

Recovery and Preemption: The Collision of the Medicare Secondary Payer Act and the Medical Device Amendments

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Congress often uses its power to preempt state laws when a uniform nationwide regulatory environment is desirable. Unfortunately, preemption may have unintended, far-reaching effects. When Congress enacted the Medical Device Amendments of 1976 (“MDA”), it included an express preemption clause to ensure that only the Food and Drug Administration (“FDA”) could establish ex ante, premarket requirements for medical devices, thus allowing the Agency to establish a uniform regulatory floor. Just four years later, Congress enacted the Medicare Secondary Payer Act (“MSP”), part of a series of amendments to the Medicare program designed to improve the program’s finances. The MSP included provisions that allow the United States to recover payments Medicare had made on behalf of its beneficiaries, by standing in the place of those beneficiaries in state tort actions against tortfeasors. These provisions gave Medicare broad authority to seek recovery from the manufacturers of defective medical devices when the program had paid for the devices. However, in many cases the express preemption clause of the MDA and the Supreme Court’s overly broad implied preemption jurisprudence preempt Medicare beneficiaries’ state law claims. Since Medicare’s ability to recover under the MSP is based on its beneficiaries’ rights, the MDA may also prevent Medicare from recovering under the MSP. This collision between two statutes drafted within four years of one another illustrates the unintended effects that a broad preemption doctrine may have. This Comment argues that both Congress and the Supreme Court need to review and narrow the reach of preemption under the MDA—without completely

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abandoning preemption—so that both the MDA and the MSP may serve the purposes Congress intended.

Introduction	1354
I. Medicare’s Perpetual Financial Difficulties and the Medicare Secondary Payer Act	1359
A. Reforms That Increase Funding to Medicare.....	1360
B. Reforms That Limit the Amount Medicare Will Pay for Services.....	1362
1. Reforms That Directly Limit Payment	1363
2. Reforms That Utilize Market Mechanisms.....	1364
C. Reforms That Limit the Services for Which Medicare Will Pay	1365
D. Reforms That Enable Medicare to Recover Payments Already Made	1366
1. The Medicare Secondary Payer Act	1366
2. Subrogation.....	1368
II. Regulation of Medical Devices: The Tension Between Common Law Claims and Agency Regulation	1371
A. The Medical Device Amendments: History and Structure	1372
B. Laying the Foundation for a Preemption Doctrine: <i>Lohr</i> , <i>Riegel</i> , and <i>Buckman</i> (“Trio”).....	1375
C. Justifications for a Broad Preemption Doctrine	1379
D. The Consequences of a Broad Preemption Doctrine: How the Trio Frustrates the Goals of the Medicare Secondary Payer Act	1381
III. The Government’s Existing, Non-Ideal Recovery Tools.....	1385
A. Civil Monetary Penalties	1386
B. Criminal Penalties.....	1388
C. Forfeiture	1390
D. Equitable Remedies: Restitution and Disgorgement	1391
E. False Claims Act and Qui Tam Actions	1393
IV. Proposals to Avoid the Bar on Recovery Under Existing Federal Preemption Doctrine: Repeal, Narrowing, and Compensation.....	1395
V. A Finer Approach to the Preemption Problem: Wholesale Recovery in the Post-Recall Context	1397
Conclusion	1402

INTRODUCTION

Federal preemption of state law is a powerful tool that Congress may wield to ensure that regulations are uniform across the nation. But this tool can easily become a blunt truncheon, one that wreaks unanticipated harms. Courts faced with the question of whether a federal statute preempts a state law

traditionally look to the purposes that the enacting Congress evinced.¹ But it can be difficult to determine whether Congress intended to displace state law. In spite of this difficulty, it seems clear that Congress, in enacting a provision preempting state law, would not have intended to displace a *federal* law absent a clear indication. And yet, this is precisely what has happened in the collision between two statutes that Congress enacted within the span of a few years, the Medicare Secondary Payment Act (“MSP”) and the Medical Device Amendments of 1976 (“MDA”).² This collision and the harm that it inflicts on the federal Medicare program demonstrate why, after the creation of a preemptive regime, both Congress and the courts must periodically review the regime’s impact in order to ensure that impact is limited to the boundaries Congress intended.

Congress has revised the Medicare program numerous times, attempting to ensure the program’s solvency.³ One of the tools Congress created is a cost-recovery mechanism included in the MSP that provides Medicare with the right of subrogation to its beneficiaries.⁴ The “subrogation clause” allows Medicare to recover payments for medical services made on behalf of its beneficiaries, where another payer is legally bound to function as the primary payer.⁵ A second tool that the MSP confers on Medicare is the right to directly sue tortfeasors and their insurers who become responsible to make payments to a beneficiary.⁶ For example, under the MSP, the government was able to recover payments it had made on behalf of some of the 400,000 class members involved in the silicone breast implant litigation.⁷

In contrast, Medicare is unable to recover payments it made for many other medical devices, even where the manufacturer’s negligence or product defects may be responsible for injuries to beneficiaries. A recent and dramatic example involves the litigation over the Medtronic Sprint Fidelis lead, a medical device that is part of an implantable cardioverter-defibrillator system.⁸ This lead, described overly simplistically by one court as an “insulated wire,”⁹

1. *Retail Clerks Int’l Ass’n Local 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963) (“[To determine] whether the Congress had precluded state enforcement of select state laws adopted pursuant to its authority[, t]he purpose of Congress is the ultimate touchstone.”); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (“[T]he purpose of Congress is the ultimate touchstone’ in every preemption case.”); *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (same).

2. Neither the House Report nor the Conference Report for the Omnibus Reconciliation Act of 1980, through which the MSP was enacted, mentioned the MDA. *See* H.R. REP. NO. 96-1167, at 389–90 (1980); H.R. CONF. REP. NO. 96-1479, at 133 (1980).

3. JONATHAN OBERLANDER, *THE POLITICAL LIFE OF MEDICARE* 47 (2003).

4. 42 U.S.C. § 1395y(b)(2)(B)(iv) (2012); *see also* 22 ERIC MILLS HOLMES, *HOLMES’ APPLEMAN ON INSURANCE* § 141.1[A] (2d ed. 1996).

5. 42 U.S.C. § 1395y(b)(2)(B)(iv).

6. *Id.* § 1395y(b)(2)(B)(iii).

7. *United States v. Baxter Int’l, Inc.*, 345 F.3d 866, 888 (11th Cir. 2003).

8. *In re Medtronic Sprint Fidelis Lead Prods. Liab. State Court Litig.*, Nos. 27-CV-07-22446, etc., 2009 WL 3417867, at *18 (Minn. Dist. Ct. Oct. 20, 2009).

9. *See id.* at *2.

carries electrical impulses generated by the heart to the defibrillator, where the heart rhythm is analyzed. If the defibrillator detects a potentially fatal heart rhythm disorder, the lead carries a large shock, intended to restore the rhythm to normal, from the defibrillator back to the heart. Over two hundred thousand people in the United States had a Sprint Fidelis lead implanted between the initial FDA approval in 2004 and the manufacturer's withdrawal of the lead from the market in late 2007.¹⁰ The withdrawal stemmed from a tendency of one of the internal wires of the lead to fracture, resulting in electrical "noise" which the defibrillator interpreted as a potentially fatal rhythm disturbance.¹¹ In response, some patients' defibrillators sent unneeded, often repetitive, shocks to the heart, in some cases delivering over one hundred shocks in the course of a few hours, each feeling like "being kicked in the chest by a horse."¹² It is impossible to fully quantify the human costs wrought by these lead failures, but the costs to health care insurers are clear: one study estimated that Medicare lost between \$287 million and \$1.2 billion due to the failed Spring Fidelis leads.¹³

Unlike the silicone breast implant cases, Medicare cannot recover its Sprint Fidelis payments on behalf of its beneficiaries through the subrogation and direct action clauses of the MSP.¹⁴ In early 2008, over six hundred separate lawsuits against Medtronic alleging strict liability and negligence were consolidated into a single multidistrict litigation action.¹⁵ On October 20, 2009, the trial court dismissed all of the cases with prejudice.¹⁶ The beneficiaries' rights and remedies were foreclosed by federal preemption of state law.

10. Gautham Kalahasty & Kenneth A. Ellenbogen, *Management of the Patient with Implantable Cardioverter-Defibrillator Lead Failure*, 123 CIRCULATION 1352, 1352 (2011). The number of Sprint Fidelis leads implanted worldwide was approximately 286,000. David H. Birnie et al., *Clinical Predictors of Fidelis Lead Failure: Report from the Canadian Heart Rhythm Society Device Committee*, 125 CIRCULATION 1217, 1218 (2012).

11. Reggie Groves, *Urgent Medical Device Information: Sprint Fidelis® Lead Patient Management Recommendations*, MEDTRONIC 1 (Oct. 15, 2007) (last updated Sept. 22, 2010), <http://www.medtronic.com/product-advisories/physician/sprint-fidelis/PROD-ADV-PHYS-OCT>.

12. Personal communication from a patient who experienced 106 shocks due to a fractured Sprint Fidelis lead.

13. A.K. Mehrotra et al., *Medtronic Sprint Fidelis Lead Recall: Determining the Initial Five-Year Management Cost to Medicare*, 8 HEART RHYTHM 1192, 1197 (2011), <http://www.ncbi.nlm.nih.gov/pubmed/21377552>. This study likely underestimates the total cost to Medicare because it considers only the cost of surgical removal of the leads and not the costs associated with increased monitoring, patient counseling, treatment of anxiety disorders related to the risk of failure and of suffering multiple shocks, and other medical care. However, similar estimates of the cost to Medicare have been derived by Fidelis plaintiffs' lawyers. See H. DENNIS TOLLEY, EXAMINING THE SPRINT FIDELIS EFFECT ON MEDICARE COSTS 18 (2010) (estimating cost to Medicare system of Sprint Fidelis failure from \$375 million to \$1 billion).

14. I do not argue that the Sprint Fidelis lead was negligently designed or that the plaintiffs would have prevailed had the case been allowed to go to trial; my point is simply that all possibility of recovery was foreclosed.

15. *In re Medtronic Sprint Fidelis Lead Prods. Liab. State Court Litig.*, Nos. 27-CV-07-22446, etc., 2009 WL 3417867, at *1-2 (Minn. Dist. Ct. Oct. 20, 2009).

16. *Id.* at *1.

Subrogation was then of no value to Medicare: the government, substituting for the beneficiaries, could not exercise those federally preempted rights. Nor was the independent right of action helpful: this clause only allows the government to act directly against entities “*required or responsible . . . to make payment,*”¹⁷ and Medtronic would have become responsible to pay the plaintiffs only if a judgment were rendered against it or a settlement were reached.

To understand the different outcomes in these cases, it is necessary to understand the MDA, the law that governs the approval and regulation of medical devices.¹⁸ The MDA created a two-track system for device approval. For devices that are similar to a device already on the market, a manufacturer may gain approval through the relatively simple 510(k) process. This process requires the manufacturer to demonstrate only that the device is “substantially equivalent” to a device already on the market.¹⁹ The silicone breast implants at issue in *United States v. Baxter International, Inc.* had been approved through the 510(k) process.²⁰ In contrast, the Sprint Fidelis lead had been approved under the rigorous Premarket Approval (“PMA”) process, which requires a manufacturer to submit extensive evidence showing that the new device is both effective and safe.²¹ The specific approval process has a determinative impact on would-be plaintiffs in state-law negligence and products liability claims. Suits alleging harm due to a device approved under the rigorous PMA process are often foreclosed either by an express preemption clause written into the MDA²² or by Supreme Court decisions that have extended the preemptive effect of this clause through the doctrine of implied preemption.²³ For example, in the actions brought by plaintiffs alleging harm stemming from defects in the Sprint Fidelis lead, the district court held that state law claims fell within either § 360k(a), the express preemption clause, or the implied preemption doctrine.

A number of trends and developments suggest that the Sprint Fidelis outcome will become more frequent. The baby boomer cohort is entering the age range in which the need for Class III medical devices like defibrillators and hip prostheses is more likely. An increasing number of device approvals use the PMA process,²⁴ so more patients will have devices from manufacturers that

17. 42 U.S.C. § 1395y(b)(2)(B)(iii) (2012) (emphasis added).

18. Medical Device Amendments of 1976, 21 U.S.C. §§ 301c–301m (2012).

19. 21 U.S.C. § 360e(b)(1)(B).

20. *Medical Devices: Regulatory History of Breast Implants in the U.S.*, FDA.GOV (Sept. 25, 2013), <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064461.htm>.

21. *In re Medtronic Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1203 (8th Cir. 2010).

22. 21 U.S.C. § 360k.

23. *See infra* Part II.B.

24. Between 2003 and 2007, the FDA approved 1,062 Class III medical devices, comprising 228 devices approved through the 510(k) process and 834 new and supplemental approvals through the PMA process. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-09-370T, MEDICAL DEVICES:

are immune from tort suit on the basis of federal preemption. And recently proposed legislation may allow the FDA to approve devices through the 510(k) process but also to impose certain device-specific restrictions, forming a hybrid 510(k)-PMA approval process.²⁵ These device-specific requirements could broaden the availability of the federal preemption defense to device manufacturers. Thus, an increasing number of Medicare beneficiaries are likely to receive an increasing number of Class III medical devices for which recovery under the MSP will be barred by federal preemption.

