of the medical device."); Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 836–37 (S.D. Ind. 2009) (discussing plaintiff's claim against medical device manufacturer for failing to warn about unreasonable risks).

[94] *See generally* 72A C.J.S. *Products Liability* §§ 6–8 (2012) (explaining that the defective condition of the product must exist at the time of sale for a strict liability claim).

[95] *See, e.g.*, Bass v. Stryker Corp., 669 F.3d 501, 514–15 (5th Cir. 2012) (discussing strict liability claims under Texas law); Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 283–84 (E.D.N.Y. 2009) (holding that defendant's strict liability claims for design and manufacturing defects were preempted).

determines that a product is unreasonably dangerous, the manufacturer will likely be found liable to other individuals who were injured by the product.

3. Breach of Implied Warranty. Finally, a plaintiff might be able to hold a device manufacturer liable for breach of the implied warranties of merchantability or fitness for a particular purpose. While breach of an implied warranty is most commonly recognized as a contractual claim based on the implied warranty provisions of the Uniform Commercial Code (U.C.C.), certain states have continued the common law tradition of recognizing these claims as tort actions.[96] In these states, a manufacturer can incur tort liability if it impliedly represents that a product is of good and merchantable quality (or fit and safe for its ordinary intended use), the consumer reasonably relies upon this representation, and the consumer is injured as a result.[97] Because the reliance-related element of the claim requires plaintiff-specific findings, a defendant's liability in one suit is unlikely to be considered dispositive of its liability in other suits.

B. CONTRACT CLAIMS

Contract law provides another basis for injured consumers' claims. Not only does contract law give individuals the ability to hold other parties accountable for breaching the terms of an agreement, but it also protects individuals by giving weight to their reasonable expectations and imposing consumer-friendly default rules on transactions. Each of these aspects is implicated in the medical device setting—manufacturers can incur contractual liability both when their products fail to live up to their promises as well as when their products fail to meet general standards of merchantability and fitness for use.

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[96] *See, e.g.*, Sirlouis v. Four Winds Int'l Corp., 2012 WL 1068709, at *15 (N.D. Ohio Mar. 29, 2012) (recognizing a common-law cause of action for "implied warranty in tort"); JCW Elecs., Inc. v. Garza, 257 S.W.3d 701, 704–06 (Tex. 2008) (finding that a breach of implied warranty claim is treated as a tort under a Texas statute); Kare v. Christenberry, 637 P.2d 452, 456 (Kan. Ct. App. 1981) ("[I]t now appears settled that in Kansas a person suffering damage from a person suffering damage from a breach of implied warranty may proceed upon either a contract or tort theory, or both, in initially framing his cause of action."); *see also* JAMES BARR AMES, LECTURES ON LEGAL HISTORY 136–37 (1913) (discussing the origins of the action for "false warranty").

[97] *See, e.g.*, *Sirlouis*, 2012 WL 1068709, at *15 (discussing an implied warranty in tort).

Because it is uncommon for medical practitioners and patients to negotiate (or even discuss) the terms of their commercial deals, it might seem peculiar to think of a procedure like the installation of an artificial knee as involving a contract for the sale of a good. The lack of negotiation or a written contract between the parties, however, does not prevent a transaction that includes a sale of goods from being governed by contract law.[98] As long as obtaining the device plays the central role in the patient's motivation for entering into the larger medical transaction, the transaction qualifies as a sale of goods and will be governed by Article 2 of the U.C.C.[99] Finally, because the majority of jurisdictions have abandoned privity requirements for consumer claims, consumers who purchase devices from intermediaries will typically be able to assert contractual claims directly against device manufacturers.[100]

Contract claims differ from the tort claims discussed earlier in two critical ways: (1) the degree to which claims can be generalized across transactions and (2) the origin of the parties' obligations. First, whereas a manufacturer's tort liability will be determined by comparing its conduct to generalized standards of care, a seller's contract liability will depend on the terms of the parties' agreement and the facts surrounding the transaction.[101] Because

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[98] *See, e.g.*, 810 ILL. COMP. STAT. 5/2-201(3) (2012) (enforcing contracts that fail the formal requirements of the statute of frauds but nonetheless are valid in other respects).

[99] *See* Zayre Corp. v. S.M. & R. Co., 882 F.2d 1145, 1153 (7th Cir. 1989) ("In determining whether Article 2 governs a mixed contract, Illinois courts look to see what the contracts' predominant purpose' is."). *See generally* 77A C.J.S. *Sales* § 12 (2013) (adopting the predominate factor test for mixed contracts). Every state, except Louisiana, has legislatively enacted Article 2 of the U.C.C. *Uniform Commercial Code Locator*, LEGAL INFO. INST., http://www.law.cornell.edu/uniform/ucc.html (last visited May 15, 2014).

[100] *See, e.g.*, Jordan v. Four Winds Int'l, Inc., 2010 WL 1337691, at *7–8 (W.D. Penn. Mar. 31, 2010) (discussing Pennsylvania's abolishment of the privity requirement); Szajna v. Gen. Motors Corp., 503 N.E.2d 760, 763 (Ill. 1986) (noting Illinois's movement away from strict privity requirements); Crest Container Corp. v. R.H. Bishop Co., 445 N.E.2d 19, 25 (Ill. App. Ct. 1982) (noting an exception to the privity requirement where "the remote manufacture knows the identity, purpose and requirements of the dealers customer and manufactured or delivered the goods specifically to meet those requirements." (quotation marks omitted)); Media Prod. Consultants, Inc. v. Mercedes-Benz of N. Am., Inc., 262 So. 2d 377, 380–81 (La. 1972) (stating that Louisiana law allows consumers that lack privity to recover under implied warranty theories); Dawson v. Canteen Corp., 212 S.E.2d 82, 82–83 (W. Va. 1975) (noting the erosion of the privity requirement in cases of breach of express or implied warranty); *see also* John L. Watts, *Fairness and Utility in Products Liability: Balancing Individual Rights and Social Welfare*, 38 FLA. ST. U. L. REV. 597, 616–18 (2011) (discussing the privity of contract requirement, and describing competing policy concerns).

[101] *See, e.g.*, O'Gara *ex rel.* Estate of Portnick v. Countrywide Home Loans, Inc., 282 F.R.D. 81, 87 (D. Del. 2012) (looking to "[t]he basic factual circumstances supporting Plaintiff's

there are often significant variances in the contract terms and circumstances surrounding commercial transactions, contractual liabilities tend to be less generalizable than tort liabilities.[102] Second, while a manufacturer's tort duties are set by state law, its contractual duties—aside from general common law duties not to breach the agreement and to act in good faith—are defined by the terms to which it has agreed.[103] Put differently, tort liability involves a judgment that the manufacturer violated a state-imposed standard, and contract liability consists of a judgment that the manufacturer violated a self-imposed standard. The significance of these distinctions will become apparent in Part V, when arguments in favor of permitting individuals to file contract based claims against manufacturers will be presented.

Because of the transaction-specific nature of contract claims, whether any given individual will be able to bring certain claims against a manufacturer will vary. There are three types of claims, however, that are most likely to arise in the medical device context: breach of implied warranty of merchantability, breach of implied warranty of fitness for particular purpose, and breach of express warranty claims.

1. Breach of Implied Warranty of Merchantability. A plaintiff could attempt to impose liability on a device manufacturer for breaching the implied warranty of merchantability. Section 2-314 of the U.C.C. states that when a merchant sells goods, "a warranty that the goods shall be merchantable is implied" in the contract unless the merchant takes action to exclude or modify this obligation.[104] A good is merchantable only if it meets several standards that are set forth in the statute; most relevant to this discussion are the requirements that the item is "fit for the

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claims" in determining typically for class certification in contractual dispute); Green v. FedEx Nat'l, LTL, Inc., 272 F.R.D. 611, 616 (M.D. Fla. 2011) (denying class certification because "in determining whether [the defendant's] conduct constitutes breach of the Contract, each Contractor's conduct . . . would have to be examined").

[102] *See, e.g.*, Moskowitz v. La Suisse, Societe D'Assurances sur la Vie, 282 F.R.D. 51, 62 (S.D.N.Y. 2012) (denying class certification because the individualized contractual issues are subject to generalized proof); Iberia Credit Bureau, Inc. v. Cingular Wireless, 2011 WL 5553829, at *6–7 (W.D. La. Nov. 9, 2011) (noting that there were too many individualized issues surrounding each contract to permit class certification), *rev'd in part, vacated in part on other grounds by* Ackal v. Centennial Beauregard Cellular L.L.C. (5th Cir. 2012).

[103] *See* DAN B. DOBBS, DOBB'S LAW OF TORTS § 5 (2d ed. 2000).

[104] U.C.C. § 2-314 (2013); *see, e.g.*, 810 ILL. COMP. STAT. 5/2-314 (2012) (implementing the U.C.C. implied warranty of merchantability provision in Illinois).

ordinary purposes for which such goods are used" and that it "conform[s] to the promises or affirmations of fact made on the container or label if any."[105] An individual who receives a defective or malfunctioning medical device might be able to allege that the good that they purchased failed to satisfy the merchantability requirements.[106] In order to resolve such claims, courts would have to decide whether the warranty was disclaimed, determine what qualities the device would have had to possess in order to be merchantable, and decide whether the specific items that were sold actually had these qualities.[107] Given that each of these determinations is sensitive to differences among transactions, implied warranty verdicts cannot be generalized across consumers.

2. Breach of Implied Warranty of Fitness for Particular Purpose. Similarly, an injured individual could sue the maker of a faulty medical device for breaching the implied warranty of fitness for particular purpose. Section 2-315 of the U.C.C. provides that

> [w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose.[108]

Like the implied warranty of merchantability, the seller may exclude or modify this warranty.[109] A plaintiff could attempt to persuade the court that the device manufacturer knew the particular use that the individual needed the device to serve and, hence, that the manufacturer should be held liable when the

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[105] U.C.C. § 2-314; 810 ILL. COMP. STAT. 5/2-314 (2013).

[106] *See, e.g.*, Bass v. Stryker Corp., 669 F.3d 501, 516–17 (5th Cir. 2012) (holding that a claim for implied warrant of merchantability is not necessarily preempted in a defective hip prosthesis case).

[107] *See id.* at 516 ("To prevail on a breach of the implied warranty of merchantability, a plaintiff must prove that: (1) the defendant sold or leased the product to the plaintiff; (2) the product was unmerchantable; (3) the plaintiff notified the defendant of the breach; and (4) the plaintiff suffered injury." (internal quotation marks omitted)).

[108] U.C.C. § 2-315 (2013); *see, e.g.*, 810 ILL. COMP. STAT. 5/2-315 (2012) (implementing the U.C.C. implied warranty of fitness for particular purpose provision in Illinois).