The conflict between Congress's purposes in the MDA and the MSP, which were enacted within four years of one another, appears irreconcilable. Courts have noted that the preemption clause is the linchpin to achieving the MDA's goal of assuring safe and innovative medical technology because it guarantees that only one nationwide standard, established by the FDA, will apply to medical devices.²⁶ Arguably, allowing state tort suits would fatally undermine this goal.²⁷ On the other hand, the cluster of subrogation and related rights is an important tool for improving the finances of the Medicare program. Unfortunately, subrogation rights in the medical device defect context can only arise where tort liability can be established, which is rendered impossible by the preemption clause of the MDA. Although the conflict between the MSP and the MDA only arises in a small number of medical device cases, these cases involve the most advanced and costly devices.

This Comment examines the impact of this collision of doctrines and the lessons this collision provides for the application of federal preemption. Part I examines the MSP, describing how the Act is designed to help ensure the solvency of the Medicare program. Part II analyzes the MDA's preemption clause and the Supreme Court's preemption jurisprudence. This Part also explains why it is unreasonable to think that Congress intended to preempt another federal statute. Application of the preemption doctrine to bar suits after the FDA has recalled a medical device does not further the purposes of the MDA; instead, it impedes the purposes of the MSP. Part III examines the tools that the government currently possesses to recover payments made to manufacturers of defective devices, showing that none are tailored to yield appropriate recoveries and that none strike an appropriate regulatory balance.

SHORTCOMINGS IN FDA'S PREMARKET REVIEW, POSTMARKET SURVEILLANCE, AND INSPECTIONS OF DEVICE MANUFACTURING ESTABLISHMENTS, at 10 tbl.1 (2009).

25. The Medical Device Patient Safety Act, H.R. 5866, was introduced and referred to the House Committee on Energy and Commerce on May 30, 2012. *See* Medical Device Patient Safety Act, H.R. 5866, 112th Cong. (2012), <http://www.gpo.gov/fdsys/pkg/BILLS-112hr5866ih/pdf/BILLS-112hr5866ih.pdf> (last visited June 3, 2015).

26. *See, e.g.,* Riegel v. Medtronic, Inc., 552 U.S. 312, 325 (2008) (noting that, without preemption, state tort laws would "disrupt[] the federal scheme").

27. Not surprisingly, medical device manufacturers strongly supported the inclusion of the preemption clause on this basis. *See Medical Device Amendments, 1973: Hearings on S. 2368, S. 446, and S. 1337 Before the S. Subcomm. on Health of the S. Comm. on Labor and Public Welfare*, 93d Cong. (1973) (joint statement of five industry trade associations).

Part IV briefly reviews other suggestions that have been made to break the doctrinal impasse of the MDA and the MSP. Part V argues that the expansive preemption doctrine the Court has articulated is not applicable where the FDA has recalled a defective medical device. This Part also argues that either the judiciary or Congress must revise the MDA's preemption regime to end the unintended collision of the MDA and the MSP. I argue that federal preemption under the MDA should neither be completely eliminated nor completely embraced, but rather that a more granular approach to the application of preemption, based on the purposes of the MDA, is needed. Finally, Part V argues that given the far-ranging consequences of preemption, congressionally enacted preemption provisions and court-determined preemption doctrine must be continuously reviewed as the empirical effects of laws and legal doctrine become evident. I propose that, based on such a review, courts and Congress should recognize a mechanism of wholesale recovery through which Medicare can recover payments made to the manufacturers of defective medical devices that have been recalled by the FDA.

I.

MEDICARE'S PERPETUAL FINANCIAL DIFFICULTIES AND THE MEDICARE SECONDARY PAYER ACT

Medicare is chronically in financial trouble. In 2013, the program ran a \$7.1 billion deficit.²⁸ The Trust Fund for Medicare Part A, which provides hospital insurance, is projected to be exhausted in 2030.²⁹ Part of the problem is purely demographic: individuals' health care costs increase with each succeeding decade of life,³⁰ so as the baby boomer generation reaches Medicare age, the costs borne by Medicare will inexorably increase.³¹ A second major driver of health care cost increases is "new medical technology [that] may account for about one-half or more of real long-term [health care] spending growth."³² This combination threatens the long-term viability of the Medicare program.

Medicare's chronic financial problems have prompted a broad variety of congressional responses that seek through multiple avenues to buttress the

28. BDS. OF TRS., FED. HOSP. INS. & FED. SUPP. MED. INS. TRUST FUNDS, 2014 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS 7 (2014), <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2014.pdf> (total program income \$575.8 billion, total expenditures \$582.9 billion).

29. *Id.*

30. HENRY J. KAISER FAMILY FOUND., HEALTH CARE COSTS: A PRIMER 9 (2012). For eighteen to twenty-four year olds, average health care spending per year was \$1,834, while average annual spending for adults age sixty-five and over—the Medicare-age cohort—was \$9,744. *Id.*

31. See CHARLES BLAHOUS, MERCATUS CTR., THE FISCAL CONSEQUENCES OF THE AFFORDABLE CARE ACT 7 (2012), http://www.mercatus.org/sites/default/files/The-Fiscal-Consequences-of-the-Affordable-Care-Act_1.pdf.

32. KAISER FAMILY FOUND., *supra* note 30, at 25.

program's solvency. These congressional responses can be grouped into four categories: (1) reforms that increase Medicare funding, (2) reforms that limit the amount Medicare will pay for services, (3) reforms that limit the services for which Medicare will pay, and (4) reforms that enable Medicare to recover payments already made. Parts I.A, B, and C review the first three congressional avenues and their limitations. As will be clear, the limited success of these responses indicates the need for other tools. Part I.D discusses the fourth avenue, the MSP, which enables Medicare to recover payments made in certain circumstances. Application of this important recovery tool is limited by federal preemption doctrine, as this Comment subsequently shows.

A. Reforms That Increase Funding to Medicare

Although increasing funding for Medicare seems to be the most obvious way to ensure the program's solvency, this mechanism has met persistent congressional resistance. Medicare consists of four main parts, of which Parts A and B are relevant to this Comment.³³ Part A covers inpatient hospital expenses.³⁴ Part A is funded through the Hospital Insurance (HI) Trust, which is financed largely through a 2.9 percent payroll tax, which is split equally between each employee and his or her employer.³⁵ Eligibility for Part A coverage is determined by age and contribution status: individuals over age sixty-five who have sufficiently contributed through payroll taxes or who have paid a premium are eligible.³⁶ In general, all individuals who have worked and contributed to the HI Trust through payroll taxes become eligible for hospital benefits at age sixty-five.

Part B covers the costs of physician care, certain outpatient hospital expenses, and home health care.³⁷ Revenues for Part B come from the Supplemental Medical Insurance (SMI) Trust, which is funded by two major components. Approximately 22 percent of funding comes from premiums that beneficiaries elect to pay in order to secure Part B coverage.³⁸ Higher-income enrollees pay higher premiums.³⁹ Another 74 percent of the SMI Trust's

33. The Medicare program also includes Part C, which creates privately managed Medicare plans that use managed care or managed competition techniques in an attempt to control costs, and Part D, the prescription drug component. See Avik Roy, *Saving Medicare from Itself*, 8 NAT'L AFF. 35, 48–50 (2011).

34. LISA POTETZ ET AL., KAISER FAMILY FOUND., *MEDICARE SPENDING AND FINANCING: A PRIMER* 17–18 app. B (2011). Part A also covers part of beneficiaries' post-hospitalization care, home health care, and hospice care. *Id.*

35. *Id.* at 17 app. B. The payroll tax accounts for 85 percent of the HI Trust Fund's revenues. *Id.*

36. *Id.* Disabled individuals and those with end-stage renal disease may be eligible at a younger age. *Id.*

37. *Id.* at 17–18 app. B.

38. *Id.* at 17 app. B.

39. *Id.* In 2011, the baseline monthly premium was \$115.40. As of 2007, beneficiaries earning over a threshold of \$85,000 (\$170,000 for couples) pay higher premiums. *Id.* The threshold was

funding comes from general federal tax revenue.⁴⁰ Thus, to obtain Part B coverage, an individual must be over age sixty-five and must pay a monthly premium.⁴¹ Part B can be seen as a heavily subsidized health insurance plan in which seniors may elect to enroll.

The costs of medical device failures may fall on both Parts A and B. Patients with recalled medical devices often require hospital care, such as surgery to replace the devices; Medicare Part A will make payments on behalf of beneficiaries for this care. Patients may also require outpatient visits for evaluation, monitoring, and counseling, with payment for these office visits coming from Part B. Estimates of the cost to Medicare for just one high-profile medical device failure—the Medtronic Sprint Fidelis defibrillator lead—ranged from \$287 million to \$1.2 billion.⁴² These figures likely underestimate Medicare’s true costs, as they include only hospital costs covered by Part A and not the outpatient costs covered by Part B.

These amounts are significant. While they represent less than 1 percent of annual Medicare Part A expenditures⁴³ and would likely be spread over a several year period, they represent the cost of just a single device failure. With the aging population, the number of beneficiaries with medical devices will continue to increase so that costly failures are likely to occur with increasing frequency. Part A ran a \$23.8 billion deficit in 2012,⁴⁴ so the additional costs of high-profile device failures could drive the finances of Part A further into the red.

However, for nearly thirty years, Congress has been reluctant to increase payroll taxes to address shortfalls in the HI Trust. In response to early rises in program expenses, Congress incrementally raised the tax from 0.35 to 1.30 percent over a period of fifteen years.⁴⁵ But the last increase in payroll taxes was implemented in 1986, when the tax on employees and employers was raised to 1.45 percent each.⁴⁶ Congress continued to raise the maximum level of earnings subject to the payroll tax, finally eliminating the cap in 1994.⁴⁷ Thus, prior to the enactment of the Affordable Care Act (“ACA”), the last boost to HI Trust revenues had occurred twenty years earlier.

The ACA took modest steps at enhancing Medicare revenues through increased taxes. The ACA froze the threshold level above which Part B

indexed to prevent inflation from forcing more and more individuals and households into paying higher premiums. *See id.* at 6.

40. *Id.* at 17 app. B.

41. *See id.* at 1, 17 app. B.

42. *See supra* note 13 and accompanying text.

43. In 2013, Medicare hospital expenditures under Part A were \$136.8 billion. *See* BDS, OF TRS., FED. HOSP. INS. & FED. SUPP. MED. INS. TRUST FUNDS, 2014 ANNUAL REPORT, *supra* note 28, at 11 tbl.II.B1.

44. *Id.*

45. *See* OBERLANDER, *supra* note 3, at 97 tbl.4.2.

46. *Id.*

47. *Id.*

enrollees pay higher premiums.⁴⁸ Thus, as wages rise, the percent of enrollees in the higher premium bracket will increase from 5 to 14 percent by 2019.⁴⁹ The ACA also increased the payroll tax, which goes to the HI Trust to pay for Part A benefits, on high earners (individuals earning over \$200,000 per year or couples earning over \$250,000).⁵⁰ Further, the Act imposed taxes on brand-name prescription drug and medical device manufacturers; the revenue collected from the drug makers will go into the SMI Trust.⁵¹

Although these provisions may appear to suggest that enhancing program revenues is a viable approach to Medicare's long-term financial problems, this possibility is more illusory than real. First, the ACA was a contentious piece of legislation passed on a strictly partisan basis. Repeal efforts in Congress and challenges in court continue, some threatening the entire Act.⁵² Second, some revenue-enhancing provisions, such as the freeze on the Part B premium threshold, are temporary. Third, and most importantly, the controversy over the ACA is part of a long-term argument about the use of taxes to finance health care. Although first proposed during the administration of President Franklin Delano Roosevelt,⁵³ a broadly accessible government-sponsored health insurance program was not enacted until thirty years later, enabled by the "massive Democratic electoral victories in 1964."⁵⁴ It is rare for an electoral mandate to arise that strongly supports the use of government and taxation to address access to health care. It is even more rare, if not unheralded, for a bipartisan mandate to occur. The ACA was the product of neither, and its halting implementation has reflected this national ambivalence. This context strongly suggests that opposition to raising taxes to support Medicare has deep historical roots, and that relying on tax increases to keep Medicare solvent is a bet with very long odds.

B. Reforms That Limit the Amount Medicare Will Pay for Services

Reforms that limit the amount Medicare will pay for services fall into two general categories: those that directly impose a limit on payments, and those that utilize market mechanisms to lower costs and payments. Both have been used extensively but with only modest success.

48. LISA POTETZ ET AL., *supra* note 34, at 6.

49. *Id.*

50. *Id.*

51. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, §§ 9008, 9009, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029, § 1404 (2010).

52. See *King v. Burwell*, 135 S. Ct. 2480 (2015).

53. THEODORE R. MARMOR, *THE POLITICS OF MEDICARE* 8 (1st ed. 1970).

54. *Id.* at 56.

1. Reforms That Directly Limit Payment

Medicare began as an “open-ended payment method” in which doctors and hospitals were paid a “reasonable” or “prevailing” rate that they themselves determined.⁵⁵ This led to dramatic increases in both physician and hospital fees.⁵⁶ As a result of these increases, Medicare sought to limit how much it would pay for certain services. The overall impact of this approach, however, has been modest.

One of the first attempts to rein in health care costs came as part of President Richard Nixon’s 1971 wage and price freeze, implemented to control inflation.⁵⁷ The freeze was temporarily successful in controlling health care costs. However, this strategy is unlikely to be useful in the future. Health care costs rose promptly upon the discontinuation of Nixon’s freeze in 1974.⁵⁸ Further, such economy-wide interventions are unusual, and a narrow freeze that applied solely to Medicare could result in provider flight to other, better paying insurers.⁵⁹ This shift away from a low-paying insurer has been a problem in state Medicaid programs.⁶⁰ The provider shortages that Medicaid has long experienced underscore the risk that imposing severe limitations on Medicare payments may drive providers out of the program. Concerns over this possibility limit the potential use of payment freezes to control costs.

The primary way that Medicare payments have been contained has been through the Prospective Payment System (“PPS”), which began as an experimental program in 1972. Under the PPS, hospital payments are calculated based upon the patient’s diagnosis, with a single predetermined amount paid for that diagnosis.⁶¹ Starting in 1989, physician payments were

55. *Id.* at 89.

56. *See id.* at 89–90. Physician fee increases jumped from 3.8 to 7.8 percent in the year following Medicare’s enactment, while hospital fees increased by 21.9 percent that year. *Id.* at 89 & tbl.6.1.

57. *See* Timothy S. Jost, *Eight Decades of Discouragement: The History of Health Care Cost Containment in the USA*, FORUM FOR HEALTH & POLICY, Sept. 2012, at 53, 59.

58. *See id.*

59. Congress did freeze Medicare payments to physicians between 1984 and 1986. In spite of this, physician payments increased 11.6 percent annually during that time. *See* OBERLANDER, *supra* note 3, at 127. The increase was attributed to increases in the volume of physician services provided. *Id.*; *see also infra* notes 66–68 and accompanying text.

60. *See* PETER CUNNINGHAM & JESSICA MAY, CTR. FOR STUDYING HEALTH SYS. CHANGE, MOUNTING PRESSURES: PHYSICIANS SERVING MEDICAID PATIENTS AND THE UNINSURED, 1997–2001 2 (2002), <http://www.hschange.com/CONTENT/505/?topic=topic02> (“Physicians who are heavily involved with managed care are increasingly closing their practices to new Medicaid patients.”); PETER CUNNINGHAM & JESSICA MAY, CTR. FOR STUDYING HEALTH SYS. CHANGE, MEDICAID PATIENTS INCREASINGLY CONCENTRATED AMONG PHYSICIANS 1 (2006), <http://www.hschange.com/CONTENT/866/866.pdf> (“Medicaid payment rates, which are considerably lower than physician payment rates under Medicare or private insurance, historically have deterred physician participation in Medicaid. . . . Low physician participation in Medicaid has been shown to negatively affect enrollee access to medical care.”).

61. *See* OBERLANDER, *supra* note 3, at 120–21.

calculated based on the value of the physician services provided.⁶² The hospital payment system has been seen as modestly successful at containing costs,⁶³ while the physician payment system is generally seen as merely redistributing payments among generalist and specialist physicians.⁶⁴

Finally, the ACA contains several payment-reduction measures designed to reduce Medicare costs. The largest savings is projected to occur through reduced payments under Medicare's traditional (fee-for-service) and managed care (Medicare Advantage) plans.⁶⁵ These savings will be accomplished by a legislatively predetermined restriction in Medicare payment increases due to inflation. These measures are projected to save \$293 billion over ten years.⁶⁶

Many commentators see these types of measures as having the potential to modestly constrain price increases.⁶⁷ Unfortunately, two factors have tended to increase the payments Medicare is obligated to make. First, the aging of the population has increased the percentage of the population eligible for Medicare.⁶⁸ Second, the use of costly high-technology care has continued to increase.⁶⁹ These factors have negated the benefits of direct reductions in Medicare payments, and will continue to limit the overall impact of direct payment reduction mechanisms.

2. Reforms That Utilize Market Mechanisms

Medicare was a relative latecomer to the managed care revolution. By the early 1990s, Health Maintenance Organizations ("HMOs") covered approximately 25 percent of the U.S. population.⁷⁰ However, it was not until the Balanced Budget Act of 1997 ("BBA") that Medicare began to incorporate managed care or managed competition principles with the Medicare+Choice plan.⁷¹ Under the BBA, Medicare began to offer coverage through managed care plans, and encouraged competition between these Medicare managed care plans and private managed care plans.⁷² This plan became the Medicare Advantage plan under the Medicare Modernization Act of 2003.⁷³ The

62. See Jost, *supra* note 57, at 66.

63. See OBERLANDER, *supra* note 3, at 125.

64. See Jost, *supra* note 57, at 65–66.

65. See LISA POTETZ ET AL., *supra* note 34, at 5.

66. See *id.* at 16 app. A (\$157 million savings from reduced annual provider payment updates and \$136 million savings from Medicare Advantage payment reform).

67. See, e.g., Mark McClellan, *Medicare and the Federal Budget: Past Experience, Current Policy, Future Prospects*, 15 TAX POL'Y & ECON. 167, 170–71 (2001) (noting that "between the mid-1980s and mid-1990s, Medicare payments for hospital services increased by over 1.5 percent less than the hospital 'market basket'"); LISA POTETZ ET AL., *supra* note 34, at 5.

68. See McClellan, *supra* note 67, at 170–71.

69. *Id.*

70. See Jost, *supra* note 57, at 66.

71. See *id.* at 70.

72. *Id.*

73. MARSHA GOLD ET AL., MONITORING MEDICARE+CHOICE: WHAT HAVE WE LEARNED? FINDINGS AND OPERATIONAL LESSONS FOR MEDICARE ADVANTAGE I (2004). The major change

Medicare+Choice plan was regarded as a failure,⁷⁴ and the Medicare Advantage plan has not successfully constrained health care spending.⁷⁵

C. Reforms That Limit the Services for Which Medicare Will Pay

Early on, Medicare attempted to limit the services for which it would pay by restricting the number of inpatient hospital beds that a given locality could add.⁷⁶ Although initially popular, by 1986, evidence indicated that planning may have “facilitated anticompetitive actions by providers,” leading to the abandonment of this strategy.⁷⁷

Since then, “utilization review” has been the primary means of limiting the services for which Medicare will pay. Established first in 1972, utilization review subjects physicians’ treatment decisions to external review, with the goal of discouraging overuse of medical services.⁷⁸ Despite modification on several occasions, the program has never achieved its promise of reducing health care spending.⁷⁹ Commentators have attributed this failure to the fact that review of treatment decisions was delegated to the very individuals whose decisions were driving up health care costs: physicians.⁸⁰ Yet, any other form of utilization review is unlikely to gain broad acceptance. Whoever conducts the review determines who will receive treatment, meaning that either a physician or a distant bureaucrat will determine whether an individual can receive a given treatment. Since few voters are likely to agree that a distant bureaucrat should make treatment decisions, the efficacy of utilization review will likely remain limited.

Another means of restricting the services for which Medicare will pay is simply to declare certain treatments off-limits, or to pay only for specifically enumerated treatments.⁸¹ However, the utility of this technique may be limited in the era of the ACA, which seeks to make a wide range of treatments available to as many people as possible.

was that Medicare more heavily subsidized its managed care plans, increasing both costs and enrollment. Roy, *supra* note 33, at 49.

74. GOLD ET AL., *supra* note 73, at 5–6. Medicare+Choice plans “raised their enrollee premiums, cut benefits, and abandoned the program in droves.” Jost, *supra* note 57, at 71.

75. See Jost, *supra* note 57, at 72.

76. See *id.* at 55–56. This effort was based on “Roemer’s Law,” which held that “the more hospital beds are provided in a community, the more days of hospital care will be used.” *Id.* at 55 (citing Max Shain & Milton Roemer, *Hospital Costs Relate to the Supply of Beds*, 92 MOD. HOSP. 71 (1959), and Milton Roemer, “*Bed Supply and Hospital Utilization*,” 35 J. AM. HOSP. ASS’N 36 (1961)).

77. *Id.* at 64.

78. See *id.* at 57.

79. See *id.* at 64.

80. See *id.* at 57; see also OBERLANDER, *supra* note 3, at 119.

81. For example, Medicare will not pay for certain experimental devices or treatments. See 42 C.F.R. § 411.15(o) (2014).

D. Reforms That Enable Medicare to Recover Payments Already Made

All of the methods employed in the attempt to contain health care spending have failed to “control[] health-care costs over the long term.”⁸² In spite of this failure, these methods should not be abandoned; each can help to incrementally constrain health care spending. However, as the history of Medicare shows, none alone is sufficient. Sustaining the program requires a wide range of approaches to cost control. One additional strategy does not focus solely on reducing the amount that is spent on health care; instead, this strategy also focuses on recovering expenditures due to fraud, kickbacks, and other impermissible reasons.⁸³ Medicare began using this strategy with the enactment of the MSP in 1980.⁸⁴

In the remainder of this Section, I will describe the MSP. In Section I.D.1, I discuss the history of the MSP and show that through a series of amendments Congress has demonstrated its intention to enable Medicare to recover payments made to a broad range of entities. Then, in Section I.D.2, I explain the principle of subrogation, the equitable bases of which underlie the MSP’s recovery mechanisms.

1. The Medicare Secondary Payer Act

The history of the MSP shows that Congress has progressively sought to narrow the range of beneficiaries on behalf of whom Medicare will make primary payments. Initially, Medicare was the primary payer on behalf of its beneficiaries.⁸⁵ Insurers such as employer-sponsored health plans and auto liability carriers were responsible only for the expenses for which Medicare did not reimburse beneficiaries’ health care providers.⁸⁶ The MSP reversed this prioritization, making Medicare the secondary payer for services where another automobile, liability, or no fault insurance payer had already made payment or could be expected to make payment.⁸⁷ This was designed to reduce costs by allowing Medicare to avoid paying for care where an employer-sponsored health plan or an auto liability insurer could pay.⁸⁸

82. Jost, *supra* note 57, at 73.

83. See *infra* Part III.B.

84. Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, 94 Stat. 2599 (1980) (codified at 42 U.S.C. § 1395y(b) (2012)).

85. Parkview Hosp., Inc. v. Roesse, 750 N.E.2d 384, 388 (Ind. Ct. App. 2001) (citing Michael A. de Freitas, Annotation, *Validity, Construction, and Application of Medicare Secondary Payer Provisions of Social Security Act (42 U.S.C. § 1395y(b)) and Regulations Promulgated Thereunder*, 126 A.L.R. FED. 553 (1995)).

86. In the typical outpatient setting, Medicare paid 80 percent of a provider’s usual and customary charges, leaving the other insurers responsible for only 20 percent of those charges. 42 U.S.C. § 1395l(a)(1) (2012).

87. United States v. Baxter Int’l, Inc., 345 F.3d 866, 877 n.6 (11th Cir. 2003); Omnibus Reconciliation Act of 1980 § 953.

88. See 42 U.S.C. § 1395y(b)(2)(A) (2012).

Over the next several years, Congress expanded the range of payers who were required to take the primary role, adding group health coverage plans for patients requiring dialysis in 1981;⁸⁹ large employers with health plans covering working employees (and their spouses) between ages sixty-five and sixty-nine in 1982;⁹⁰ and large employers with health plans covering disabled individuals in 1986.⁹¹

Congress not only constricted *whom* Medicare may make primary payments on behalf of; importantly, it also progressively expanded *how* Medicare may recover payments already made. The original MSP, as enacted in 1980, afforded the federal government subrogation rights⁹² to its beneficiaries, allowing the program to stand in the shoes of its beneficiaries in actions against payers alleged to bear responsibility for payment.⁹³ In 1984, Congress gave Medicare the additional authority to bring actions directly against primary payers, unconnected to any subrogation rights.⁹⁴ Two years later, Congress strengthened this authority, allowing Medicare to seek double damages in direct actions.⁹⁵

These amendments enacted during the 1980s demonstrate Congress's intent to expand the ways in which Medicare may recover payments made on behalf of its beneficiaries. The amendments give Medicare broad powers to recover amounts that other payers were required to pay.⁹⁶ In circumstances in which a responsible payer is deemed unlikely to make prompt payment, Medicare may make "conditional payments"—payments that are conditioned on later reimbursement of the Trust Fund by the responsible primary plan.⁹⁷ The Centers for Medicare and Medicaid Services estimate that the MSP allows Medicare to save or recoup more than \$8 billion annually.⁹⁸ With Medicare running a \$7.1 billion deficit in 2013,⁹⁹ recovery under the MSP is important to the financial state of the program; indeed, allowing the MSP to function as broadly as Congress intended is an important method for maintaining the long-term finances of the program.

89. *Baxter*, 345 F.3d at 877 n.6; Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2146, 95 Stat. 357, 800 (1981).

90. *Baxter*, 345 F.3d at 877 n.6; Taxpayer Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 116, 96 Stat. 324, 353 (1982).

91. *Baxter*, 345 F.3d at 877 n.6; Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9319, 100 Stat. 1874, 2010 (1986) (codified at 42 U.S.C. § 1395y(b)(2)(B)(ii) (2012)).

92. *See infra* notes 99–101 and accompanying text.

93. Currently codified at 21 U.S.C. § 1395y(b)(2)(B)(iv).

94. *Baxter*, 345 F.3d at 877–78; Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2344, 98 Stat. 494, 1095 (1984) (codified at 42 U.S.C. § 1395y(b)(2)(B)(iii)).

95. *Baxter*, 345 F.3d at 878; Omnibus Budget Reconciliation Act of 1986 § 9319.

96. *United States v. Geier*, 816 F. Supp. 1332, 1336–37 (W.D. Wis. 1993).

97. 42 U.S.C. § 1395y(b)(2)(B)(i) (2012).

98. DEP'T OF HEALTH & HUMAN SERVS., MEDICARE SECONDARY PAYER FOR PROVIDERS, PHYSICIANS, OTHER SUPPLIERS, AND BILLING STAFF (2015), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MSP_Fact_Sheet.pdf.