[109] U.C.C. § 2-316 (2013); *see, e.g.*, 810 ILL. COMP. STAT. 5/2-316 (2012).

device fails to perform adequately.[110] When deciding whether the seller of a good breached this warranty, courts would have to make a number of transaction-specific determinations: whether the warranty was disclaimed; what the seller knew about the purposes for which the goods were needed; whether the seller knew about the consumer's reliance on its judgment; and whether the device provided was fit for the particular use.[111]

3. Breach of Express Warranty. Finally, a plaintiff could claim that the device manufacturer breached an express warranty. Express warranties are discussed in Section 2-313 of the U.C.C., which states that "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise."[112] Depending on the facts surrounding the transaction, an individual who is injured by a medical device might be able to claim that the seller of the device made representations as to its efficacy or safety—most likely when communicating directly with the customer, in advertisements, or on the product's labeling—and that the device did not conform to these representations.[113] A court faced with such claims would have to determine whether any express warranties were made and, if so, whether the supplied goods performed as promised.[114] Verdicts entered on express warranty claims that are based on representations that are uniform across transactions—e.g., labeling information—will be more generalizable than those based on unique representations—e.g., verbal efficacy promises made by an agent of the manufacturer. Adjudication of both of these types of claims, however, will require

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[110] *See, e.g.*, Rattay v. Medtronic, Inc., 482 F. Supp. 2d 746, 763 (N.D. W. Va. 2007) (discussing the alleged statutory claim for breach of implied warranty of fitness).

[111] *See, e.g.*, *id.* (concluding the breach of implied warranty claim is not preempted); U.C.C. § 2-315.

[112] U.C.C. § 2-313; *see, e.g.*, 810 ILL. COMP. STAT. 5/2-313 (2012) (implementing the U.C.C. express warranty provision in Illinois).

[113] *See, e.g.*, Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 839 (S.D. Ind. 2009) (alleging that hip implant failed to meet promises of label and packaging inserts); Parker v. Stryker Corp., 584 F. Supp. 2d 1298, 1302 (D. Colo. 2008) (discussing claim for breach of express warranty that was premised on product's labeling); *Rattay*, 482 F. Supp. 2d at 762–63 (noting that labeling materials related to a catheter contained "some language that apparently is intended to address what [defendant] will and will not warrant").

[114] *See* cases cited *supra* note 113.

a determination as to whether the specific device tendered satisfied the express warranty.

C. STATUTORY CLAIMS

In addition to tort- and contract-based claims, an injured individual might be able to bring statutory claims against the manufacturer of a faulty device. Most states have enacted consumer protection statutes that prohibit businesses from engaging in deceptive acts in the course of commerce.[115] Many of these statutes create a private cause of action for individuals who are injured as a result of a business's fraudulent or deceptive acts.[116] While there is significant variation in the specific elements that must be established in each statutory scheme, a plaintiff making such a claim would probably need to allege that the manufacturer's advertising, labeling, or other affirmative representation misled the plaintiff into believing that its medical device was safe.[117] While transaction-specific facts—for instance, where the device was sold and whether the plaintiff was actually misled by the representation—would likely play a part in determining a seller's liability, facts that are the same across different transactions—for instance, the representations contained on the device's label—would also factor into a court's analysis. Hence, a verdict entered on a statutory claim might help establish some elements of a manufacturer's liability to individuals that were not part of the underlying suit. However, it would not be entirely dispositive on the issue.

IV. THE SUPREME COURT'S MEDICAL DEVICE PREEMPTION JURISPRUDENCE

The preceding part has established that the law, at least in theory, provides individuals who have been injured by faulty medical devices with numerous causes of action. This picture

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[115] For example of state statutes, see Consumers Legal Remedies Act, CAL. CIV. CODE § 1770 (West 2014); N.Y. GEN. BUS. LAW § 349(a) (McKinney 2013); Deceptive Trade Practices Consumer Protection Act; TEX. BUS. & COM. CODE ANN. § 17.46 (West 2013).

[116] For examples of statutes with private rights of action, see CAL. CIV. CODE § 1780; N.Y. GEN. BUS. LAW § 349(h); TEX. BUS. & COM. CODE ANN. § 1750.

[117] *See, e.g.*, Weiss v. Polymer Plastics Corp., 802 N.Y.S.2d 174 (N.Y. App. Div. 2005) (dismissing plaintiffs' claim under Section 349 of the N.Y. General Business Law for failure to show that they had been deceived).

changes drastically when one takes into account the enactment of the Medical Device Amendments and the Supreme Court's decisions in *Medtronic v. Lohr, Inc.*[118] and *Riegel v. Medtronic, Inc.*[119] Once these events are accounted for, many of the claims discussed above become unavailable to plaintiffs.

Following the enactment of the Medical Device Amendments in 1976, the Judiciary has been the most important actor in the world of device liability. The Court's medical device jurisprudence has centered around two key Supreme Court decisions—*Lohr* and *Riegel*. In each case, the Court decided whether an individual's ability to pursue state common-law claims against the manufacturer of a Class III medical device was preempted by the existence of the federal regulatory system.[120]

Despite their similarity in subject matter, the *Lohr* and *Riegel* Courts approached the issue of federal preemption from radically different positions. The *Lohr* Court indicated that there was a presumption against interpreting federal regulatory schemes in ways that preempt state common-law claims and, relying on this presumption, concluded that individuals were not precluded from bringing tort claims against the manufacturers of devices that had gone through the 510k approval process.[121] The *Riegel* Court, on the other hand, expressed little concern about foreclosing individuals' state law claims and held that that the MDA grants manufacturers of devices that have gone through the pre-market approval process immunity from nearly all state law claims.[122] While the holdings of *Lohr* and *Riegel* are technically consistent with one another—the two rulings apply to different categories of devices—the logic articulated in each decision presents wildly contrasting views of the MDA's preemptive scope.

In order to determine whether there are gaps in the armor that *Riegel* provided to the manufacturers of certain Class III devices, it is necessary to analyze both the Court's anti-preemption and pro-preemption decisions. Reviewing what motivated the Court to find that the MDA preempts state law claims against certain manufacturers, but not others, will provide insight into what

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[118] 518 U.S. 470 (1996).
[119] 552 U.S. 312 (2008).
[120] *Lohr*, 518 U.S. at 474–77; *Riegel*, 552 U.S. at 315–20.
[121] *Lohr*, 518 U.S. at 485, 503.
[122] *Riegel*, 552 U.S. at 324–25.

factors influence courts' views about the preemptive impacts accorded to federal regulation. This analysis will play a role in Part V, informing the arguments that will be presented in favor of finding that certain state law claims are not preempted by the MDA.

A. *MEDTRONIC V. LOHR*

When she was twenty-seven, Lora Lohr became aware that her heart did not function properly.[123] In order to guard against future heart failures, she had a Medtronic pacemaker surgically installed into her body.[124] The pacemaker was equipped with leads—specialized wires that connect the heart and the mechanism that emits electronic pulses to regulate heartbeats which had also been manufactured by Medtronic.[125] Both the pacemaker and the leads were Class III devices that had obtained approval through the FDA's 510k process.[126] Three years after the device's implantation, Lohr's pacemaker stopped functioning properly.[127] Its failure caused her to suffer a blockage, which forced her to undergo emergency surgery.[128] Evidence indicated that the device's failure was likely due to a defect in the unit's leads.[129]

Lohr filed suit against Medtronic,[130] alleging that the company had violated Florida tort law and was liable for her injuries.[131] More specifically, she claimed that the company committed negligence by failing to use reasonable care in the design, manufacture, assembly, and sale of the pacemaker and leads.[132] She also sought to hold Medtronic strictly liable for her injuries,

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[123] *See Lohr*, 518 U.S. at 480–81 (noting that Lohr received a pacemaker in 1987); Anthony Collings, *Faulty Pacemaker Case May Set Precedent for Implant Patients*, CNN, Apr. 24, 1996, http://www.cnn.com/US/9604/24/scotus.pacemakers/; Ron Word, *Florida Woman Revels in Supreme Court Win*, LAKELAND LEDGER, June 27, 1996, at B5 (noting that Lohr was thirty-seven in 1996).

[124] *Lohr*, 518 U.S. at 480.

[125] *Id.*

[126] *Id.* at 477, 480.

[127] *Id.* at 480–81.

[128] *Id.* at 481.

[129] *Id.*

[130] Lohr v. Medtronic, Inc. 56 F.3d 1335, 1340 (11th Cir. 1995).

[131] *Id.* Lohr also filed a contractual breach of warranty claim, but this claim was dismissed early on in the litigation and, due to the fact that Lohr did not appeal this dismissal, was not before the Court. *Id.* at 1340 n.3.

[132] *Lohr*, 518 U.S. at 481.

asserting that the devices it sold to her were defective when they left the company's control and were unreasonably dangerous to its foreseeable users.[133]

Medtronic responded to Lohr's suit by filing a motion for summary judgment arguing that Lohr's tort claims were preempted by Section 360k of the FDCA.[134] As discussed in Part II, Section 360k prohibits states from establishing any device-related requirement that is "different from, or in addition to, any requirement applicable under [the FDCA] and which relates to the safety or effectiveness of the device."[135] Medtronic contended that holding it liable for Lohr's injuries under Florida's tort law would contravene the preemption statute by imposing additional, non-FDCA-based requirements on its device.[136] The company's stance was that manufacturers could only be held liable for injuries caused by their products if they violated one of the regulations set forth in the FDCA or promulgated by the FDA.[137]

Lohr's opposition to summary judgment contained two main counter-arguments. First, she claimed that Section 360k did not bar common-law actions because the liabilities imposed by such claims would not subject device manufacturers to different or additional requirements.[138] Second, she argued that, even if the Court found that such liabilities were requirements, Section 360k would not prevent her claims because the bar on other requirements only applies when the FDA has established specific requirements for a device, which the FDA never did for the pacemaker model at issue.[139]

The district court initially denied Medtronic's motion but reconsidered its decision after the Court of Appeals for the Eleventh

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[133] *Id.*

[134] *Id*.

[135] *Id*. at 481–82 (quoting 21 U.S.C. § 360k (2012)).

[136] *Id.* at 486.

[137] *See id*. at 487 ("Under Medtronic's view . . . Congress effectively precluded state courts from affording state consumers any protection from a defective medical device.").

[138] *See id*. at 492 (noting Lohr's argument that even if the FDA's rules preempt *different* state law requirements, "360k does not pre-empt state rules that merely duplicate some or all of those federal requirements").

[139] *See* Lohr v. Medtronic, Inc., 56 F.3d at 1335, 1343–44 (11th Cir. 1995) (addressing Lohr's argument for deference to the agency's interpretation that state requirements are preempted only when the FDA established specific requirements "applicable to a particular device").

Circuit issued an opinion on a related issue.[140] It ultimately concluded that all of Lohr's claims were, in fact, preempted.[141] Lohr appealed to the Eleventh Circuit, which partially reversed the district court, finding that Lohr's negligence and strict liability design claims were not preempted.[142] The court, relying on the FDA's regulations on preemption, concluded that neither the 510k process nor the FDA's minimal continued surveillance of the pacemaker imposed device-specific requirements that would conflict with any requirements that could be imposed by these state claims.[143]

Both parties filed petitions for certiorari seeking review of the Eleventh Circuit's decision.[144] Because the circuits courts were divided about the FDCA's preemptive scope in the context of medical devices the Supreme Court granted the petitions.[145] Perhaps unsurprisingly, the issue that had fractured the circuit courts also split the Justices.