99. *See supra* note 28 and accompanying text.

2. Subrogation

The recovery mechanisms established by the MSP may be understood through the concept of subrogation. Subrogation means simply to put in the place of or to substitute.¹⁰⁰ In the insurance context, an insurer, having indemnified its insured, stands in as a substitute for, or is subrogated to, all of the insured's rights and remedies against a third party.¹⁰¹ An insurer who provides health insurance to *X*, who was injured by the negligence of *Y*, may be obligated to pay the cost of *X*'s medical care. In the absence of the insurer's right to subrogation, *X* has a right to seek recovery from *Y* in a negligence suit. However, once the insurer has paid *X*'s medical bills, the insurer is subrogated to *X*'s rights, which it may assert against *Y*.

Subrogation rights arise in one of three ways: (1) by contract; (2) by statute; or (3) by "equity to compel the ultimate discharge of an obligation by the one who in good conscience ought to pay it."¹⁰² In health insurance policies, insurers' rights generally arise by contract; however, Medicare, which covers nearly 49 million people,¹⁰³ has only certain statutorily created subrogation rights. In general, neither private health insurers nor Medicare are recognized as having equitable subrogation rights; the reason typically given for this is that the insurer's "exact loss is not fixed or easily ascertainable."¹⁰⁴ Nonetheless, these equitable principles provide an analytic framework that permits an understanding of recovery under the MSP.

Standard treatises describe three purposes served by subrogation—whether contractual, statutory, or equitable—all based on the equitable principle of adjusting the costs "between the parties by securing the ultimate discharge of a debt by the person who in equity and good conscience ought to pay it."¹⁰⁵ To illustrate, consider the above example of the insurer who provides health insurance to *X*, who was injured by the negligence of *Y*. First, *X*, the insured, is prevented from the unjust enrichment that would occur were

100. 22 HOLMES, *supra* note 4, § 141.1[A].

101. *Id.*

102. *In re Bayonne Med. Ctr., Inc.*, Bankr. No. 07-15195 (MS), 2009 WL 1025123, at *15 (Bankr. D.N.J. Feb. 3, 2009) (quoting *Culver v. Ins. Co. of N. Am.*, 115 N.J. 451, 456 (1989)).

103. BDS. OF TRS., FED. HOSP. INS. & FED. SUPP. MED. INS. TRUST FUNDS, 2012 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS (2012), <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2012.pdf> (data from 2011).

104. 22 HOLMES, *supra* note 4, § 141.1[C][1]; *see Williams v. Erie Ins. Grp.*, 621 N.E.2d 770, 772–73 (Ohio Ct. App. 1993). In the context of this Comment—allocating the expenses of medical care that result from medical device defects—this argument fails: once a health insurance provider has paid its insured's medical bills, the loss has been determined. However, as I am not arguing for an extension of equitable subrogation rights to health insurance providers, I will not further challenge this rationale.

105. 16 STEVEN PLITT ET AL., COUCH ON INS. § 222:8 (3d ed. 2014); *see* 22 HOLMES, *supra* note 44, § 141.2[D]. These purposes appear to underlie all subrogation rights, whether they arise by equity, contract, or statute.

she to recover both from her insurer and from *Y*.¹⁰⁶ This effectuates the principle of indemnity, that one should not recover more than one has lost.¹⁰⁷ Second, *X*'s insurer is enabled to recover its payment to *X*. This justification is controversial, since payment of claims is a necessary concomitant of the risk transfer that underlies the insurance contract¹⁰⁸: the insurer assumes the small risk of having to pay for an insured's large loss in exchange for the insured's assumption of a certain risk of a small loss—payment of a premium. Taken to a hypothetical extreme, allowing an insurer to recover its payments could allow the insurer to avoid all risk: if every insured's loss could be recovered from a third party, the insurer would have provided its insured with a small but certain loss in exchange for no risk to itself at all. However, not all losses can be laid at the feet of a third party, and not all responsible third parties can pay, so an insurer's solvency is always a matter of the calculation of the risks of unknown and often unknowable future events. Thus, allowing the insurer to recover helps to assure its solvency and assures that all of its insureds reap the benefit of their risk pooling and risk transfer.¹⁰⁹ Third, "a wrongdoer who is legally responsible for the [insured's] harm should not receive the windfall of being absolved from liability because the insured had the foresight to obtain . . . insurance."¹¹⁰

The function of subrogation under the MSP may be illustrated in *Casualty Reciprocal Exchange v. Johnson*.¹¹¹ Johnson brought suit against O'Friel, a motorist who allegedly ran him over. Medicare paid Johnson's hospital bills. The government interpleaded to obtain a declaration that it had priority to any award or settlement, in the amount of its payments for Johnson's medical care.¹¹² Here, Johnson was in the position of the insured, *X*, while Medicare was in the position of his insurer, and O'Friel was in the position of *Y*, the negligent tortfeasor. As permitted by the MSP,¹¹³ Medicare substituted itself for its beneficiary.

In this case, subrogation assured that Johnson was not unjustly enriched by a double recovery, having his medical bills paid once by Medicare and once again by O'Friel as part of a settlement or an award in the tort suit. Subrogation also allowed Medicare to recover its payment, helping to assure the program's

106. 22 HOLMES, *supra* note 4, § 141.1[D][1].

107. The moral hazard argument is typically used to support the indemnity principle, but in the health care context the risk of encouraging the insured to sustain a loss—to deliberately court injury or illness—is minimal.

108. See GARY L. WICKERT, ERISA AND HEALTH INSURANCE SUBROGATION §§ 1.05, 1-33 to 1-34 (4th ed. 2010).

109. See *id.*

110. 16 STEVEN PLITT ET AL., *supra* note 105, § 222:8.

111. Cas. Reciprocal Exch. v. Johnson *ex rel.* Johnson, No. 91-2357, 1992 WL 300769 (E.D. La. Oct. 6, 1992).

112. *Id.*

113. 42 U.S.C. § 1395y(b)(2)(B)(iv) (2012).

solvency.¹¹⁴ Finally, subrogation assured that O’Friel was not allowed to escape responsibility for his negligence: even had Johnson opted not to pursue the case, the government’s subrogation assured the vigorous assertion of Johnson’s rights against O’Friel.

The MSP also gives the government the right to proceed directly—as opposed to indirectly through the rights of Medicare beneficiaries—against tortfeasors responsible for the costs paid on behalf of those beneficiaries and against tortfeasors’ insurers.¹¹⁵ Although not a subrogation right, allowing Medicare to proceed against tortfeasors’ insurers may be analyzed through the equitable principles that underlie subrogation. The standard justification of subrogation, and the simplistic three-party model on which it is based, leaves out tortfeasor *Y*’s liability insurer. Failure to consider *Y*’s liability insurer allows an additional possibility of unjust enrichment: if *X*, the insured, elects not to take action (or cannot take action) against *Y*, not only does *Y* gain an unjust enrichment, but so does *Y*’s insurer. Subrogation and direct action reduce the likelihood that *Y*’s liability insurer can avoid paying a claim. Functionally, *Y*’s liability insurer is important because under *Y*’s general liability policy, once *X*, or his subrogated insurer, obtains a judgment against *Y*, *Y*’s liability insurer’s obligation to indemnify *Y* is triggered; it is through this payment that *X*, or *X*’s insurer, is made whole again.

Congress recognized this principle during the drafting of the MSP.¹¹⁶ One of the specific aims of the MSP was to allow one insurer, Medicare, to recover payments it made on its insureds’ behalf from auto liability insurers in situations where negligent motorists injured Medicare beneficiaries.¹¹⁷ The MSP aimed to assure that a tortfeasor’s insurer is included in the equitable adjusting of the costs “between the parties by securing the ultimate discharge of a debt by the person who in equity and good conscience ought to pay it.”¹¹⁸

Thus, Congress intended to provide Medicare with broad powers to recover payments it made on behalf of its beneficiaries from negligent tortfeasors and from their liability insurers. But in order for Medicare to recover conditional payments under the MSP, a beneficiary must have a right of action against the tortfeasor. The government can subrogate to the rights of its beneficiaries only when those beneficiaries can bring a suit. And the

114. Recovery of payments made on behalf of Medicare beneficiaries for automobile-related injuries could be significant: a recent study showed that recovery of motor vehicle-related health care payments by Medicare through the MSP provisions could result in \$1 billion annually for the Trust Fund. See Eric Helland & Fred Kipperman, *Recovery Under the Medicare Secondary Payer Act: Impact of Reporting Thresholds*, RAND INST. FOR CIVIL JUSTICE (2011), http://www.rand.org/content/dam/rand/pubs/occasional_papers/2011/RAND_OP332.pdf.

115. 42 U.S.C. § 1395y(b)(2)(B)(iii).

116. See H.R. REP. NO. 1167 (1980).

117. *Id.*

118. 16 STEVEN PLITT ET AL., *COUCH ON INS.* § 222:8 (3d ed. 2014); see *supra* note 105 and accompanying text.

government can exercise its right of direct action only where the manufacturer or its insurer has incurred the legal obligation to pay for a harm. In the complex world of federal preemption of state tort suits, Medicare beneficiaries may have no right to sue, and thus manufacturers may incur no legal obligation to compensate, rendering the MSP subrogation and direct action mechanisms useless. Part II details the express preemption clause in the MDA, and the trio of Supreme Court cases that have broadly interpreted the reach of preemption; my goal is to demonstrate how broad preemption conflicts with Congress's purposes in the MSP.

II.

REGULATION OF MEDICAL DEVICES: THE TENSION BETWEEN COMMON LAW CLAIMS AND AGENCY REGULATION

Regulation of medical device manufacturers may be broken down into two broad categories. First, regulation may occur through private litigation, which is typically based on state tort law. Private regulation is applicable only to devices that are already on the market—postmarketing regulation—and often occurs on a case-by-case basis in individual suits.¹¹⁹ Second, regulation may occur through agency action based on congressionally granted authority. Agency regulation may occur in either the premarket or postmarket phase. In the premarket phase, the FDA may deny manufacturers permission to sell their devices, require certain changes prior to granting marketing approval, and require postmarketing surveillance and reporting. In the postmarket phase, agencies may proceed against manufacturers on a case-by-case basis, but most often bring actions against certain device models or types.

Until relatively recently, most regulation of manufacturers occurred through private regulation. State courts had been receptive to claims of manufacturers' negligence or strict product liability.¹²⁰ The legal landscape became more complicated after the Supreme Court's decision in *Cipollone v. Liggett Group*.¹²¹ In *Cipollone*, the Court held that the Public Health Cigarette Smoking Act of 1969¹²² preempted certain state-law damages claims.¹²³ *Cipollone*, however, left significant uncertainty as to the specific language the Court would look for to determine whether Congress intended to preempt state tort actions against cigarette makers: although the Court distinguished the

119. Many actions brought by individuals harmed by medical devices may be consolidated into single actions. See, e.g., *United States v. Baxter Int'l, Inc.*, 345 F.3d 866, 888 (11th Cir. 2003) (multidistrict litigation involving thousands of private actions against manufacturers of silicone breast implants).

120. Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691, 695 (1997).

121. 505 U.S. 504 (1992).

122. Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222 (codified as amended at 15 U.S.C. §§ 1331–1340 (2012)).

123. *Cipollone*, 505 U.S. at 521.

language of an earlier federal cigarette labeling law¹²⁴ from the 1969 version, the differences in the wording of the two acts hardly made a clear case for differences in congressional intent regarding the scope of preemption.¹²⁵

The MDA left little doubt, though, that Congress intended to preempt many state law actions against medical device makers: the MDA includes a clause that expressly preempts certain state-law-based actions against some FDA-approved devices.¹²⁶ Over the past twenty years, the Supreme Court has expanded federal preemption doctrine to bar many state law tort actions against medical device manufacturers for negligence or product liability.¹²⁷ This has largely eliminated, in certain classes of medical devices, the role of private regulation of medical device makers; unfortunately, there has not been a corresponding increase in administrative agency regulation.¹²⁸ In Part II.A, I review the history and structure of the MDA. In Part II.B, I examine the trio of cases through which the Court has articulated an expansive vision of federal preemption. In Part II.C, I review the justifications for an expansive federal preemption doctrine put forth by the Court and commentators. And in Part II.D, I describe how this vision of federal preemption makes it impossible in some cases to achieve the purposes of the MSP.

A. *The Medical Device Amendments: History and Structure*

Over the past century, dramatic advances in medical technology led to dramatic changes in the way the medical device industry is regulated. As innovators developed increasingly sophisticated medical devices, more and more patients came to depend on medical device technology. Although no published information on the total number of Americans who have an implanted Class III medical device¹²⁹ is readily available, data on just three specific Class III devices demonstrates that the total runs well into the tens of

124. Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92 (codified at 15 U.S.C. §§ 1331–1340 (1965)).

125. The 1965 Act established that “[n]o statement relating to smoking and health, other than the statement required by § 4 of this Act, shall be required on any cigarette package,” while the 1969 Act established that “[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes” Leflar & Adler, *supra* note 120, at 697 (emphasis removed). The Court found that the “no statement . . . other than the statement required [by federal law]” language of the 1965 Act did not preempt state law actions, while the “no requirement or prohibition . . . shall be imposed [if the packages are labeled according to federal law]” language of the 1969 Act did preempt state law actions. *Cipollone*, 505 U.S. at 521.

126. 21 U.S.C. § 360k(a) (2012).

127. Leflar & Adler, *supra* note 120, at 698.

128. *See infra* Part II.C.1.