Justice Stevens delivered the Court's majority opinion, which found that none of Lohr's claims were preempted by the FDCA.[146] Justice Stevens began his analysis by noting that the Court traditionally relies upon two presumptions when interpreting the preemptive scope of legislation.[147] First, the Court utilizes a presumption against preemption, assuming that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[148] Second, the Court attempts to accord enactments with the preemptive effect that effectuates Congress's legislative intent.[149]

With these presumptions in mind, the majority considered each of Lohr's claims. They began by ruling that her defective design claims were not preempted because the FDCA's 510k approval process for Class III devices does not impose requirements on

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[140] *Lohr*, 518 U.S. at 482–83.
[141] *See id.* at 483 ("[T]he District Court . . . dismissed the Lohrs' entire complaint.").
[142] *Id.* at 483–84.
[143] Lohr v. Medtronic, Inc., 56 F.3d at 1347–52.
[144] *Lohr*, 518 U.S. at 484.
[145] *Id.*
[146] *Id.* at 503.
[147] *Id.* at 485.
[148] *Id.* (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).
[149] *See id.* at 485–86 (emphasizing the role of congressional intent).

devices that are concrete enough to conflict with any requirements resulting from a successful common-law suit.[150] Focusing on the fact that the FDA's only concern when acting on a 510k application is whether a device is equivalent to a preamendment device, the Court held that the approval process fails to impose substantive requirements regarding a device's design, labeling, or manufacturing.[151] While the manufacturers of 510k-approved devices must comply with the Act's general marketing and manufacturing standards, the majority felt that these standards—which apply to Class I and II goods as well—were too generic to trigger preemption under Section 360k.[152]

Justice Stevens's opinion continued on to find that the MDA did not preempt Lohr's manufacturing and labeling claims.[153] The majority found that Section 360k only authorizes the preemption of state law when "a particular state requirement threatens to interfere with a specific federal interest."[154] It based this conclusion, in part, on two FDA-promulgated regulations. The first was 21 C.F.R. § 808.1(d), which states that state requirements are preempted only when the FDA has established specific counter-regulations or other specific requirements applicable to a particular device.[155] The second was 21 C.F.R. § 808.1(d)(1), which states that the MDA is not meant to preempt state requirements of "general applicability where the purpose of the requirement relates either to other products in addition to devices or . . . to unfair trade practices."[156] The Court took these regulations as strong indications that Congress only intended to preempt state law when either federal regulation of an issue was comprehensive or the state requirement was specific to medical devices.[157] Because devices approved as substantially equivalent are only subject to the FDCA's most generic labeling and manufacturing requirements, and the common-law claims brought by Lohr were based on duties imposed on all manufacturers, the

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[150] *Id.* at 492–94.
[151] *Id.* at 493–94.
[152] *Id.*
[153] *Id.* at 502.
[154] *Id.* at 500.
[155] *Id.* at 498–99.
[156] *Id.* (alteration in original).
[157] *Id.* at 500–01.

majority found that there were no grounds for preemption of these claims.[158]

Finally, in a part of Justice Stevens's opinion that only drew support from three other Justices, he rejected Medtronic's argument that Section 360k preempts all common-law claims against manufacturers because such claims, if successful, would impose conflicting requirements.[159] This section of the opinion emphasized that this interpretation would be contrary to the statute's goal of "provid[ing] for the safety and effectiveness of medical devices intended for human use."[160] It would also be contrary to the Legislature's motivation for including Section 360k, which was to prevent the problems that would arise if each state attempted to impose their own specific regulatory requirements on medical devices.[161] Further, he noted that the MDA's legislative history contained no support for Medtronic's proposed construction of Section 360k and that an analysis of the MDA's provision indicates that the term "requirement" was meant to refer to state statutes and regulations, not common-law duties.[162] While Justice Stevens conceded that it was conceivable for a common-law duty to impose a conflicting requirement, he felt that this would only occur in rare cases.[163]

Justice Breyer wrote separately, concurring in part with the majority opinion and concurring in the judgment. Justice Breyer stated that, while he thought that the majority opinion was correct in acknowledging that verdicts entered in state common-law actions could impose requirements that would be preempted by Section 360k,[164] he felt the majority underestimated the frequency with which this would occur.[165] He believed a hypothetical state court finding that a manufacturer was negligent for deciding to use a 2-inch wire instead of a 1-inch wire in a device should be viewed as equivalent to a state statute mandating the use of 1-inch

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[158] *Id.*

[159] *Id.* at 486–91.

[160] *Id.* at 487 (quoting the preamble of the Medical Device Amendments of 1975, Pub. L. No. 94-295, 90 Stat. 539 (1976)).

[161] *Id.* at 489–91.

[162] *Id.*

[163] *Id.* at 502–03.

[164] *Id.* at 503 (Breyer, J., concurring).

[165] *Id.* at 508.

wires.[166] Hence, if Section 360k would preempt a state statute regulating wire length as a requirement different from or additional to a federal requirement, then the statute should also preempt a negligence claim that is based on a manufacturer's wire length decision.[167] Justice Breyer also went on to list a number of factors supporting the majority's interpretation of the MDA's preemptive scope: the ambiguity of Section 360k's text; the FDA's authority to determine the scope of the act's preemption; the text of 21 C.F.R. § 808.1(d); "and the ordinary principles of conflict and field preemption, namely that preemption occurs only when compliance with both [state and federal requirements]."[168]

Finally, Justice O'Connor wrote on behalf of a four-Justice block, concurring in part and dissenting in part. Justice O'Connor stated that the Court's past precedents made it clear that, because common-law damages actions force manufacturers to comply with common-law duties, such actions impose requirements on manufacturers.[169] She thought that Section 360k's language clearly indicated that all requirements imposed by state law were preempted.[170] She felt that because there was no ambiguity in the statute, it was improper for the Court to defer to the FDA's stance on the issue or the regulations issued by the agency.[171] Based on these views, the dissenting Justices concluded that Lohr's manufacturing and failure-to-warn claims were preempted because they could impose requirements that would conflict with the FDCA's generic manufacturing and labeling requirements.[172] Despite their generally pro-preemption construal of the statutory scheme, they felt that Lohr's design defect claim was not preempted because nothing in the FDCA or the 510k approval process had imposed any federal requirements concerning the device's design.[173]

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[166] *Id.* at 504 (Breyer, J., concurring).
[167] *Id.*
[168] *Id.* at 505–08.
[169] *Id.* at 510–11 (O'Connor, J., dissenting).
[170] *Id.*
[171] *Id.* at 512.
[172] *Id.* at 513–14.
[173] *Id.* at 513.

B. *RIEGEL V. MEDTRONIC*

After suffering a heart attack, Charles Riegel underwent a coronary angioplasty—a medical procedure used to open clogged heart arteries.[174] As part of the angioplasty, the doctors needed to insert a balloon catheter into his artery.[175] At the time of the procedure Riegel's right coronary artery was diseased and heavily calcified.[176] When the physicians inserted the catheter to inflate this artery, the catheter burst.[177] The burst catheter caused Riegel to develop a complete heart blockage, which forced him to go on life support and undergo an emergency coronary bypass.[178] While he survived the severe injuries that were caused by the device's failure, the incident left him with permanent disabilities.[179]

In 2002, Riegel filed suit against Medtronic, Inc., the company that manufactured the catheter, in the United States District Court for the Northern District of New York.[180] Riegel's complaint set forth a number of common-law claims—strict liability, breach of implied warranties, breach of express warranties, and negligence in the design, marketing, manufacturing, and sale of the catheter—each of which, if proven, would establish Medtronic's liability for his injuries.[181]

The district court noted that, like the pacemaker leads that were at the heart of the *Lohr* litigation, Medtronic's balloon catheter was a Class III device that had been approved through the FDA's premarket approval process.[182] The court held that "this extensive approval procedure [constitutes] a device-specific federal requirement for preemption purposes" and that

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[174] Riegel v. Medtronic, Inc., 552 U.S. 312, 320 (2008); *No Compensation for Faulty Medical Devices*, NEW SCIENTIST, Mar. 1, 2008, at 6, *available at* 2008 WLNR 4049853; Linda Greenhouse, *Supreme Court Hears Medical Device Case*, N.Y. TIMES, Dec. 5, 2007, at C3, *available at* http://nytimes.com/2007/12/05/Washington/05bizcourt.html.

[175] *Riegel*, 552 U.S. at 320; Greenhouse, *supra* note 174.

[176] *Riegel*, 552 U.S. at 320.

[177] *Id.*

[178] *Id.*

[179] *Id.*; Aaron Smith, *Medical Devices Put To Legal Test*, CNNMONEY.COM (Dec. 3, 2007), http://money.cnn.com/2007/11/29/news/companies/Medtronic/index.htm; Pete Yost, *Court Limits Suits Over Medical Devices*, USA TODAY (Feb. 20, 2008), http://www.usatoday.com/news/washington/2008-02-20-2714352837_x.htm.

[180] *Riegel*, 552 U.S. at 320.

[181] *Id.* at 320; Riegel v. Medtronic, Inc., No. 99-CV-0649 (LEK/RWS), 2002 WL 34234093, at *1 (N.D.N.Y. Mar. 18, 2002).

[182] *Riegel*, 552 U.S. at 320.

"[a]pplication of state common-law requirements . . . would potentially impose standards different from, or in addition to, these specific federal requirements."[183] Because Section 360k of the MDA expressly prohibits state law from imposing requirements on devices, the court concluded that Riegel's negligence, strict liability, and implied warranty claims were preempted.[184] On a later date, the district court granted summary judgment against Riegel's remaining claims, finding that they lacked sufficient factual and evidentiary support.[185]

On appeal, the Second Circuit affirmed the district court's decisions, largely echoing the district court's preemption analysis.[186] The appellate court held that the device manufacturer was "clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved" premarket approval application and that actions based on common-law liabilities would impose conflicting requirements.[187] The Supreme Court granted Riegel's petition for certiorari.[188] After reviewing the parties' briefs and conducting oral argument, the Court affirmed the decisions below.[189]

Justice Scalia, joined in full by six other Justices and joined in part by Justice Stevens, wrote the Court's majority opinion.[190] Justice Scalia began his analysis of the preemption question by considering whether the federal government had established requirements that governed the production and sale of the catheter.[191] He reviewed the Court's decision in *Lohr*, noting that it established that generic requirements imposed by the MDA on all devices are insufficiently specific to constitute requirements for preemption purposes.[192] He went on to find that the holding in *Lohr* was largely irrelevant to Riegel's suit because devices that

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[183] *See Riegel*, 2002 WL 34234093, at *6.

[184] *See id.* at *1, *5–7 (granting summary judgment against Riegel's strict liability, breach of implied warranty, and non-manufacturing-related negligence claims).

[185] *See* Riegel v. Medtronic, Inc., No. 99-CV-0649, 2003 WL 25556778, at *7–8 (N.D.N.Y. Dec. 2, 2003) (granting summary judgment against Riegel's express warranty and negligent manufacture claims).

[186] Riegel v. Medtronic, Inc., 451 F.3d 104, 127 (2d Cir. 2000), *aff'd*, 552 U.S. 312 (2008).

[187] *Id.* at 118, 121.

[188] *Riegel*, 552 U.S. at 321.

[189] *Id.* at 330.

[190] *Id.* at 313.

[191] *Id.* at 321.

[192] *Id.* at 322.

had gone through the PMA process—like Medtronic's catheter—were not only subject to the MDA's general requirements, but also had to comply with an extensive set of device-specific rules.[193] In the majority's view, manufacturers were subject to device-specific requirements regarding a device's design because the FDA, as part of its grant of premarket approval, prohibited the sale of devices that diverged from the design, manufacturing, and marketing specifications that it had reviewed and found to be safe.[194]

Having decided that the PMA process imposes specific federal requirements on Class III devices, Justice Scalia turned to the issue of whether Riegel's common-law claims, if successful, would also impose requirements on device manufacturers.[195] He began by noting that, in *Lohr*, five Justices held that common-law actions for negligence and strict liability could impose requirements that would be preempted if they conflicted with a device-specific federal requirement.[196] He pointed out that this conclusion was in line with the Court's decisions in cases in which it had to construe similar statutory language found in other federal regulatory schemes, such as the Federal Insecticide, Fungicide, and Rodenticide Act and the Public Health Cigarette Smoking Act.[197] Justice Scalia summarized the Court's logic in these rulings, stating that, because a manufacturer's liability for a common-law claim is "premised on the existence of a legal duty," a tort judgment can only be understood as a judgment that the manufacturer has violated some requirement imposed by state law.[198] He claimed that this conclusion makes sense because "tort law that requires a manufacturer's catheters to be safer . . . than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect."[199]

The majority opinion went on to reject Riegel's argument that a broad construal of Section 360k's preemptive scope would be incongruous with the MDA's purpose, as previously noted by the

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[193] *Id.* at 320, 322–23.

[194] *See id.* at 323 ("[T]he FDA requires a device . . . to be made with almost no deviations from the specifications in its approval application.").

[195] *Id.*

[196] *Id.* at 323–24.

[197] *Id.* at 324.

[198] *Id.* (quoting Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 522 (1992)).

[199] *Id.* at 325.

Court in *Lohr*.[200] More specifically, Riegel's contention was that foreclosing an injured individual's ability to seek judicial recourse could not be reconciled with the fact that the Legislature's intent in enacting the MDA was to protect consumers, not insulate manufacturers from liability.[201] Justice Scalia responded to these claims by stating that it was not the Court's "job to speculate upon congressional motives."[202] He went on to note that even if the Court were to engage in such an activity, it would be limited to considering the text of the statute, which, in his eyes, unambiguously indicated that Congress had decided that it would be net beneficial to preclude the majority of individuals' common-law claims.[203]

Finally, Justice Scalia dismissed Riegel's contention that, even if common-law claims impose requirements, such requirements escape preemption because Section 360k only preempts requirements that are maintained " 'with respect to devices' " and does not preempt requirements that are general in nature.[204] He began by stating that there was nothing in the text of Section 360k limiting its scope of preemption to state requirements that singled out specific devices or the medical device field as a whole.[205] While he conceded that one of the FDA's regulations—21 C.F.R. § 808.1(d)(1)—unambiguously stated that the MDA's preemption clause does not apply to "state or local requirements of general applicability," he gave two reasons why he felt this regulation provided insufficient support for Riegel's argument.[206] First, he made reference to the fact that it was still unsettled as to whether an agency's regulation could, as a matter of law, influence the scope of statutorily imposed preemption.[207] Second, he stated it was unclear, based on the text of the regulation, whether the tort duties underlying Riegel's claims would qualify for the regulation's

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[200] *See id.* ("[I]t is implausible that the MDA was meant to grant greater power . . . to a single state jury than to . . . the lawmaking process." (internal quotation marks omitted)).

[201] Brief for Petitioners at 14–23, Riegel v. Medtronic, Inc., 552 U.S. 312 (2008) (No. 06-179).

[202] *Riegel*, 552 U.S. at 326.

[203] *See id.* (noting Congress's "solicitude for those who would suffer without new medical devices" if "the tort law of so states [applied] to all innovations").

[204] *Id.* at 327 (quoting Brief of Petitioners, *supra* note 201, at 34).

[205] *Id.* at 328.

[206] *Id.* (quoting 21 C.F.R. § 808.1(d)(1) (2013)).

[207] *See id.* ("Even assuming that the regulation could play a role in defining the MDA's preemptive scope. . . ."); *see also infra* note 237.

exemption from preemption.[208] Not only did the regulation fail to include common-law duties in its list of examples of non-preempted requirements, but other sections of the same regulation indicated that, as a general rule, court-imposed common-law duties were meant to be preempted.[209]

Having decided that the PMA process imposes specific requirements on Class III devices and that the liabilities stemming from tort law duties could also constitute requirements, the majority concluded that Section 360k preempted all of Riegel's claims.[210] Perhaps uneasy with the idea that its decision appeared to leave injured individuals without a means for recovery, the Court noted that nothing in the MDA would preclude a plaintiff from using a state law cause of action to impose liability on manufacturers who fail to satisfy the federal requirements.[211] Such claims, also known as "parallel claims," will be discussed further in Part VI.

Justice Stevens wrote separately, concurring in part and concurring in the judgment. While Justice Stevens felt that the majority reached the proper conclusion concerning the preemptive scope of Section 360k, he wanted to make it clear that his support of the decision was based on the use of the term "requirements" in the statute and the Court's precedents establishing that common-law duties can constitute requirements.[212] Even though Justice Stevens believed that the enactors of the MDA did not intend for the preemption provision to foreclose state common-law remedies, he felt that intent alone provided insufficient grounds for narrowing the statute's plain text meaning.[213]

Justice Ginsburg was the only Justice to dissent.[214] Recalling the majority decision in *Lohr*, she began her analysis with a discussion of the presumption against preemption that the Court has historically applied to federal regulatory preemption

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[208] *Riegel*, 552 U.S. at 328 ("[T]he regulation excludes from pre-emption requirements that relate only incidentally to medical devices, but not other requirements."); *id.* at 329 ("[W]e think that § 808.1(d)(1) and add nothing to our analysis but confusion.").

[209] *See id.* at 329 ("Section 808.1(6) states that the MDA sets forth a 'general rule' pre-empting state duties 'having the force and effect of law (whether established by statute . . . or court decision).' ").

[210] *See id.* at 330 (affirming the judgment of the circuit court).

[211] *Id.*

[212] *Id.* at 331–33 (Stevens, J., concurring).

[213] *Id.* at 331–32.

[214] *Id.* at 333 (Ginsburg, J., dissenting).

questions.[215] She went on to identify several key factors that had influenced the Court to limit the preemptive impact of other federal statutes: whether Congress intended to preempt state law claims; whether the claims that would be preempted are in an area that has been traditionally occupied by state law; and whether the text of the preemption clause is susceptible to more than one interpretation.[216]

While Justice Ginsburg believed all of these factors counseled against the interpretation of Section 360k embraced by the majority opinion, she focused her discussion on the mismatch between the majority's holding and congressional intent.[217] In her view, the legislative history of the MDA clearly established that the statute was enacted to protect individuals from dangerous products that could be sold in an unregulated medical device market.[218] The core idea of the legislation was to replace the patchwork set of state regulatory systems with one uniform administrative process that all device manufacturers had to pass through prior to selling their goods on the market.[219] She noted that nothing in the MDA's history indicated that Congress had even considered, much less endorsed, the idea that the statute would foreclose injured individuals' ability to sue manufacturers via common-law claims.[220]

C. THE AFTERMATH OF *LOHR* AND *RIEGEL*

The majority opinions in *Lohr* and *Riegel* contain incredibly different approaches to conducting a federal preemption analysis. Whereas the majority of Justices in *Lohr* gave heavy credence to the Court's traditional presumption against preemption, the *Riegel* decision's only discussion of it appears in Justice Ginsburg's dissent. The Court in *Riegel* claimed that the scope of preemption should be determined exclusively through an analysis of statutory text, a stark departure from the *Lohr* Court's attempt to accord the statute the preemptive effect that Congress intended, which led it

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[215] *Id.* at 334.
[216] *Id.* at 334–35.
[217] *Id.* at 333–45.
[218] *Id.* at 335–37.
[219] *Id.* at 340–42.
[220] *See id.* at 341–42.

to review the statute's legislative history, related FDA regulations, and other materials.

While *Lohr* and *Riegel* created clear precedent for certain types of claims, the divergent views expressed in these opinions have created uncertainty among the lower courts about whether other device-related claims are preempted. Since the Supreme Court's decisions, lower courts have uniformly held that the manufacturers of 510k-approved devices can be sued for breach of some common-law duties.[221] These courts have also found that the creators of premarket approved devices cannot be held liable under state tort or products liability laws.[222] But courts have reached less uniform results when deciding whether individuals can use common-law actions to hold the manufacturers of premarket approved devices liable for breaching contractual warranties or failing to comply with federal requirements.[223] These inconsistencies have made it increasingly unclear what legal remedies exist for individuals who have been injured by premarket approved devices. As discussed in the following parts of the Article, many of these decisions have interpreted *Riegel*'s holding so expansively that they have undercut consumers' contractual entitlements and authorized governmental intrusion into otherwise private commercial relationships.

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[221] *See, e.g.*, Armstrong v. Optical Radiation Corp., 57 Cal. Rptr. 2d 763, 764, 771–73 (Cal. Ct. App. 1996) (allowing various state law claims against manufacturer of jelly used as an aid in eye surgery); Kernats v. Smith Indus. Med. Sys., Inc., 669 N.E.2d 1300, 1308–09 (Ill. App. Ct. 1996) (applying the *Lohr* analysis and finding plaintiff's tort claims against catheter manufacturer not preempted); Walker v. Johnson & Johnson Vision Prods., Inc., 552 N.W.2d 679, 684–85 (Mich. Ct. App. 1996) (rejecting the conclusion that Section 360k(a) provides for blanket preemption of all state products liability claims).

[222] *See, e.g.*, *In re* Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1166 (D. Minn. 2009) (discussing all of plaintiff's claims against manufacturer of PMA-approved cardiac defibrillator leads); Link v. Zimmer Holdings, Inc., 604 F. Supp. 2d 1174, 1178 (N.D. Ill. 2008): Heisner v. Genzyme Corp., 2008 WL 2940811, at *6 (N.D. Ill. July 25, 2008).

[223] *Compare* Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 275, 282–86 (E.D.N.Y. 2009) (finding plaintiff's negligence claims preempted for failure to demonstrate that her injuries resulted from federal violations and her contractual claims preempted to the extent that they rest on FDA-approved representations), *with* Rattay v. Medtronic, Inc., 482 F. Supp. 2d 746, 761–63 (N.D. W. Va. 2007) (finding plaintiff's [only] tort claims "preempted insofar as they allege liability on any grounds other than violation of FDA regulations" and denying defendant's summary judgment motion on plaintiff's contractual claims).