129. Medical devices are divided into three classes. Class III devices are those intended to be used for supporting or sustaining human life, for preventing impairment of health, or which “present[] a potential unreasonable risk of illness or injury[.]” 21 U.S.C. § 360c(a)(1)(C)(II). Examples of Class III devices include artificial heart valves, implantable brain stimulators, and pacemakers. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008).

millions.¹³⁰ With the increasing sophistication of these devices and with the vital functions for which they are employed, the risks of catastrophic failures leading to widespread injury and death have risen. In the aftermath of one high-profile device failure, the Dalkon shield, in the late 1960s and early 1970s, individual states began to enact requirements that manufacturers had to meet before they could market their devices in those states. By 1976, thirteen states had enacted their own statutes that regulated the type of information device manufacturers were required to present before marketing a medical device within their borders.¹³¹ These state-level requirements were a form of ex ante regulation—they regulated devices before they could be sold. California’s Sherman Law, enacted in 1970, was considered the most rigorous.¹³² The law required medical device manufacturers to submit an application to market a new device to the State Department of Health.¹³³ The application required full reports of safety and efficacy data; detailed descriptions of device components and composition, manufacturing practices, properties, and principles of operation; samples; and specimens of labels and advertising.¹³⁴

Congress passed the MDA, amending the Food, Drug, and Cosmetic Act (“FDCA”), in 1976. Prior to this, the FDA had been able to regulate devices “only after they entered interstate commerce and only if the agency could show that the device was mislabeled or dangerous.”¹³⁵ There was no provision for premarket, ex ante review and approval. Although the FDA made sporadic attempts to regulate medical devices through its authority to regulate drugs, these efforts relied upon courts’ willingness to expansively interpret the FDCA to cover devices.¹³⁶ This was not a recipe for reliable oversight of medical devices.

The MDA provided for a uniform, nationwide system of premarket, ex ante device evaluation and approval under the direction of the FDA. The Act’s

130. An estimated 4.5 million Americans currently have an artificial knee joint. Alexander M. Weinstein et al., *How Many Americans Are Currently Living with Total Knee Replacement?* (Am. Acad. of Orthopedic Surgeons, Presentation Paper No. 797, 2012), http://www.aaos.org/Education/anmeet/education/Adult_knee_abstracts.pdf (abstract). Approximately 3.2 million people in the United States received an implanted cardiac pacemaker or defibrillator between 1993 and 2006. Steven M. Kurtz et al., *Implantation Trends and Patient Profiles for Pacemakers and Implantable Cardioverter Defibrillators in the United States: 1993–2006*, 33 *PACING & CLINICAL ELECTROPHYSIOLOGY* 705 (2010). Nearly 3.1 million Americans receive an intraocular lens implant following cataract surgery each year. Press Release, Ctrs. for Disease Control & Prevention, U.S. Outpatient Surgeries on the Rise (Jan. 28, 2009), <http://www.cdc.gov/media/pressrel/2009/r090128.htm>.

131. Leflar & Adler, *supra* note 120, at 703 & n.66.

132. CAL. HEALTH & SAFETY CODE §§ 26000–26851 (Deering 1991); Susan B. Foote, *Loops and Loopholes: Hazardous Device Regulation Under the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act*, 7 *ECOLOGICAL L.Q.* 101, 128 n.132 (1978).

133. Foote, *supra* note 132, at 128 n.132.

134. *Id.*; CAL. HEALTH & SAFETY CODE § 26670(b)(1)–(b)(6).

135. Foote, *supra* note 132, at 107.

136. *Id.* at 109–10 (discussing FDA use of its powers to regulate drugs by classifying nylon sutures and antibiotic disks as drugs).

preamble stated that its purpose was “to provide for the safety and effectiveness of medical devices intended for human use.”¹³⁷ According to one of the Act’s sponsors, its purpose was to give “the Food and Drug Administration the necessary authority to require that medical devices be proven safe and effective *before* they reach the American consumer.”¹³⁸ To assure that individual states did not disrupt nationwide uniformity by imposing their own premarket requirements, Congress included an express preemption clause in the MDA.¹³⁹ This clause established that

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device
¹⁴⁰

The FDA’s interpretation of the “requirement applicable . . . to the device” has been that only requirements specific to a given device trigger preemption under § 360k; general rules applicable to all devices do not trigger preemption.¹⁴¹ The Supreme Court held that this interpretation was entitled to deference.¹⁴²

For the first twenty years after the enactment of the MDA, the preemption clause received little attention.¹⁴³ However, a trio of cases decided by the Supreme Court since 1996 has established a stringent bar on tort suits brought by patients allegedly injured by some Class III medical devices. These cases greatly expanded the reach of federal preemption and greatly constricted the reach of private, *ex post* regulation of medical device manufacturers.

137. Medical Device Amendments of 1976, Pub. L. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.); *see* *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996).

138. 118 CONG. REC. S1859 (daily ed. Jan. 30, 1975) (statement of Sen. Kennedy) (emphasis added).

139. 21 U.S.C. § 360k (2012).

140. *Id.*

141. 21 C.F.R. § 808.1(d) (2014) (“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, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.” (emphasis added)). These device-specific FDA requirements are distinct from the Current Good Manufacturing Practices, promulgated under 21 C.F.R. §§ 820.20–250, which apply to all devices.

142. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 498–99 (1996) (federal requirements must be “applicable to the device” in question, and, according to the regulations, pre-empt state law only if they are “specific counterpart regulations” or “specific” to a “particular device”).

143. *See, e.g.,* Leflar & Adler, *supra* note 120, at 695–96 (noting that before 1985, few courts held that federal laws (including the MDA) preempted state law products liability actions).

B. Laying the Foundation for a Preemption Doctrine: Lohr, Riegel, and Buckman (“Trio”)

Prior to 1996, § 360k(a) of the MDA lay dormant. Since then, however, in its *Lohr*, *Riegel*, and *Buckman* decisions, the Court has created an expansive preemption doctrine. In *Medtronic, Inc. v. Lohr*, the Court held that “§ 360(k) simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions.”¹⁴⁴ *Lohr* can be—and sometimes has been—read as a rejection of federal preemption of state tort law actions.¹⁴⁵ The reach of the decision, though, is limited by the structure of the MDA.

The MDA created a two-track system for approval of medical devices. Under the Premarket Approval (PMA) process, the FDA must approve the design, manufacturing plans, and proposed labeling of a device before it can be marketed.¹⁴⁶ This process involves, on average, twelve hundred hours of investigation.¹⁴⁷ This requirement created a problem for the drafters: devices already on the market in 1976 would not have FDA approval for sale. In order to avoid the withdrawal of these devices until they had undergone the lengthy PMA evaluation, the MDA also contained an expedited form of review, the 510(k) process, under which devices on the market at that time were “grandfathered” in.¹⁴⁸ To avoid conferring a market monopoly on companies with grandfathered devices, the 510(k) process was also available to devices which were “substantially equivalent” to devices already on the market.¹⁴⁹ The 510(k) process involves an abbreviated review, typically consuming a mere twenty hours of agency time, through which a manufacturer must demonstrate only equivalence, not safety.¹⁵⁰ Devices approved under the 510(k) process are subjected only to general controls such as Current Good Manufacturing Practices.¹⁵¹

In *Lohr*, the plaintiff received pacemaker leads that had been approved by the FDA under the 510(k) process.¹⁵² The *Lohr* Court held that the 510(k) process does not result in the establishment of device-specific requirements.¹⁵³

144. 518 U.S. at 491.

145. See, e.g., *Stengel v. Medtronic, Inc.*, 676 F.3d 1159, 1169 (9th Cir. 2012) (Noonan, J., dissenting) (“Nothing in the statute prevents provision by a state of ‘a traditional damages remedy’ for violation of ‘state duties’ that parallel the federal requirements.”), *majority opinion overruled by* 704 F.3d 1224 (9th Cir. 2013) (en banc), *cert. denied*, 134 S. Ct. 2839 (2014).

146. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–19 (2008), for a summary of the PMA and 510(k) approval processes.

147. *Id.*

148. *Id.* at 317.

149. *Id.*

150. *Id.* at 322–23.

151. See 21 C.F.R. § 820.1(a)(1) (2014) (“Current good manufacturing practice[s] . . . govern the methods used in, and the facilities and controls used for, the design, *manufacture*, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.” (emphasis added)).

152. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 480 (1996).

153. *Id.* at 501.

Thus, the *Lohr* plaintiffs' state law claims were not subject to federal preemption, and were allowed to proceed.¹⁵⁴ However, because *Lohr* only addressed devices approved through the expedited 510(k) process, the preemptive effect of § 360k on devices approved through the rigorous PMA process was uncertain.

In *Riegel v. Medtronic* the Court dispelled this uncertainty, holding that state-established requirements, including those arising from common law tort suits, are preempted by device-specific requirements imposed by the FDA on devices approved through the rigorous PMA process.¹⁵⁵ The plaintiff had been injured when a balloon angioplasty catheter ruptured during its inflation within a coronary artery, necessitating emergency open-heart surgery.¹⁵⁶ Justice Scalia's majority opinion noted that Riegel's physicians were using the catheter in a situation in which the device was contraindicated, and further that they inflated the balloon to greater pressures than those for which it was approved.¹⁵⁷ These observations could have furnished a basis for denying the Riegels an opportunity to proceed against Medtronic: there was no evidence before the Court that the balloon catheter had performed less well than expected, and no evidence that Medtronic had failed to alert the physicians to the risks of such off-label usage. Instead, Justice Scalia's opinion used Riegels' suit to cement several building blocks of federal preemption under § 360k. First, the Court held that verdicts in state negligence and strict product liability actions can establish specific state law requirements "different from, or in addition to, [FDA-imposed] requirements."¹⁵⁸ Second, the Court held that devices approved through the rigorous PMA process were subject to device-specific requirements.¹⁵⁹ And third, only state law requirements that "parallel" federal requirements could survive preemption under § 360k.¹⁶⁰

Lohr and *Riegel* thus create a two-track federal preemption scheme that parallels the two-track approval structure of the MDA: medical devices approved under the 510(k) process are subject only to general federal controls, and thus may be the objects of state tort law actions, while devices approved under the PMA process are subject to device-specific federal controls and are thus immunized from state tort actions by federal preemption under § 360k. This explains why injured patients were able to pursue state tort actions against the manufacturers of silicone breast implants¹⁶¹ while other injured patients

154. *Id.* at 502.

155. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322–23 (2008).

156. *Id.* at 320.

157. *Id.*

158. *Id.* at 328–29 ("General tort duties of care . . . directly regulate the device itself, including its design." (internal quotation marks omitted)); *id.* at 324 ("[A] tort judgment therefore establishes that the defendant has violated a state-law obligation." (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992))).

159. *Id.* at 322–23 (internal quotation marks omitted).

160. *Id.* at 330.

161. *Cf. United States v. Baxter Int'l, Inc.*, 345 F.3d 866 (11th Cir. 2003).

were barred from pursuing state tort actions against the manufacturer of the Sprint Fidelis ICD lead.¹⁶² Justice Scalia found several justifications for the bifurcated legal landscape that the *Riegel* opinion created. First, he wrote that although devices approved under the 510(k) process need only be substantially equivalent to a device already on the market, and thus need not “take any particular form for any particular reason,”¹⁶³ devices approved under the PMA process had “to be made with almost no deviations from the specifications in its approval application...”¹⁶⁴ Because the FDA has, in the latter situation, made a determination that “the approved form provides a reasonable assurance of safety and effectiveness,”¹⁶⁵ state legislators and trial court juries should not be allowed to second guess this expert determination. Second, he stated that while approval under the PMA process “is federal safety review,” approval under the 510(k) process is merely “focused on *equivalence*.”¹⁶⁶ Again, allowing private tort suits against devices whose safety had never been vetted by the FDA is acceptable, while allowing suits against devices that the FDA had found safe is not. And, third, he argued that any “solicitude for those injured by FDA-approved devices . . . was overcome in Congress’s estimation by solicitude for those who would suffer without *new* medical devices if juries were allowed to apply the tort law of fifty states to all innovations.”¹⁶⁷ This assertion goes beyond the stated purposes of the MDA—to assure the safety and efficacy of medical devices¹⁶⁸—adding a newly discovered purpose: to foster the development of new medical technology.

The preemptive effect of the MDA received its most expansive interpretation in *Buckman v. Plaintiffs’ Legal Committee*.¹⁶⁹ There, the Court held that nearly all suits brought under state law are, if not expressly preempted, then impliedly preempted.¹⁷⁰ The *Buckman* plaintiffs alleged that bone screws approved by the FDA through the 510(k) process had injured them.¹⁷¹ The screws had been approved for use in the long bones—typically for stabilization of fractures of the arm and leg bones—but in the plaintiffs’ cases they had been used to stabilize the spine.¹⁷² The plaintiffs alleged that Acromed, the company that had assisted the bone screw manufacturer’s 510(k)

162. Cf. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010) (holding that design defect, manufacturing defect, and failure to warn claims against manufacturer of device approved through the PMA process were all preempted either expressly or impliedly).

163. *Riegel*, 552 U.S. at 323 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996)).

164. *Id.*

165. *Id.*

166. *Id.*

167. *Id.* at 326 (emphasis added).

168. See *supra* notes 136–137 and accompanying text.

169. 531 U.S. 341 (2001).

170. See *id.* at 353.

171. *Id.* at 343, 346.