V. CONTRACTUAL IMPLIED WARRANTY CLAIMS AS THE REMEDY FOR THE COURT'S EXPANSIVE VIEW OF PREEMPTION

Having discussed the components of the federal regulatory system, the theoretical bases for manufacturer liability, and the Supreme Court's preemption decisions, it is now possible to answer the key question posed in the introduction—whether individuals who are injured by Class III medical devices have effective legal means for recovering from device manufacturers. *Lohr* comprehensively addressed this question for Class III devices that are approved through the 510k process—individuals harmed by these items can sue manufacturers for breaching common-law duties. *Riegel*, however, only provided a partial answer regarding Class III devices that have obtained premarket approval. While the Court decided that negligence and products liability claims against the manufacturers of these devices were preempted, it failed to discuss whether the MDA also precluded other state law claims.

Because *Riegel* did not hold that the MDA comprehensively preempts individual suits concerning these devices, it remains an open question as to whether the federal regulatory scheme precludes injured consumers' non-tort claims. As discussed in Part III, the non-tort claims that consumers could use to impose liability on manufacturers consist of breach of contract claims and statutory claims. While arguments could be made regarding the viability of express warranty and statutory claims, the following discussion will focus on arguing that contractual implied warranty claims remain a theoretically viable means of recovery for injured individuals.[224] This argument will be presented in three parts. First, a close scrutiny of the Court's ruling in *Riegel* will prove that the opinion does not establish that contractual implied warranty claims are preempted by the MDA. Second, a series of legal, jurisprudential, and economic reasons will establish that the MDA

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[224] There are two main reasons for focusing on implied warranty claims, as opposed to statutory claims or other contractual claims. First, because there are FDA regulations specifically exempting implied warranty claims from preclusion, a uniquely strong case can be made that they should not be preempted. 21 C.F.R. § 808.1(d)(1) (2013). Second, statutory and express warranty claims are much more difficult to discuss in the abstract, as the viability of such claims will depend on the law that is applicable in a particular jurisdiction and transaction-specific facts (e.g., additional representations that were made to the consumer).

should not be interpreted as precluding this type of contract claim. Finally, this argument will show how conflating contract and tort liability in the preemption context necessarily breaks down the theoretical division between the two and, in doing so, threatens individuals' broader contractual liberties.

A. *RIEGEL* DID NOT FORECLOSE CONSUMERS' CONTRACTUAL IMPLIED WARRANTY CLAIMS

The first hurdle facing a plaintiff who files a contractual implied warranty claim against a device manufacturer will be convincing the court that the Supreme Court's ruling in *Riegel* did not establish that Section 360k of the MDA preempts contractual claims. Indeed, in a number of post-*Riegel* decisions, device manufacturers have convinced courts to interpret the Supreme Court's decision in this manner and dismiss plaintiffs' implied warranty claims.[225] A careful analysis of the Court's opinion, however, reveals a very important, albeit technical, aspect of the *Riegel* case that prevents it from foreclosing contractual claims.

Before delving into the text of *Riegel* to establish this point, it is helpful to take a closer look at how these post-*Riegel* decisions have construed its holding. An example of such a decision is *In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation*.[226] In this suit, plaintiffs sued the manufacturer of cardiac defibrillators, alleging that the manufacturer breached common-law and statutory duties when it sold devices containing defective leads.[227] The court had to decide whether to grant the manufacturer's motion to dismiss all of the plaintiffs' claims as preempted by the MDA. In the course of finding that Section 360k preempted plaintiffs' implied warranty claims, the court stated:

> As for the implied-warranty claims, Plaintiffs ignore that the *Riegel* plaintiffs alleged a claim for breach of implied warranty and the Supreme Court affirmed the dismissal of that claim on preemption grounds. Such a claim would require a jury to determine that Medtronic

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[225] *See, e.g.*, Bentzley v. Medtronic, Inc., 827 F. Supp. 2d 443, 454 (E.D. Pa. 2011); Lemelle v. Stryker Orthopaedics, 698 F. Supp. 2d 668, 677 (W.D. La. 2010); Funk v. Stryker, 673 F. Supp. 2d 522, 531 (S.D. Tex. 2009).

[226] 592 F. Supp. 2d 1147 (D. Minn. 2009).

[227] *Id*. at 1154.

> impliedly warranted that the Sprint Fidelis leads were safe and effective and that Medtronic breached that implied warranty . . . . Such a determination clearly would interfere with the PMA process. . . . Simply put, claims such as these, which "require[ ] a manufacturer's [device] to be safer, but hence less effective, than the model the FDA has approved," necessarily "disrupt[ ] the federal scheme" and must be preempted.[228]

As discussed below, the district court's characterization of *Riegel*'s holding and its relevance to contractual claims are highly problematic.

The key error committed in many post-*Riegel* decisions is a failure to recognize that there are multiple types of implied warranty claims. As discussed in Part III, implied warranty claims that are based in tort law and those based in contract law are distinct causes of actions in some jurisdictions, with the different versions of the claim requiring plaintiffs to prove different elements.[229] As a matter of law, a judicial determination that one type of implied warranty claim is precluded by the MDA would not necessarily establish that the other type is also precluded. A careful review of the various *Riegel* decisions indicates that each court characterized all of the plaintiffs' claims as based in tort and, because of this, the Court's ruling did not address contractual claims.

The problems courts have experienced in applying *Riegel* are perhaps understandable, given how difficult it is to determine which type of implied warranty claim was before the Court. The opinions written by the district and appellate courts contain subtle indications that they viewed Riegel's claim as sounding in tort. When discussing the potential for conflict between federal regulations and state law, the district court bundled Riegel's tort and implied warranty claims together, characterizing Riegel's implied warranty claim as an attempt to get the court to subject devices to additional "state common-law requirements."[230]

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[228] *Id.* at 1164 (alterations in original) (citations omitted) (citing and quoting *Riegel*).

[229] *See* discussion *supra* Part III.

[230] *See* Riegel v. Medtronic, Inc., No. 99-CV-0649 (LEK/RWS), 2002 WL 34234093, at *5 (N.D.N.Y. Mar. 18, 2002) ("Application of state common law requirements such as those on which Plaintiff's . . . implied warranty claim [is] based. . . .").

Because a claim alleging a violation of the U.C.C. implied warranties seeks to apply requirements that are rooted in a state's *statutory* enactments, not common-law duties, the court's language is a tacit indication that it understood the claim to sound in tort. Even though the Second Circuit's opinion did not discuss the nature of Riegel's implied warranty claim, the fact that the court referred to Riegel's claims as "tort claims" throughout the opinion and exclusively cited precedents involving tort claims indicates that the appellate court also did not consider it to be a contractual claim.[231]

Finally, while the Supreme Court's decision never directly resolved this issue, there are several aspects of the opinion that indicate that the Court considered it to be a tort claim. The fact that the majority failed to discuss the implied warranty claim in any depth—only mentioning it twice[232]—and did not distinguish it from the negligence and products liability claims shows that it was considered to be one of many tort-based claims. Further reinforcing this construction of the claim are the majority's description of Riegel's suit as consisting of "common law tort claims," and its statement that Riegel's suit, including his implied warranty claim, "depends upon New York's 'continu[ing] in effect' general tort duties 'with respect to' Medtronic's catheter."[233] Last, it is highly unlikely that the Court understood Riegel to be making a U.C.C.-based claim, given that it failed to mention Riegel's implied warranty claim when it discussed 21 C.F.R. § 808.1(d), a regulation that excludes "requirements such as . . . the Uniform Commercial Code['s] (warranty of fitness)" from being preempted by the MDA.[234]

Because the plaintiffs' implied warranty claim in *Riegel* alleged that the manufacturer breached a common-law tort duty, the Court's decision cannot be interpreted as establishing the preemption status of contract-based implied warranty claims. While any number of considerations might convince a court to find that contractual claims are also preempted under the MDA, the Court's dismissal of the tort-based claims in *Riegel* does not

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[231] *See, e.g.*, Riegel v. Medtronic, Inc., 451 F.3d 104, 106 (2d Cir. 2006) ("Specifically, we must decide whether Section 360k(a) preempts common law tort claims. . . .").

[232] Riegel v. Medtronic, Inc., 552 U.S. 312, 320, 327 (2008).

[233] *Id.* at 327–28.

[234] *Id.* at 328–29.

mandate this result. Having established that existing Supreme Court precedents have not foreclosed contractual claims, the next section sets forth a number of reasons why the MDA should not be viewed as barring these claims.

B. WHY CONTRACTUAL IMPLIED WARRANTY CLAIMS ARE NOT PREEMPTED BY THE MDA

Because the Court's existing precedents have not addressed the viability of contractual implied warranty claims, whether these claims are preempted by the MDA remains an open question. A number of considerations suggest that the answer to this question should be a resounding "no." First, the text of the MDA and its associated regulations unambiguously indicate that the federal regulatory scheme does not preclude contractual implied warranty claims. Second, permitting contractual claims would be in line with the Court's preemption jurisprudence and would advance the legislative interests that inspired the federal government to regulate medical devices in the first place. Finally, permitting contractual claims will likely benefit the regulatory system as a whole by allocating the costs associated with device-related injuries to the parties most able to spread the loss and reduce injury rates.

1. MDA-Authorized Regulations Exempt Contract-Based Claims from Preemption. The text of the MDA and the regulations that have been promulgated pursuant to it unambiguously indicate that contractual claims are not preempted. Subsection (b) of 360k states that "the Secretary [of Health and Human Services] may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from [preemption] a requirement of such State or political subdivision applicable to a device intended for human use."[235] Pursuant to the authority granted by this provision, the FDA enacted Part 808 of Title 21 of the Code of Federal Regulations, titled "Exemptions from Federal Preemption of State and Local Medical Device Requirements."[236] Subsection 808.1(d) of the regulation states that:

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[235] 21 U.S.C. § 360k(b) (2012).

[236] 21 C.F.R. §§ 808.1–101 (2013); *see also* Medtronic, Inc. v. Lohr, 518 U.S. 470, 482 n.5 (1996).

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . . . *There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act* because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. . . . (1) *Section 521(a) does not preempt State or local requirements of general applicability* where the purpose of the requirements relates either to other products in addition to devices *(e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness))* . . . .[237]

Given that Section 808.1(d) specifically lists U.C.C.-based claims as an example of the types of generally applicable claims that are exempt from preemption, it is clear that the MDA does not prevent individuals from pursuing these claims.

The main problem with relying on Section 808.1(d) to support the viability of U.C.C.-based claims is the existence of judicial uncertainty about the extent to which a *regulation* issued by a federal agency can impact the preemptive scope accorded to a congressionally enacted *statute*.[238] When the Court was presented with this issue in *Riegel* it explicitly refused to resolve it.[239] Finding that it was unclear whether Section 808.1 would apply to Riegel's tort-based claims, the majority punted on the larger issue, stating that it was "[n]either accepting nor rejecting the proposition that [the] regulation can properly be consulted to determine the statute's meaning."[240]

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[237] 21 C.F.R. § 808.1(d) (emphasis added).

[238] For an overview of the ambiguities in the Supreme Court's approach to these issues, see William Funk, *Judicial Deference and Regulatory Preemption by Federal Agencies*, 84 TUL. L. REV. 1233, 1239–41 (2010).

[239] *Riegel*, 552 U.S. at 328–30.

[240] *Id.* at 329–30. The fact that the Court ended up refusing to allow Section 808.1(d) to influence its preemption analysis in *Riegel* is irrelevant in the context of U.C.C.-based claims. Because the regulation specifically identifies U.C.C.-based claims as exempt from preemption, it is clear that these claims, unlike the tort-based implied warranty claims at issue in *Riegel*, fall within the regulation's safe harbor.