172. *Id.* at 346–47.

application, had made fraudulent submissions to the FDA because the application was for use on long bones even though Acromed knew that physicians would use them on the spine.¹⁷³ As the Supreme Court noted, this type of off-label use of a medical device is a widely accepted aspect of medical practice and has statutory support.¹⁷⁴ This recognition offered a basis for rejecting the plaintiffs' fraud contention: the plaintiffs complained of a usage that was sanctioned by both medical practice and statutory enactments.

The Court, however, ruled that although § 360k(a) did not expressly preempt the plaintiffs' fraud-on-the-FDA claims,¹⁷⁵ the claims were impliedly preempted.¹⁷⁶ The Court invoked conflict preemption, holding that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud"¹⁷⁷ The Court actually seems to have had in mind obstacle, not conflict, preemption. In conflict preemption, it is impossible for an entity to comply with both the federal and state regulations;¹⁷⁸ clearly, Acromed could have complied with both simply by supplying more information to the FDA. In obstacle preemption, a state requirement stands as an obstacle to the attainment of a specific federal objective.¹⁷⁹ Here, state litigation would undercut—but not render impossible—the federal objective of solely empowering the FDA to police fraud against itself. Regardless of the terminology, the impact of *Buckman* is the same¹⁸⁰: state litigation is preempted when plaintiffs rely solely on a federal law or requirement.

The seemingly irreconcilable differences between the dicta in *Riegel*, that parallel state law claims are permitted, and the holding in *Buckman*, that parallel state law claims are preempted, have been unconvincingly explained as the result of *Riegel's* focus on express preemption under § 360k(a) and *Buckman's* focus on implied preemption.¹⁸¹ More relevantly, the *Buckman* action was based solely on federal law—there was no parallel state law on which the plaintiffs based their claims—the enforcement of which was solely assigned to the FDA.¹⁸²

173. *Id.*

174. *Id.* at 350.

175. The complaints alleged only that Acromed violated the requirement to submit factually accurate information to the Agency. *Id.* at 348.

176. *Id.*

177. *Id.* at 350.

178. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963).

179. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

180. The Court has held that the impact of preemption does not vary with the type of preemption employed. *See Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873–74 (2000) (calling the distinction between conflict and obstacle preemption “a terminological one” and finding no grounds “for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case”).

181. *See, e.g., Stengel v. Medtronic, Inc.*, 676 F.3d 1159, 1166 (9th Cir. 2012), *majority opinion overruled by* 704 F.3d 1224 (9th Cir. 2013) (en banc), *cert. denied*, 134 S. Ct. 2839 (2014).

182. 21 U.S.C. § 337(a) (2012); *Buckman*, 531 U.S. at 352–53.

Recent scholarship and litigation activity on preemption under the MDA have focused on defining “parallel claims.”¹⁸³ Lower courts have divided over whether a “narrow gap” exists through which parallel claims—those based on state laws that parallel federal laws—might slip. Some have found all products liability actions against device makers to be preempted, whether based on design defect, manufacturing defect, or failure to warn; others have held that some failure to warn claims may be viable.¹⁸⁴ In any analysis, the majority of products liability and negligence actions against the manufacturers of Class III medical devices approved through the PMA process are preempted either expressly or impliedly by the MDA.

C. Justifications for a Broad Preemption Doctrine

Although the Supreme Court has stated that its doctrine of virtually blanket application of preemption is necessary to allow the FDA to achieve the “delicate balance of statutory objectives”¹⁸⁵ committed to the Agency by the MDA, contemporary Supreme Court application of preemption doctrine to the MDA creates a brute force approach that does not allow the Act to achieve the limited purposes for which it was created in 1976. This expansive preemption doctrine frustrates the purpose of the MSP by depriving the government of subrogation rights for its Medicare beneficiaries and its right of direct action against tortfeasors.

The primary purpose of the MDA was clearly expressed in the legislative history and in the Act’s preamble: to ensure the safety of medical devices before they are marketed for use in the United States.¹⁸⁶ A second purpose was to ensure the effectiveness of medical devices during the premarket evaluation phase. A third purpose, articulated by Justice Scalia in *Riegel*, was to foster the development of new medical technology by imposing a single national standard as opposed to subjecting manufacturers to fifty different state approval

183. See, e.g., *Stengel*, 704 F.3d 1224; *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762 (5th Cir. 2011); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009); Jean Macchiaroli Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device “Parallel Claims,”* 9 J. HEALTH & BIOMEDICAL L. 159 (2013); J. David Prince, *The Puzzle of Parallel Claims, Preemption, and Pleading the Particulars*, 39 WM. MITCHELL L. REV. 1034 (2013); Catherine M. Sharkey, *Tort-Agency Partnerships in an Age of Preemption*, 15 THEORETICAL INQUIRIES L. 359 (2014).

184. Compare *In re Medtronic*, 623 F.3d 1200 (design defect, manufacturing defect, and failure to warn claims all preempted either expressly or impliedly), and *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005) (manufacturing defect and failure to warn claims were preempted), with *Hughes*, 631 F.3d 762 (only the postmarket duty to warn action viable), *Stengel*, 704 F.3d 1224 (duty to warn claim not preempted by MDA § 360k(a)), and *Riley*, 625 F. Supp. 2d 769 (a narrow statutory gap exists through which some actions may fit).

185. *Buckman*, 531 U.S. at 348.

186. See 118 CONG. REC. S1859 (daily ed. Jan. 30, 1975) (statement of Sen. Kennedy); see also *id.* (statement of Sen. Javits) (“This bill provides for both the establishment of standards and for premarket testing and scientific review.”).

requirements.¹⁸⁷ The Court had rejected this justification twelve years earlier in *Lohr*, making Justice Scalia's history questionable;¹⁸⁸ nonetheless, the proposed salutary impact of uniform regulation on new product development is an oft-cited benefit of federal preemption.¹⁸⁹

Other potential justifications may also support an expansive interpretation of preemption in the medical device context. One is that preemption is needed to protect manufacturers from potentially crushing liability. In the silicone breast implant cases, by the time of the settlement in *Baxter*, the manufacturer with the largest market share had declared bankruptcy.¹⁹⁰ This raises two important points. First, the potential exists for even very large manufacturers to be driven out of business. In areas of medical technology dominated by large manufacturers, the size of even the largest firms provides no assurance of a continued stream of new technology. Second, owing to the nature of development in certain fields, the risk is magnified by the vulnerability of smaller firms. In many medical device areas, new technologies are often developed by small start-up companies, which large, established companies then acquire with the goal of adding the new technologies to their portfolios.¹⁹¹ These smaller companies are far more vulnerable to litigation than the larger companies, even litigation that does not progress all the way to an adverse judgment.

Another proposed justification is based on institutional competence. As argued by several legal scholars,¹⁹² the FDA is the most competent regulator of the medical device industry. The Agency has internal expertise in determining facts and in navigating medical-device-related law as well as the power to convene panels of outside experts for advice on medical questions. While

187. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 326 (2008) (“[T]he text of the statute . . . suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress’s estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.”).

188. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 490 (1996) (“Indeed, nowhere in the materials relating to the Act’s history have we discovered a reference to a fear that product liability actions would hamper the development of medical devices.”).

189. *See, e.g., Buckman*, 531 U.S. at 350 (“[T]he shadow of 50 States’ tort regimes will dramatically increase the burdens facing potential applicants . . . [who] may be discouraged from seeking § 510(k) approval of devices.”).

190. At the time of the original settlement in the silicone breast implant cases, Dow Corning, which declared bankruptcy before the circuit court’s ruling in *Baxter*, had the largest market share of the defendants and was responsible for \$2.018 billion of the entire \$4.225 billion settlement. *In re Silicone Gel Breast Implant Prods. Liab. Litig.*, No. CV 92-P-10000-S, MDL No. 926, Civ. A. No. CV 94-P-11558-S, 1994 WL 578353, at *24 (N.D. Ala. Sept. 1, 1994); Jack W. Snyder, *Silicone Breast Implants: Can Emerging Medical, Legal, and Scientific Concepts Be Reconciled?*, 18 J. LEGAL MED. 133, 171 (1997).

191. *See, e.g., Yair Holtzman, The U.S. Medical Device Industry in 2012: Challenges at Home and Abroad*, MED. DEVICE & DIAGNOSTIC INDUS. (July 17, 2012), <http://www.mddionline.com/article/medtech-2012-SWOT>.

192. *See, e.g., 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 (2010).

funding and staffing issues have limited the FDA's effectiveness, these limitations do not negate the Agency's institutional competence. Critics of tort litigation have argued that courts and juries are not well suited to perform a regulatory function over medical device manufacturers.¹⁹³ Jury trials may be subject to deficient fact finding because of an inability to understand complex technology and an overreliance on emotional issues. More importantly, regulation through the aggregate effect of numerous state law actions often lacks the needed coordination to achieve the proper level of deterrence. Further, FDA staff would acquire even more expertise were the regulation of medical devices fully shifted from state tort systems to the administrative system.¹⁹⁴ And, the nationwide scale on which the Agency operates minimizes high information costs.¹⁹⁵ Therefore, "[i]f [the FDA] operated effectively, the tort system—at least in its whistleblower and deterrent capacities—might well be unnecessary."¹⁹⁶

D. The Consequences of a Broad Preemption Doctrine: How the Trio Frustrates the Goals of the Medicare Secondary Payer Act

Although the expansive preemption doctrine developed through the *Lohr*, *Buckman*, and *Riegel* decisions has been justified on many grounds, the doctrine has clearly impeded the purposes of the MSP. The original MSP amended the Medicare Act to allow Medicare to function as a secondary payer where an automobile, liability, or no-fault insurance payer had made or could be expected to make payment promptly.¹⁹⁷ Over the next several years, Congress expanded the range of insurers who were required to be primary payers, allowing Medicare to make payments in fewer and fewer circumstances.¹⁹⁸ It also expanded the means by which Medicare could recover payments already made on behalf of its beneficiaries.¹⁹⁹ Although the Supreme Court has never addressed the limits of Medicare's powers to recover under the

193. *Id.* Moncrieff further addresses the argument that market forces should be sufficient to ensure the safety of devices, finding the argument lacking in force. Information costs (the difficulty that any individual learned intermediary—the physicians—who prescribes or implants the devices) and agency costs (the fact that the costs of device failures fall on patients, not on the physicians and hospitals who determine which devices are used) are high enough to prevent the functioning of an efficient market. *Id.* at 2355–57.

194. *Id.* at 2365–66 (“This institutional learning contrasts starkly with lay juries that have been charged, one panel at a time, with evaluating plaintiffs’ individual claims. Even if expert testimony worked flawlessly to inform lay jurors, the jurors’ evaluations of that testimony would be less sophisticated and more error-prone than expert bureaucrats’ own evaluations of individual cases[.]” (citations omitted)).

195. *Id.* at 2365–69.

196. *Id.* at 2344.

197. *United States v. Baxter Int’l, Inc.*, 345 F.3d 866 (11th Cir. 2003); Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, § 953, 94 Stat. 2599 (1980).

198. *See supra* notes 88–90 and accompanying text.

199. *See supra* notes 91–94 and accompanying text.

MSP and lower courts have reached mixed results,²⁰⁰ the overall trend, as demonstrated by the Eleventh Circuit's decision in *Baxter*, has been to interpret those powers increasingly broadly.

These broad powers under the subrogation and direct action clauses of the MSP, though, run squarely into the roadblock created by the Court's preemption doctrine under the MDA. In order to recover through its subrogation rights, the government depends on the existence of the rights of its beneficiaries. These rights typically arise under state law theories. Because state law causes of action are preempted for devices approved by the PMA process, Medicare recipients have no right of recovery against a device manufacturer, and thus, the government has no rights to which it may subrogate. Likewise, because patients with devices approved through the PMA process cannot obtain verdicts against device manufacturers, the manufacturers and their insurers never become legally liable to make payment in compensation for the patients' injuries. Because of this, the government's right of direct action is never triggered.²⁰¹ The result is a doctrinal collision between an expansive vision of the government's powers to recover payments and an expansive vision of preemption.

A close examination of the justifications used to support broad federal preemption of state lawsuits against medical device manufacturers shows that in many circumstances this doctrinal collision is unnecessary and counterproductive. The two stated purposes of, and the most frequently cited justifications for, preemption under the MDA are to assure device safety and efficacy.²⁰² The MDA accomplished this by granting the FDA authority to establish a regulatory floor by setting out *ex ante*, device-specific design, manufacturing, and labeling requirements based on an intensive premarket evaluation review.²⁰³ No state could grant premarket approval to a device for sale within its borders that did not meet the FDA-established floor. Nor could a state impose *ex ante*, premarket requirements more stringent than those imposed by the FDA, making the Agency's requirements a premarket regulatory ceiling as well.

Given the FDA's primary role in premarket evaluation and approval of medical devices, there is little worry that allowing suits under state law would

200. Compare *Baxter*, 345 F.3d at 894–95 (finding broad powers under the MSP for Medicare to recover payments made from compensation fund established for recipients of silicone breast implants and interpreting “self-insurance” as applied to device manufacturers broadly), with *Thompson v. Goetzmann*, 337 F.3d 489 (5th Cir. 2003) (interpreting “self-insurance” narrowly and finding that government's power to recover under the MSP was strongly circumscribed), *modifying* *Thompson v. Goetzmann (Goetzmann I)*, 315 F.3d 457 (5th Cir. 2002).

201. See 42 U.S.C. § 1395y(b)(2)(B)(iii) (2012) (allowing the United States to “bring an action against any or all entities that are or were required or responsible . . . to make payment”). Because no legal requirement or responsibility arises in the absence of a verdict or settlement, subsection (B)(iii) never comes into play where preemption applies.