Despite the Court's agnosticism concerning the role that regulations can play in limiting the preemptive scope of federal statutes, there are particularly strong reasons for allowing Section 808.1(d) to affect MDA-related preemption. First, because Section 360k(b) explicitly authorizes the FDA to exempt state requirements from preemption, it is clear that the MDA's enactors intended for the FDA to play an active role in deciding which types of claims would be precluded.[241] Even if this were not the Legislature's intent, the text of 360k(b) is unambiguous and, hence, the Court's statutory construction doctrines dictate that they enforce it as written. Because Section 360(b) gives the FDA statutorily-conferred authority to set limits on the MDA's preemptive effects, the Judiciary must respect the agency's views.

Second, recognizing the FDA's regulation as authoritative would be consistent with the Court's opinion in *Lohr*, which relied on other portions of Section 808.1 and other regulations when interpreting the meaning of Section 360k.[242] Finally, allowing the FDA to limit the MDA's preemptive scope simply makes a great deal of sense. Because the FDA is the entity responsible for administering the MDA, it possesses a unique understanding of medical device regulation and is in the best position to determine whether particular types of state requirements would interfere with the federal government's regulatory objectives.[243]

2. The Court's Federal Preemption Doctrines Support Permitting Contractual Implied Warranty Claims. The Court's general approach to preemption issues also counsels against finding that the MDA preempts contractual implied warranty claims. While many wondered whether the majority's opinion in *Riegel* signified a permanent shift away from the traditional presumption against preemption,[244] the Court's later decisions have established that it has made no such commitment.

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[241] Medtronic, Inc. v. Lohr, 518 U.S. 470, 496 (1996) ("For example, Congress explicitly delegated to the FDA the authority to exempt state regulations from the pre-emptive effect of the MDA . . . .").

[242] *Id.* at 495–97; *id.* at 505–06 (Breyer, J., concurring).

[243] *Id.* at 506 (Breyer, J., concurring).

[244] *See* Mary J. Davis, *On Restating Products Liability Preemption*, 74 BROOK. L. REV. 759, 770–71 (2009) (noting that the Court's language is expansive); Catherine M. Sharkey, *What* Riegel *Portends for FDA Preemption of State Law Products Liability Claims*, 102 NW. U. L. REV. 437, 438–39 (2008) (stating that *Riegel* may allow for more room to resort to judicial policymaking in preemption cases).

Subsequent to *Riegel*, the Court issued a decision in a medical drug preemption case—*Wyeth v. Levine*[245]—that indicated that the doctrine was still alive and well.[246] In *Wyeth*, the Court reasserted its view that the Judiciary should regard "the purpose of Congress [to be] the ultimate touchstone" when deciding preemption issues.[247] Further, it stated that when "Congress has legislated in a field which the States have traditionally occupied, 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 purpose of Congress."[248] The status of the presumption against preemption remains somewhat uncertain, however, given the Court's decision in *Mutual Pharmaceutical Co. v. Bartlett*.[249] As in *Riegel*, the *Bartlett* majority failed to mention the presumption when deciding whether the federal drug regulatory system preempted consumers' state common-law claims.[250]

If one applies the presumptions articulated in *Wyeth* in the context of medical device regulation, it is clear that the MDA should not be interpreted as preempting implied warranty claims. First, there is no evidence suggesting that Congress meant for the federal regulatory system to insulate device manufacturers from liabilities imposed by state common-law claims.[251] Indeed, the timing of the statute's enactment and its legislative history indicate that Congress's primary motivation for including Section 360k in the statute was its concern that conflicts could develop between the federal system and the premarket regulatory systems that certain states had developed.[252] Even in the sections of the MDA's legislative history discussing congressional concerns about

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[245] 555 U.S. 555 (2009).

[246] *See* Gillian E. Metzger, *Federalism and Federal Agency Reform*, 111 COLUM. L. REV. 1, 18–20 (2011) (noting that *Wyeth* prominently invoked the presumption against preemption). *But see* Smirniotopoulos, *supra* note 13, at 821–22 (arguing that the presumption against preemption continues to be a "jurisprudential myth").

[247] *Wyeth*, 555 U.S. at 565 (quoting *Lohr*).

[248] *Id.* (alterations in original) (internal quotation marks omitted) (quoting *Lohr*).

[249] 133 S. Ct. 2466 (2013).

[250] *Id.* at 2470.

[251] *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 336–39 (Ginsberg, J., dissenting) (discussing the "MDA's failure to create any federal compensatory remedy").

[252] *See id.* at 340–42 (noting that a preemption clause was not needed "in earlier federal laws regulating drugs and additives, for states had not installed comparable control regimes in those areas").

device manufacturers being stifled by legal restrictions, it is clear that Congress considered the principal threats to be conflicting state and federal regulations or an overly-complex federal regulatory system—not liability imposed on manufacturers by consumer suits.[253]

Second, because of the central role that state law historically played in medical device litigation, the only way a federal statute could preclude contractual claims would be if preemption was "the clear and manifest purpose of Congress."[254] As discussed in Part II, prior to the MDA's enactment, the regulation of medical devices fell firmly within states' traditional police powers.[255] Further, in the decades preceding the MDA's enactment, the propriety of using state law claims to impose liability on device manufacturers was well established. Because Congress was unquestionably aware of these facts, the only way it could have quashed state law's role in this field would be if it was absolutely clear that it intended to preempt device-related claims based on state law.

Not only does the legislative history of the MDA fail to satisfy the standards articulated in *Wyeth*, but the text of the preemption provision also fails to express the requisite congressional intent. As noted by Justice Stevens, if Congress had intended to immunize manufacturers from liability for violating all duties imposed by state law, it would have been easy for it to achieve this result.[256] For instance, it could have written the statute so that it barred courts from awarding any "remedy under state law relating to medical devices."[257] Additionally, the fact that Section 360k states that conflicting state law requirements are preempted should not be considered a clear expression of preemptive intent with regard to common-law claims, as at the time of the MDA's enactment, it was unclear whether the liabilities imposed by state common-law claims constituted requirements.[258] Further, the way that

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[253] Medtronic, Inc. v. Lohr, 518 U.S. 470, 489–91 (1996).

[254] *Id.* at 485 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

[255] *Id.* at 475, 485 ("States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." (quoting Metro. Life Ins. Co. v. Mass., 471 U.S. 724, 756 (1985))).

[256] *See id.* at 487 (noting how Congress could preclude common-law claims in the MDA).

[257] *Id.*

[258] The case generally credited for establishing that a statute that preempts "requirements" could include common-law duties—*Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)—was not decided until 1992. *See also Lohr*, 518 U.S. at 510 (O'Connor, J., concurring) (acknowledging *Cippollone*'s importance).

"requirements" is used in the remainder of Section 360k indicates that the term was meant to refer to "device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries."[259]

3. The Costs Associated with Immunizing Manufacturers from Liability Outweigh the Potential Costs of Allowing Consumer Suits. A basic economic analysis of the likely impacts of allowing contractual implied warranty claims suggests that the law should permit these claims. If one accepts that the fundamental goal of a regulatory system is to maximize welfare across society, it becomes possible to assess the desirability of alternative regulatory systems by comparing the total welfare that each system would create. Obviously, it would be incredibly difficult—if not impossible—to do any sort of precise valuation of the welfare generated by alternative regulatory schemes. But as long as the analysis remains sufficiently abstract and the key factors that will impact welfare generation can be identified, it is possible to draw conclusions about the desirability of rival schemes.

The simplest way to assess whether it would be beneficial to allow individuals to file contractual implied warranty claims is to compare two regulatory systems that are identical to one another except in the preemption status of these types of claims. Thankfully, this type of comparison does not require a model that captures the immense number of factors that influence the total welfare generated by the larger medical device regulatory system. Rather, because of the similarity of the two systems, the model only needs to account for the set of welfare-influencing factors that would be impacted by differing stances on implied warranty claims. While a number of factors could potentially fall within this set, those with the greatest impact on welfare would be: (1) device-caused injuries (reduces welfare); (2) fear-based under-consumption of medical devices (reduces welfare); and (3) medical device innovation, development, and commercial availability (increases welfare).

Comparing the effects that allowing (or barring) implied warranty claims would have on these factors will provide a general

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[259] *Lohr*, 518 U.S. at 489 (Stevens, J., plurality opinion).

sense of how regulatory systems embracing each of these stances would stack up to one another:

- A system that permits implied warranty claims would likely decrease the welfare reductions associated with factors (1) and (2), but it might also decrease the welfare generation associated with factor (3). By giving individuals a means for seeking compensation for device-caused injuries, this system would create a threat of liability that would incentivize manufacturers to make safer products. Authorizing such claims would also decrease the likelihood that consumers' fears about lacking effective legal recourse would cause an underutilization of medical devices. The threat of financial losses posed by these claims, however, could impair welfare by threatening the profit margins of device manufacturers, discouraging investment in the medical device industry, and limiting the availability of devices.
- A system that does not allow implied warranty claims would likely increase welfare reductions associated with factors (1) and (2), but it might also increase the welfare generation associated with factor (3). By foreclosing individuals' ability to sue device manufacturers for injuries, this system would not push manufacturers to take appropriate measures to ensure that their products are safe. Further, this system could lead to individuals under-consuming welfare-generating medical devices due to fears that they will be injured by a device and lack any way of obtaining compensation. Finally, by insulating medical device manufacturers from contractual liabilities, this system might increase welfare by incentivizing innovation and investment in this industry.

While the results of the preceding analysis might appear to be inconclusive as to determining whether the regulatory system

should allow implied warranty claims, supplementing it with additional observations demonstrates why welfare will most likely be maximized in a system that permits these claims. First, as a general matter, policy evaluations must take into account the fact that entities vary in their capacity to assess and manage loss.[260] Second, it is generally accepted that it is preferable to allocate liability to parties that are in the best position to prevent, mitigate, or spread losses.[261]

It is clear that manufacturers and individuals have vastly different capabilities when it comes to handling the losses that these regulatory systems would place on them. Manufacturers who are concerned about the financial liabilities associated with implied warranty suits can: (1) incorporate estimates of their potential losses into product pricing, increasing their profit margins to mitigate against future litigation costs;[262] (2) procure liability insurance policies that would shift the costs of these liabilities to insurance companies; or (3) increase the time and capital they spend ensuring that their products are safe, thus reducing the likelihood that their products will injure consumers. On the other hand, individuals who are barred from suing manufacturers will often lack an effective means for mitigating, transferring, or avoiding the losses they could experience due to a faulty medical device. Not only are individuals limited in their

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[260] *See* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 93 (3d ed. 1986) (noting that the cheaper insurer amongst contracting parties can be determined by comparing their measurement costs and transaction costs of a potential event rendering a contract uneconomical); Roger B. Godwin, *Negligent Interference with Economic Expectancy: The Case of Recovery*, 16 STAN. L. REV. 664, 677–89 (1964) ("[B]etween an individual and a business enterprise the enterprise is almost always the better distributor of the loss and consequently should be made to bear it. . . ."); Ronen Perry, *Relational Economic Loss: An Integrated Economic Justification for the Exclusionary Rule*, 56 RUTGERS L. REV. 711, 763 (2004) ("[A]mong commercial entities the larger are usually better loss spreaders[,] and among equally large commercial entities the ones that operate in the less competitive market are usually better loss spreaders.").