202. See *supra* note 138.

203. *Id.*

adversely affect device safety. In a mass tort situation arising from a recalled medical device, multiple safety requirements could be avoided by the consolidation of all individual actions into a single multidistrict litigation or the formation of a class action. And even if multiple different safety requirements were to arise from actions in different states, none could fall below the FDA-established floor. Thus, no threat to device safety and efficacy would occur. In this circumstance, allowing device recipients to bring suit under state law *after* a device has been recalled raises no premarket issues: any requirement that may result on the basis of a state jury verdict would have no impact on whether the device may be sold within that state, since the device has already been removed from the market. For example, in the Medtronic Sprint Fidelis litigation, where the court dismissed on the basis of federal preemption the plaintiffs' consolidated actions against the manufacturer of a device placed under FDA recall,²⁰⁴ a requirement based on a jury verdict would have had no impact, since the Fidelis lead had already been removed from the market.

Justice Scalia's justification in *Riegel*—that preemption under the MDA operates to foster new technological development by exposing manufacturers to just a single regulatory regime²⁰⁵—is largely irrelevant in the post-recall context. Permitting state law actions against the manufacturers of recalled devices is *ex post* regulation, and any “requirements” that jury verdicts may impose are applicable not only to the device at issue, but also to devices under development. Medical devices have relatively short market lives; for example, a new model may supersede a model of an implanted cardiac defibrillator within two or three years.²⁰⁶ The time required to identify a pattern of device failures, to assemble and litigate a case, and to reach a verdict or a settlement virtually guarantees that by the time a state law requirement is imposed on a particular device through a trial verdict, that device will have been superseded. Even absent litigation in state courts, if the device had been recalled by the FDA, the Agency would have found that the problematic technology should not be used in future devices. State court verdicts would merely replicate this finding: an adverse verdict simply incentivizes a manufacturer not to use the identical technology; thus, state requirements would not implicate § 360k, the express preemption clause, since those requirements—not to use the already FDA-banned technology—are the same as those imposed by the Agency. Nor would state requirements implicate *Buckman*'s implied preemption bar, since the state requirements would arise under state law and would parallel those of

204. See *In re Medtronic Sprint Fidelis Lead Prods. Liab. State Court Litig.*, Nos. 27-CV-07-22446, etc., 2009 WL 3417867 (Minn. Dist. Ct. Oct. 20, 2009).

205. See *supra* notes 162–167.

206. Between 1989 and 2009, Medtronic released twenty-one ICD models. Although each release did not supersede all earlier models, the rate of newly marketed devices, more than one per year, demonstrates the rapid turnover in certain fields. See *Other Medtronic ICD Defibrillators*, MEDTRONIC.COM (May 29, 2012), <http://www.medtronic.com/for-healthcare-professionals/products-therapies/cardiac-rhythm/implantable-cardioverter-defibrillators-icds/historical-icd-defibrillators>.

the FDA. Returning to the Sprint Fidelis example, a state bar on the unique feature of the lead that led to its failure would have no impact on technological development, since that technology had already failed.

The institutional competence justification for preemption also lacks force in the context of a device that the FDA has recalled: the Agency itself has already determined that removal of the device from commerce is necessary. Professor Catherine Sharkey has suggested that courts should solicit input from the relevant agency when deciding whether permitting a suit to proceed based on state law would interfere with the Agency's enforcement prerogatives.²⁰⁷ In effect, this would give the Agency the ability to determine on a case-by-case basis whether federal law should preempt a state lawsuit. Permitting the FDA to determine the preemptive effect of a recall could enable the Agency to tailor its actions, allowing some recalled devices to be exempted from state actions and thus protecting vulnerable but productive manufacturers while removing a dangerous device from the market.

Finally, courts could minimize the risk of bankruptcy as a disincentive to medical device manufacturers by ensuring that all recovery actions are channeled through a single action. While the risk to device manufacturers—particularly smaller and newer manufacturers—of bankruptcy-producing litigation is real, preserving some level of risk may serve a desirable deterrent purpose. The use of consolidated pretrial hearings or mandatory class action procedures to screen out meritless claims can mitigate the concern that allowing suits under state law may expose manufacturers to successive suits and potentially crushing liability.²⁰⁸ Knowing that it might face a single action (as opposed to multiple individual actions) allows a manufacturer to plan for worst-case possibilities.

Recognizing that state-law-based suits against the manufacturers of FDA-recalled medical devices need not be barred by federal preemption would also satisfy the equitable subrogation principles underlying the MSP. Doing so would facilitate the balancing of inequities that exist by virtue of federal preemption between Medicare, device manufacturers, and the manufacturers' liability insurers. Enabling Medicare to recover its payments to beneficiaries would put the program back into the position it was in before the device failure, hold the device manufacturer responsible for the safety of its devices, and prevent the manufacturer's liability carrier from being unjustly enriched at Medicare's expense. Unfortunately, given the Supreme Court's present, expansive preemption jurisprudence, the MDA stands as an obstacle to these goals of the MSP.

The impact of the doctrinal collision between the MDA and the MSP is somewhat mitigated by two factors. First, the preemption-invoking PMA

207. Sharkey, *supra* note 183, at 359–60.

208. See 28 U.S.C. § 1407 (2012).

process approves only a minority of medical devices; the majority are approved through the 510(k) process.²⁰⁹ Therefore, most medical devices are not protected from negligence or products liability suits by the express or implied preemption doctrines. Medicare recipients may bring state law actions against the makers of these devices; these actions may form the basis of governmental actions under the subrogation and direct action clauses of the MSP. Second, the government has an array of other tools at its disposal—including *qui tam* actions, criminal actions, etc.²¹⁰—that may allow it to recover against the manufacturers of defective devices.

Unfortunately, neither of these considerations is sufficient to prevent Medicare from absorbing the cost of many defective devices, an outcome clearly not intended by Congress when it enacted the MDA. Even though preemption bars governmental recovery for only a minority of devices, these devices, by the nature of the technology that led to their approval through the PMA process, are often quite expensive. To use the example discussed earlier, estimates of the cost of the Sprint Fidelis lead failure to Medicare range from \$287 million to \$1.2 billion.²¹¹ The failure of even one high-cost, widely used device can have a substantial impact on Medicare's finances.²¹² And, while the other legal means available to the government allow recovery in some circumstances, these means are not ideal for many device-failure situations. The limitations of the currently available means are the topic of Part III.

III.

THE GOVERNMENT'S EXISTING, NON-IDEAL RECOVERY TOOLS

Removing the road block of federal preemption for suits brought under state law against the manufacturer of a defective medical device that has been recalled by the FDA would facilitate the purposes of the MSP without impeding the purposes of the MDA. To maintain FDA primacy, Congress could limit suits to those against the makers of devices that the FDA had placed under recall, assure that only *ex post* regulation occurred, and require input

209. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008) (“In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices.”). Although the ratio has become less strongly tilted in favor of 510(k) approval, a strong majority of approvals is through the 510(k) process: a review of the FDA online database showed that in January 2013, 266 devices were approved through the 510(k) process, compared with only 128 through the PMA process. *Medical Devices: Device Approvals, Denials and Clearances*, FDA.GOV (Aug. 11, 2014), <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances>.

210. See *infra* Part III.B.

211. Mehrotra et al., *supra* note 13, at 1197; TOLLEY, *supra* note 13, at 18.

212. The potential cost of the Sprint Fidelis recall to Medicare is likely the best documented of recent Class III device failures. However, recovery actions following the failure of other PMA-approved Class III devices used by Medicare-aged individuals also have been dismissed because of preemption under § 360k. See *Riegel*, 552 U.S. 312 (coronary artery stents); *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (spinal stabilizing hardware).

from the Agency regarding whether its requirements had preemptive effect. Individual actions could be consolidated to permit resolution through a single litigation.

In spite of preemption, the government is far from lacking in other tools to recover payments made on behalf of its beneficiaries. Through civil fines, criminal penalties, qui tam actions, and other means, it is estimated that the FDA alone recovered over \$847 million in 2008.²¹³ Congress has expanded many of these tools since the enactment of the original Food, Drug, and Cosmetic Act of 1938.²¹⁴

The 1938 Act gave the Agency only limited postmarketing oversight of devices: the FDA was permitted to argue that the court should remove a device from the market through “injunctions, criminal actions, or civil seizures.”²¹⁵ At that time, the Agency was focused on fraudulent devices—quack instruments touted for unsubstantiated benefits.²¹⁶ Importantly, the powers conferred by Congress afforded no authority to recover government payments made to device makers. This is not surprising given that in 1938, only 1.5 percent of federal government spending was for health care.

As medical technology came to occupy a more central role in health care and as expenditures for overall health care in general, and for medical devices in particular increased, the government’s powers to recover payments to device makers expanded. Most of these powers, however, were derived from the FDA’s original mission of preventing the sale of fraudulent devices and are thus based on punitive and deterrence rationales. These rationales are far from ideal in the context of recovery under the MSP. What follows is a brief examination of these powers.

A. Civil Monetary Penalties

The Safe Medical Devices Act of 1990 amended the MDA, conferring on the FDA new authority to impose civil monetary penalties.²¹⁷ The amount that may be collected is currently \$15,000 for each violation of the MDA with a maximum penalty of \$1 million total for violations adjudicated in a single proceeding.²¹⁸ The FDA considers these penalties to be deterrent, stating that

213. See FDA, THE ENFORCEMENT STORY, FISCAL YEAR 2008, at 10-2 (undated), <http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129823.pdf>.

214. See *supra* notes 88–94 and accompanying text.

215. Rodney R. Munsey, *Trends and Events in FDA Regulation of Medical Devices over the Last Fifty Years*, 50 FOOD & DRUG L.J. 163, 164 (1995).

216. See *id.*; Richard A. Merrill, *Regulation of Drugs and Devices: An Evolution*, 13 HEALTH AFF. 47, 56 (1994).

217. Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 17, 104 Stat. 4511, 4526–27 (codified at 21 U.S.C. § 333 (2012)); FDA, DRAFT GUIDANCE FOR FDA STAFF: CIVIL MONETARY PENALTY POLICY (released for comment June 8, 1999), http://www.elsevierbi.com/~media/Images/Publications/Archive/The%20Gray%20Sheet/35/046/01350460003/111609_cmp_policy.pdf.

218. 21 U.S.C. § 333(f)(1)(A).

they were “designed to influence future conduct . . . either directly, by affecting current violative conduct, or indirectly, by serving to deter future violative conduct.”²¹⁹

This focus on deterrence is apparent in the use of penalties against individual corporate officers. Courts have long recognized the Agency’s authority to impose sanctions for violations of the FDCA on individual corporate officers.²²⁰ Section 333(f) establishes that “any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty”²²¹ The agency has used this authority to impose civil monetary penalties on corporate officers, notably in failure to warn cases.²²² Targeting corporate officers—as opposed to the corporation itself—reflects the FDA’s focus on deterrence as opposed to recovery, since a corporation’s vastly superior resources compared to those of its individual officers would make the corporation the logical target were the Agency’s goal recovery.

The FDA’s assessment of civil monetary penalties does meet some of the criteria for an ideal recovery tool. All claims against a manufacturer based on a single design defect, manufacturing flaw, or failure to warn can be resolved in one action, avoiding the risks of multiple litigation and potentially unlimited liability. And the extensive procedural guarantees under the Administrative Procedure Act ensure that the penalties are neither arbitrary nor excessive. An administrative law judge, whose decision is reviewable by the Departmental Appeals Board (“DAB”) within the Department of Health and Human Services, must approve fines sought by the Agency.²²³ The circuit courts may review decisions by the DAB.²²⁴

Unfortunately, the remedy of civil monetary penalties falls short of the remedies available under the MSP in several ways. Most importantly, while under the MSP the government may recover all of its payments, under civil monetary penalties there is no link between the amount that the government may recover and the total cost of the device failure to Medicare. For example, in the Sprint Fidelis case, estimates of the cost of each failure range between \$13,800 and \$46,535.²²⁵ While the low end of this range would suggest that civil monetary penalties could completely reimburse Medicare for its device-related costs, if the upper range is more accurate, then recovery would be far

219. FDA, DRAFT GUIDANCE FOR FDA STAFF, *supra* note 217, at 6.

220. *United States v. Dotterweich*, 320 U.S. 277 (1943); *United States v. Hodges X-Ray, Inc.*, 759 F.2d 557, 560–61 (6th Cir. 1985) (citing *United States v. Park*, 421 U.S. 658 (1975)).

221. 21 U.S.C. § 333(f)(1)(A).

222. *See, e.g.*, *TMJ Implants, Inc. v. U.S. Dep’t. of Health & Human Servs.*, 584 F.3d 1290, 1302–03 (10th Cir. 2009) (imposing civil fines totaling \$170,000 for seventeen violations of FDA reporting requirements under 21 U.S.C. § 360i (2012)).

223. *See id.* at 1293–94.

224. *Id.* at 1294.