[261] *See* Guido Calabresi, *Fault, Accidents, and the Wonderful World of Blum and Kalven*, 75 YALE L.J. 216, 225 (1965) ("Economic theory suggests . . . that the party who can beter evaluate the risk of accidents is the better loss bearer. . . ."); Godwin, *supra* note 260, at 677–78 (discussing loss spreading).

[262] Building litigation costs into the price of a product is particularly viable in the medical device context, where firms typically have few competitors and the market in general is considered to be thin.

ability to insure against device-related losses,[263] but special characteristics of the medical device market make it extremely difficult for individuals to engage in the types of risk-mitigating actions that are available in other markets.[264] Given these considerations, it is clear that the burdens imposed by a pro-liability regulatory regime could be minimized more easily than the burdens imposed by a system that prohibits contractual claims.[265]

C. CONFLATING CONTRACTUAL LIABILITY WITH TORT LIABILITY IGNORES CRUCIAL DISTINCTIONS BETWEEN THE TWO AND UNDERMINES INDIVIDUAL CONTRACT LIBERTIES

The lower courts that have preempted consumers' contractual claims have completely failed to recognize fundamental differences between the nature of contract and tort liability. As discussed earlier, these courts' rulings have relied on the Court's tort-specific holding in *Riegel* to justify dismissing consumers' contractual claims.[266] Further, it is common for these opinions to contain essentially no discussion of the theoretical bases of plaintiffs' claims or whether it makes sense for particular claims to be preempted. This section will describe two characteristics—transaction specificity and origin of obligation—that differentiate contract and tort liability in the regulatory preemption context. It will show why the reasons for preempting tort claims are less persuasive for contract claims and discuss how preemption opinions that fail to acknowledge this point pose a threat to contractual liberties.

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[263] While standard health insurance policies would provide coverage for medical care expenses that are incurred due to faulty devices, these policies would do nothing to compensate individuals for their non-pecuniary losses.

[264] For instance, because individuals are unable to predict their future needs for any particular medical device, it is typically impossible for them to proactively engage in the types of economic, educational, or political activities that could impact the safety-related decisions made by the manufacturers of the device they need. Further undercutting the ability of individuals to preemptively spread risk is the fact that, when an individual is in need of a medical device, their demand is urgent. Finally, at least for certain types of devices, there are few—if any—available substitute goods, inhibiting the ability of consumers to avoid device-related risks altogether.

[265] *See* Elizabeth A. Weeks, *Beyond Compensation: Using Torts to Promote Public Health*, 10 J. HEALTH CARE L. & POL'Y 27, 29–32 (2007) (discussing the benefits of loss-spreading created by the tort system). *See generally* STEVEN SHAVELL, ECONOMIC ANALYSIS OF ACCIDENT LAW (1987) (explaining and analyzing the basic theory of cost spreading).

[266] *See supra* Part V.A.

A defendant's liability for a negligence or products liability tort claim is premised on the idea that the common law requires members of society to observe certain duties of care when engaging in acts that could injure others.[267] While a number of factors will influence the degree of care a defendant owes to any particular individual, a defendant will generally owe identical duties across groups of individuals with whom the defendant shares identical relationships.[268] For instance, a manufacturer is likely to owe very similar duties of care to each consumer that purchases one of its products. Because of the similarities of these duties, a judicial finding that a manufacturer is liable in tort to one individual who purchased its product will typically have much broader impacts, establishing that the manufacturer breached its duty of care to all of the product's consumers.[269] The degree to which these findings can be generalized across sales of the device is an essential component of why tort liabilities can be viewed as imposing "requirements" on the device.[270]

A defendant's liability for a contract claim, on the other hand, is premised on the idea that the common law requires parties to abide by the promises they make when entering into transactions with one another.[271] While the common law provides a governing rule that applies to everyone who enters into a contract—parties must not breach their contractual obligations—it does not dictate the substance of each party's obligations.[272] Because the contract is the progenitor of each party's duties to one another, it is generally the agreement itself—not a common-law duty—that will determine whether contractual liability exists.[273] Given that even the smallest differences—whether it is the parties' identities, the exact terms of the deal, or the circumstances surrounding the transaction—can affect parties' obligations to one another, it is

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[267] *See* discussion *supra* Part II.A.

[268] *See* discussion *supra* Part II.A.

[269] *See* discussion *supra* Part III.A.

[270] *See* Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 521–22 (1992) ("[C]ommon law damages actions . . . are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose 'requirements' . . . ."). *But see* Medtronic, Inc. v. Lohr, 518 U.S. 470, 502–03 (1996) ("It will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device.' " (quoting 21 C.F.R. § 808.1(d)(6)(ii) (1995))).

[271] *See* discussion *supra* Part III.B.

[272] *See* discussion *supra* Part III.B.

[273] *See* discussion *supra* Part III.B.

more difficult to generalize contractual liability across transactions.[274]

The transaction-specific nature of contractual obligations means that verdicts entered on such claims have very different implications for manufacturers. Because an individual's contractual obligations are created and defined by the terms of each agreement he enters into, a finding that a manufacturer's conduct breached obligations when selling a product to one customer would not prove that it breached obligations originating from transactions with other consumers. Hence, a finding that a device failed to satisfy a contractual warranty would not necessarily impact the device's manufacturers in the same way a tort judgment would.

Not every contract, however, is an island unto itself. While the contracts used in certain types of transactions will be negotiated and differ significantly from one another, the contracts used in other commercial contexts will not. Given the informal manner in which medical devices are sold to individuals—through an intermediary, with little negotiation or debate over the terms of the deal, and typically with no written record—it is common for the contracts underlying these transactions to consist primarily of default provisions supplied by the U.C.C. Because of this, a device manufacturer's transactions with its consumers will bear a high degree of similarity with one another and many provisions—such as the implied warranties of merchantability and fitness for particular purpose—will be identical across transactions. In such an environment, there is a significant likelihood that a judicial determination that a manufacturer breached one of these warranties could be generalized across transactions.[275] If the key factor for determining whether a claim imposes a requirement is the degree to which a verdict would be applicable across consumer

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[274] *See* discussion *supra* Part III.B.

[275] *See, e.g.*, Seekamp v. It's Huge, Inc., No. 1:09-CV-00018 (LEK/DRH), 2012 WL 860364 at *3–4 (N.D.N.Y. Mar. 13, 2012) (finding that plaintiff met commonality and typicality prerequisites to class certification against seller of allegedly illegal insurance product); Boundas v. Abercrombie & Fitch Stores, Inc., 280 F.R.D. 408, 415 (N.D. Ill. 2012) (discussing the principle of predominance and how it can be resolved on a class-wide basis without any individual variation); Hayes v. Wal-Mart, 281 F.R.D. 203, 214 (D.N.J. 2012) (allowing plaintiffs to pursue claim under state consumer fraud act where harm alleged arose from defendant's company-wide conduct); Winkler v. DTE, Inc., 205 F.R.D. 235, 243 (D. Ariz. 2001) (discussing predominance test in action brought by plaintiffs who had bought vehicles with a standard purchase contract).

transactions, then contractually implied, warranty-based claims would impose requirements in the same manner as a tort action.

The transferability of liability determinations, however, is not the only thing that differentiates tort and contract liability. Nor is it the sole criterion for determining whether the resolution of a claim would impose a requirement. Section 360k(a) prohibits states from establishing device-related requirements, but says nothing about private actors imposing additional requirements on themselves.[276] Why does this distinction matter? Assume that a court enters a judgment that imposes tort liability on a device manufacturer, finding that the company was negligent for failing to include a back-up power source in its surgically implanted device. Under the Court's reasoning in *Riegel*, this verdict creates a requirement because it states that the common law dictates that medical devices of a certain type must be designed and assembled in a particular way.

Now consider a judicial determination that the same manufacturer is liable to a consumer because their failure to include a back-up power source breached the contract of sale's implied warranties. Such a finding would necessarily include a determination that the product supplied by the manufacturer failed to satisfy the standards of merchantability (or fitness for a particular purpose) contained in the parties' contract. But this verdict would not constitute a judgment that a state's common law requires the device to be designed, manufactured, or sold in a particular manner. Rather, it would simply indicate (1) that standards of merchantability or fitness for a particular purpose require a back-up power source and (2) that the state will impose liability on entities that promise to satisfy these standards and subsequently breach their obligations.

Within the context of regulatory preemption, the distinction between liabilities that are based on mandatory, state-originated standards and those based on optional, self-imposed standards is of critical importance.[277] Judicial determinations about whether certain acts violate tort-based standards of care can pose a direct threat to a regulatory system that is tasked with authorizing or

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[276] 21 U.S.C. § 360k(a) (2013).

[277] *See* Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 526 (1992) (stating that "a common-law remedy for a contractual commitment voluntarily undertaken should not be regarded as a requirement . . . *imposed under State law* . . ." (internal citations omitted)).

policing behavior within the relevant sphere of activity. If the law allows both bodies to set standards, it is inevitable that the regulatory agency and the Judiciary will disagree on certain issues, and it will be impossible for an actor to be in compliance with each authority's rules. This problem simply cannot arise within the context of contractual claims. Since the parties to a contract are free to set the terms of the contract—i.e., they can avoid making express warranties and can waive or modify implied warranties—judicial determinations regarding breach of contract cannot be viewed as a threat to the regulatory system's authority.[278]

Bolstering this conception of the relationship between contractual claims and regulatory preemption is the fact that embracing the opposite conclusion—that breach of contract judgments can constitute requirements—would lead to absurd results. Consider a situation wherein a manufacturer's agreement with a consumer obligates it to deliver artificial knee joints to the consumer on July 1st. The agreement does not actively disclaim the U.C.C.'s implied warranties, so the agreement also obligates the manufacturer to provide devices that are merchantable. Further, the contract expressly warrants that the joints will be free of any defects. On July 1st, the manufacturer breaches both of these obligations—it provides the consumer with knee joints with manufacturing defects and the joints are not fit for use. The consumer files suit against the manufacturer, alleging that the manufacturer breached the contract by failing to supply the proper quantity of devices and by providing devices that were not of merchantable quality.

There are not analytically sound grounds for distinguishing between such a consumer's implied warranty and express warranty claims in the context of making a Section 360k preemption determination. Both claims are basic breach of contract actions. As breach of contract actions, the two claims are

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[278] One might wonder whether it makes sense to distinguish the preemption status of tort and contract liabilities on the grounds of disclaimability, given the ease with which manufacturers could immunize themselves from contractual claims. Even if it is true that, if courts adopted this rule, manufacturers would be likely to take affirmative acts to ensure that they could not be held liable for breaching implied warranties, it does not follow that the doctrinal change would be inconsequential. The acts taken by the manufacturers would necessarily increase consumers' knowledge about the risks associated with use of the device, informing their consent.

functionally identical—each seeks to impose liability on the manufacturer for failing to satisfy a contractual obligation. If a court concluded that the consumer's implied warranty claim against the manufacturer is preempted because the liability imposed by the claim would constitute a requirement that conflicted with the federal scheme, then the court would be compelled to find that the consumer's express warranty claim is preempted for the same reason. Attempting to distinguish the claims on the grounds that the express warranty claim constitutes a self-imposed requirement that goes beyond the federal standard, whereas the implied warranty claim is an attempt to supplant existing regulatory standards is a dead-end. Section 360k(a) explicitly preempts state requirements that are "in addition to," as well as "different from," the federal scheme.[279]

The idea that the MDA preempts both of these contractual claims is highly unpalatable and highlights one of the ways current preemption jurisprudence assaults basic contractual liberties. The right of individuals to hold their contractual partners liable for breaching their promises is a fundamental part of modern economies. Even the most ardent supporter of federal preemption would find it difficult to argue that regulatory systems should be permitted to extinguish individuals' right to sue manufacturers for breaching unambiguous promises set forth in their contracts. Because viewing contract-based liabilities as imposing requirements would force this conclusion, interpreting contractual claims in this way is an untenable position.

Bundling a device manufacturer's contract and tort liabilities for preemption purposes also undermines the basic safeguards that the law has developed for protecting the rights of parties involved in commercial transactions. As discussed earlier, the U.C.C. imposes liability on the seller of a good when its product fails to satisfy the implied warranties of merchantability and fitness for particular use or any express warranties made by the seller.[280] By imposing default rules that hold parties selling goods responsible in these ways, the U.C.C. has ensured that consumers' reasonable expectations concerning contractual liability are respected. Out of respect for individuals' contractual liberty, the U.C.C. allows parties to negotiate the applicability of warranty

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[279] 21 U.S.C. § 360k(a)(1) (2012).

[280] *See supra* Part III.B.

liability, meaning that the seller of a good can avoid this liability by disclaiming it in the sales contract or obtaining a waiver from the purchaser. Considering how medical device sales typically occur, it would be difficult (but not impossible) for a manufacturer to disclaim warranty liabilities. However, when we take into consideration the severity of the injuries that are common in this context and the fact that, absent such disclosure, there would be no way for consumers to know that they cannot sue for breach, it seems fair to put this burden on manufacturers.

Finally, the Judiciary's preemption-based intrusion into contract law is wholly gratuitous. Judicial abrogation of private actors' basic contractual rights is detrimental to contractual liberty and, as such, should only occur when it is necessary to achieve an important goal. As discussed above, it is wholly within the power of manufacturers to immunize themselves from warranty-based contractual liability via disclaimers and waivers. The availability of this entirely private solution debunks the argument that an expansive preemptive scope is needed to avoid putting manufacturers in a position where they cannot satisfy both regulatory and common-law standards.

D. CONCLUSION

The preceding sections have established why, contrary to the holdings of several district and appellate courts, the MDA should not preclude consumers from bringing contractual implied warranty claims against device manufacturers. The first section showed that the Supreme Court's opinion in *Riegel* did not find that the MDA preempts contractual implied warranty claims. A careful analysis of the claims that were before the Court in *Riegel* and the text of the opinion reveals that the Court never even considered this issue. The second section provided several justifications for finding that contractual implied warranty claims fall outside the scope of the MDA's preemption provision. Chief among these reasons is the fact that the MDA authorizes the FDA to exclude state requirements from preemption and one of the FDA's regulations specifically exempts these claims from preemption. Additionally, it was shown that precluding these claims would violate the Court's federal preemption jurisprudence and that a regulatory system that permits such claims would be more likely to maximize general welfare. The third section

discussed the fundamental differences that distinguish contract and tort liability and explained why conflating these claims in the regulatory preemption context poses a threat to contractual liberties.

VI. PARALLEL REQUIREMENT CLAIMS AS A SUPPLEMENT TO CONTRACTUAL CLAIMS

While this Article's primary focus has been on exploring whether contractual implied warranty claims can give consumers a viable means for suing the manufacturers of faulty devices, a brief discussion of the one other type of claim that could help consumers—parallel requirement claims—is warranted. A parallel requirement claim is not a particular cause of action itself, but a categorical term that refers to any common-law or statutory claim attempting to impose liability on a manufacturer for violating federal regulatory requirements.[281] Because the Supreme Court has stated that the PMA does not preempt parallel requirement claims, they can be an attractive option for individuals seeking to recover from device manufacturers.[282] These claims do not present a panacea for all injured consumers, however, given that they are limited in a number of ways.

The Court's first discussion of parallel requirement claims can be found in its *Lohr* decision. In *Lohr*, the majority noted that even if the court found that a medical device was subject to specific federal requirements concerning its design, manufacture, or labeling, Section 360k would not preempt individuals from suing manufacturers for violating common-law duties unless the common-law duties were "different from, or in addition to" the

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[281] *See* Mark Herrmann, David Booth Alden & Bradley W. Harrison, *The Meaning of the Parallel Requirements Exception Under* Lohr *and* Riegel, 65 N.Y.U. ANN. SURV. AM. L. 545, 545–46 (2010) (noting the *Lohr* Court's observation that nothing in Section 360k denies a state the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements).

[282] *Id.* (noting that the Court said that Section 360k does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations when the state duties parallel, rather than add to, federal requirements); Elliot Sheppard Tarloff, Note, *Medical Devices and Preemption: A Defense of Parallel Claims Based on Violations of Non-Device Specific FDA Regulations*, 86 N.Y.U. L. REV. 1196, 1196 (2011) (observing that the Court has clearly indicated that consumers injured by medical devices can bring lawsuits based on claims that are parallel to the FDA's requirements).

federal requirement.[283] They stated that Section 360k did not prohibit individuals from using state common-law causes of action to hold device manufacturers liable for injuries that can be linked to the company's failure to comply with federal requirements.[284] In support of this conclusion, the Court pointed to the fact that numerous provisions of the MDA suggest that the FDA has broad authority to determine the statute's preemptive scope and that the regulations subsequently promulgated by the FDA "expressly support the conclusion that § 360k 'does not preempt State or local requirements that are equal to, or substantially identical to requirements imposed by or under the act.' "[285]

The Court's decision in *Riegel* further endorsed the viability of parallel requirement claims. The majority concluded that, because "[s]tate requirements are pre-empted under the MDA only to the extent that they are different from, or in addition to the requirements imposed by federal law," the statute does not "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations."[286] The majority refused to discuss whether plaintiffs could use common-law tort claims as a vehicle for alleging a parallel requirements violation, finding that this issue was not properly before the Court.[287]

Unfortunately, suits attempting to impose liability on manufacturers via parallel requirement claims have established that these claims suffer from a number of limitations. First, because district and appellate courts have disagreed with one another about whether particular causes of actions provide a suitable vehicle for alleging parallel requirement claims, it has been difficult for plaintiffs to figure out how to bring these claims.[288]

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[283] Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996).

[284] *Id.*

[285] *Id.* at 496–97 (quoting 21 C.F.R. § 808.1(d)(2) (1995)).

[286] Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (internal quotation marks omitted).

[287] *Id.*

[288] *See In re* Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Lit., 623 F.3d 1200, 1209–14 (8th Cir. 2010) (Melloy, J., concurring in part and dissenting in part) (observing that the combination of the rigid application of *Twombly* and the parallel claim exception to Section 360k preemption has led to the dismissal of numerous potentially meritorious lawsuits, and this is unjust due to the complexity of this evolving area of law); Stengel v. Medtronic, Inc., No. CV10-318-TUC-RCC, 2010 WL 4483970, at *2–3 (D. Ariz. Nov. 9, 2010) (noting that plaintiff's amended complaint, raising allegations that defendant failed to warn, is impliedly preempted); Frank-Jackson, *supra* note 11, at 492–95 (noting that new pleading rules and unclear precedent have presented further obstacles and challenges with regards to how plaintiffs are to bring these parallel requirement claims; Tarloff, *supra* note

Second, parallel requirement claims impose significantly heavier pleading burdens on plaintiffs at an earlier stage of litigation than most other claims.[289] In order to properly plead a parallel requirement claim, plaintiffs must identify the specific federal requirements that were allegedly breached, which is no small task given that much of the critical information about device specifications is kept confidential as a matter of federal law.[290] Finally, and most significantly, there will be situations where the circumstances surrounding an individual's injury would prevent him from being able to allege a parallel requirement claim. For instance, an individual could be injured by a device that, despite being in compliance with the applicable federal requirements, is unfit for use. In such a case, the individual would not be able to recover under a parallel requirement claim.

Were it not for the significant limitations of parallel requirement claims, the viability of contractual implied warranty claims might be a purely academic question. Because these shortcomings exist, however, it is best to consider parallel requirement claims and contractual implied warranty claims to be complements to one another. While plaintiffs will sometimes be eligible to recover under both types of claims, it will often be the case that only one of the two fit the facts.

VII. CONCLUSION AND FUTURE IMPLICATIONS

The status quo's failure to provide individuals with recourse against the manufacturers of defective medical devices must be remedied. There are strong legal, theoretical, and economic reasons for rejecting the Judiciary's expansive construction of the MDA's scope of preemption. Because immunizing manufacturers

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282, at 1198–1201 (arguing the Court failed to define precisely the concept of a parallel claim).

[289] *See* Clark v. Medtronic, Inc., 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008) (observing that plaintiff's claims failed because, when faced with a motion for summary judgment, plaintiff offered no evidence to support his assertions); Frank-Jackson, *supra* note 11, at 492–95 (stating that requiring plaintiffs to properly state a parallel claim to survive pleading dismissal, when there is no clear precedent on what parallel causes of actions exist, is a near-impossible burden and invites arbitrary dismissal of claims against medical device manufacturers).

[290] *See* Bausch v. Stryker Corp., 630 F.3d 546, 560 (7th Cir. 2010) (observing that a victim of a genuinely defective product may not be able to determine without discovery and further investigation whether the problem is a design or manufacturing problem).

from consumer-based liabilities shifts the costs of device-related injuries away from the entities that are in the best position to manage losses, doing so is economically inefficient. Further, a comprehensive analysis of the statutes and regulations that compose the federal regulatory system establishes that contractual claims are not preempted. Finally, the lower courts' decisions fail to recognize fundamental differences in the nature of tort and contract liabilities. Acknowledging these differences—particularly the private, self-imposed origin of contractual liabilities—counsels against finding that federal regulatory systems preempt contractual claims.

Many of the arguments developed in this Article are relevant to larger questions about federal preemption doctrines and the rules governing the Judiciary's interpretation of complex statutory and regulatory schemes. In particular, the discussion of the differences between tort and contract liability and the implications that these distinctions have in the preemption context merits further analysis. Future work should explore the viability of contractual claims in other industries where there is a strong federal regulatory presence, survey judicial decisions analyzing the nature of tort and contract liabilities, and empirically evaluate the economic impacts of imposing contractual liability on product manufacturers. This Article's discussion of judicial construction of statutes and regulations in complex federal regulatory schemes identifies another issue that is ripe for further research. Until the Supreme Court clarifies the nature of the relationship between statutory preemption provisions and statutorily authorized regulations that limit preemption, this issue is bound to arise in litigation involving federally regulated industries.