225. TOLLEY, *supra* note 13, at 11.

less than the costs. Further, the \$1 million recovery cap limits the government's recovery to only sixty-seven device failures (\$1 million total recovery divided by \$15,000 per recovery). Even the most conservative estimates of the Sprint Fidelis lead suggest that 2,625 patients will experience a lead failure each year.²²⁶ Thus, even if the per failure recovery rate fully reimburses Medicare for an individual failure, recovery is capped far below an amount that would completely reimburse the program. Even if the \$1 million cap on recovery were raised, without substantial revision nothing in § 333(f) would tie the size of the penalty to the loss sustained by Medicare.²²⁷ Thus, manufacturers would be unable to take into account their potential liability when weighing the costs of greater precautions against the risk of a civil monetary penalty in the event of a systematic device failure. The disconnect between the costs incurred by Medicare and the range of civil monetary penalties results in distorted incentives to device manufacturers to assure device safety, making these penalties a suboptimal recovery tool.²²⁸

B. Criminal Penalties

Section 333(a) establishes criminal penalties, including prison terms for certain violations of the FDCA, and fines of \$1,000 for initial violations and \$10,000 for repeat, fraudulent, or misleading violations.²²⁹ Since the enactment of the Criminal Fine Improvements Act of 1987,²³⁰ "all federal offenses are governed by the alternative fine provision in 18 U.S.C. § 3571[]." ²³¹ Section 3571 establishes fines on individuals up to \$250,000 for felonies and misdemeanors resulting in death and up to \$100,000 for misdemeanors.²³² For corporations, fines up to \$500,000 are permitted for felonies and misdemeanors resulting in death.²³³ Further, § 3571 establishes an alternative fee structure

226. See Amit K. Mehrotra et al., *supra* note 13, at 1197. Mehrotra conservatively assumed an annual failure rate of 1.5 percent occurring among 175,000 Fidelis leads. This yields a calculated 2,625 failures per year.

227. See 21 U.S.C. § 333(f) (2012).

228. The Social Security Act also provides for civil monetary penalties under 42 U.S.C. § 1320a-7a. However, the government does not appear to have ever attempted to use this statute against medical device providers in the products liability arena: a WestlawNext search for the term "1320a-7a" performed on September 7, 2013 yielded 196 cases in which the statute was cited. None of these cases was a products liability case. Even if § 1320a-7a could be applied to products liability cases, the penalties would be calculated based on the price paid by the government for the device itself but would not include the substantial hospital and physician costs.

229. 21 U.S.C. § 333(a).

230. Pub. L. No. 100-185, § 6, 101 Stat. 1279, 1280 (1984) (codified as amended at 18 U.S.C. § 3571 (2012)).

231. *Burgos v. United States*, 968 F. Supp. 380, 383 (N.D. Ill. 1997).

232. 18 U.S.C. § 3571(b)(3)–(b)(5) (2012).

233. *Id.* § 3571(c)(3)–(c)(5).

under which a defendant who “derives pecuniary gain from the offense . . . may be fined . . . twice the gross gain.”²³⁴

The government has used these criminal fines in several recent high-profile drug and medical device cases. One recent example is the government’s action against the medical device manufacturer Guidant.²³⁵ In 2005, several different implantable cardiac defibrillator models manufactured by Guidant exhibited increased rates of failure, some resulting in patient deaths.²³⁶ The company failed to inform the FDA of these problems.²³⁷ In response, the government brought a criminal action against Guidant and several corporate officers, resulting in a plea agreement that included a criminal fine of \$253,962,251.²³⁸ This amount was calculated based on the alternative fine mechanism in § 3571: the government and Guidant agreed that the corporation’s profits on the sales of all affected devices amounted to \$144,410,693, which was multiplied by a factor less than two to obtain the ultimate fine.²³⁹

Although the imposition of criminal fines has the benefit of dealing with a device failure in a single action, several considerations render criminal fines an imperfect tool for the recovery of Medicare payments. First, the intent of criminal fines is punitive and deterrent as opposed to recovery oriented. Second, while the FDA may pursue criminal penalties, the Agency must still convince an occasionally reluctant Department of Justice to prosecute the case.²⁴⁰ The United States Attorney in the region where the Agency seeks to bring the case may decline to prosecute and, although rare, may allot FDA requests for action a low priority.²⁴¹ Third, there is no necessary correlation between the government’s loss through Medicare payments and the fines assessed. In *Guidant*, the fine was based on the corporation’s profit,²⁴² essentially the difference between what the government paid for each device and the cost of making the device. This amount bears no relationship to Medicare’s cost, which includes not only the price of the device but also hospital charges, physicians’ fees, and other health care expenses. Using the

234. *Id.* § 3571(d). If the defendant’s action causes a loss to another party, the fine may be up to twice the other party’s loss. *Id.*

235. *United States v. Guidant, LLC*, No. 10-MJ-67 DWF, 2011 WL 7395041 (D. Minn. 2011). Boston Scientific acquired Guidant in 2006. Press Release, Bos. Sci., Boston Sci. & Guidant Announce Signing of Merger Agreement Valued at \$27 Billion (Jan. 25, 2006), <http://bosonscientific.mediaroom.com/index.php?s=24913&item=22235>.

236. Barry Meier, *Maker of Heart Device Kept Flaw from Doctors*, N.Y. TIMES (May 24, 2005), <http://www.nytimes.com/2005/05/24/business/maker-of-heart-device-kept-flaw-from-doctors.html>.

237. *Id.*

238. *See Guidant*, 2011 WL 7395041, at *9.

239. *Id.*; 18 U.S.C. § 3571(d). The court did not explain its choice of the multiplier.

240. JAMES T. O’REILLY, *FOOD AND DRUG ADMINISTRATION* §§ 8-34 to 8-35 (3d ed. 2012).

241. *Id.* § 8-35.

242. *Guidant*, 2011 WL 7395041, at *9.

government's loss as the basis for Medicare's cost calculation could conceivably minimize this discrepancy.²⁴³ However, this mechanism has not been tested. The fourth, and most limiting, problem with the criminal fine mechanism is that many medical device failures do not involve criminal activity. Design flaws and manufacturing defects may occur because of non-criminal negligence and perhaps more commonly because the inherent limits in the medical device knowledge base preclude recognition of problems before they manifest. And failure to warn issues raise perhaps the most complex issue in medical device products liability: When does a manufacturer *know* that a device is defective?

C. Forfeiture

The government has used forfeiture to recover Medicare payments for defective medical devices. The FDA has authority pursuant to 21 U.S.C. § 334 to move for the condemnation in a U.S. district court of adulterated or misbranded medical devices.²⁴⁴ The devices are liable to seizure, and if actions are brought in multiple district courts, § 334 calls for the consolidation of the actions.²⁴⁵ Devices that are condemned under § 334 may be destroyed or sold, with "the proceeds thereof . . . paid into the Treasury of the United States."²⁴⁶

However, the medical device context often creates a difficult issue for the application of the condemnation-seizure-sale mechanism: implanted medical devices cannot be removed without significant risk and expense. For example, removal and replacement of an implanted cardioverter-defibrillator such as the Guidant Ventak Prizm II was associated with a risk of major complications of up to 5.8 percent in one study.²⁴⁷ Sometimes, a high risk of failure of an implanted device, when weighed against the rate of complications of surgery, leads to a recommendation in favor of the prophylactic replacement of devices under FDA recall.²⁴⁸ More often, though, the official recommendation is that the devices be left in place and closely monitored. As a result, the government cannot seize and sell the affected devices.²⁴⁹ In *Guidant*, the government and

243. See 18 U.S.C. § 3571(d).

244. 21 U.S.C. § 334(a)(2)(D) (2012).

245. 21 U.S.C. § 334(b).

246. 21 U.S.C. § 334(d)(1).

247. Paul A. Gould & Andrew D. Krahn, Canadian Heart Rhythm Soc'y Working Grp. on Device Advisories, *Complications Associated with Implanted Cardioverter-Defibrillator Replacement in Response to Device Advisories*, 295 JAMA 1907, 1910 (2006).

248. See, e.g., Birnie et al., *supra* note 10, at 1224 (recommending that Sprint Fidelis leads be prophylactically removed and replaced only when the patient undergoes a routine surgery to replace the defibrillator when the battery is exhausted).

249. See, e.g., Motion for Preliminary Order of Forfeiture at 2, 4, *United States v. Guidant, LLC*, No. 10MJ00067, 2011 WL 7431168 (D. Minn. Jan 6, 2011) ("Clearly, the Contak Renewal I defibrillator devices are not available for forfeiture."). Notably, even if all of the affected devices were removed and made available to the government, federal law prohibits the resale and reuse of implanted medical devices. Thus, seizure and resale are even less feasible.

the company reached a plea agreement, part of which included an agreement by the company to pay a forfeiture of \$42,079,675.²⁵⁰ This amount was based on the “scrap value” of the devices: because Guidant estimated the scrap value to be \$4,675 per device and had sold 9,001 devices in the United States, the court deemed the value of the defective devices as just over \$42 million.²⁵¹

The condemnation-seizure-forfeiture mechanism suffers from many of the same limitations as the criminal penalties mechanism. Most importantly here, the mechanism leads to recoveries that are unrelated to the costs borne by Medicare. Basing recovery on the scrap value of all devices sold bears no relation to the total cost to Medicare for the care related to the defective and potentially defective devices.

D. Equitable Remedies: Restitution and Disgorgement

In criminal proceedings, the FDA has occasionally used the equitable remedies of restitution and disgorgement to recover from drug manufacturers.²⁵² The distinction between restitution and disgorgement has not always been clear in court decisions. Restitution of money payments focuses on returning the claimant to the position occupied before the exchange and is thus calculated as the amount paid by the claimant.²⁵³ Disgorgement, on the other hand, focuses on the defendant’s gains.²⁵⁴ Disgorgement seeks to strip the defendant of all ill-gotten profits, even if this leads to recovery of an amount greater than the claimant’s loss.²⁵⁵ This means that as a remedy, disgorgement is not concerned primarily with who should get the money afterward, whereas in restitution the money must be returned to the person(s) or entities who paid the defendant.²⁵⁶

Perhaps because of this attribution problem, the FDA has often pursued disgorgement in drug cases in which it would likely prove prohibitively difficult to attribute payments to thousands of drug purchasers via complex health care and pharmaceutical coverage plans. By contrast, this attribution

250. *Id.*

251. *Id.* at 6.

252. *See, e.g.*, *United States v. Rx Depot, Inc.*, 438 F.3d 1052, 1058 (10th Cir. 2006) (holding that disgorgement is available under the FDCA in the absence of “clear legislative command or necessary and inescapable inference prohibiting disgorgement” or inconsistency with purposes of FDCA); *United States v. Lane Labs*, 427 F.3d 219 (3d Cir. 2005) (finding restitution to fall within the “broad equitable power granted to the district courts,” whether or not Congress specifically contemplated restitution when enacting the FDCA). *But see* *United States v. Philip Morris USA, Inc.*, 396 F.3d 1190 (D.C. Cir. 2005) (finding that equitable relief was not available under RICO statutes).

253. *See* RESTATEMENT (THIRD) OF RESTITUTION AND UNJUST ENRICHMENT § 49(2) (AM. LAW INST. 2011).

254. *See id.* § 51(4) & cmt. a.

255. *Id.*

256. *See* Eric M. Blumberg, *Universal Management, Abbott, Wyeth, Schering-Plough, and . . . : Restitution and Disgorgement Find Another Home at the Food and Drug Administration*, 58 FOOD & DRUG L.J. 169, 173 (2003).

problem is not present in the medical device context, where the government would be seeking return of the payments that a single entity—Medicare—had made. Even so, courts have been hesitant to order disgorgement. In civil proceedings in *United States v. Universal Management Services, Inc.*, the FDA sought an order for the disgorgement of Universal's profits from the sale of adulterated medical devices. The district court held that it had the authority to order disgorgement but questioned—based largely upon the fact that no prior cases brought by the FDA had led to a disgorgement order—the appropriateness of this remedy; instead, the court ordered restitution.²⁵⁷ On appeal, the district court's ruling was upheld.²⁵⁸ And in *United States v. Abbott Laboratories*, the FDA obtained an order for restitution to the U.S. Treasury of profits from the sale of devices manufactured in violation of established standards.²⁵⁹

Although courts have been willing to grant restitution orders in drug and device cases, commentators in the legal academy and in practitioners' journals have been highly critical of the government's attempts at using disgorgement. Some commentators have argued forcefully that the FDCA did not authorize courts to order disgorgement for violations of the Act, that Congress did not intend to authorize disgorgement, and that the legislative history actually demonstrated a congressional intent not to authorize disgorgement.²⁶⁰ Others have argued that the Agency failed to articulate a clear policy that justified the use of disgorgement and abused its power to withhold drug approvals in order to coerce manufacturers into signing consent decrees containing disgorgement orders.²⁶¹

Ultimately, these equitable remedies fall short of the ideal for the MSP-established recovery mechanism. Neither restitution nor disgorgement fully repays Medicare's costs—at best, the program can recover the amount it paid the device manufacturer, leaving the program short the amount it paid to hospitals, physicians, and other entities.

257. *United States v. Universal Mgmt. Servs., Inc. (Universal I)*, 999 F. Supp. 974, 980 (N.D. Ohio 1997), *aff'd*, *United States v. Universal Mgmt. Servs., Inc. (Universal II)*, 191 F.3d 750 (6th Cir. 1999).

258. *Universal II*, 191 F.3d at 762.

259. *United States v. Abbott Labs.*, No. 99C 7135, 1999 U.S. Dist. LEXIS 18897 (N.D. Ill. Nov. 2, 1999).

260. Erika King & Elizabeth M. Walsh, *The Authority of a Court to Order Disgorgement for Violations of the Current Good Manufacturing Practices Requirement of the Federal Food, Drug, and Cosmetic Act*, 58 FOOD & DRUG L.J. 149, 155–60 (2003).

261. William W. Vodra & Arthur N. Levine, *Anchors Away: The Food and Drug Administration's Use of Disgorgement Abandons Legal Moorings*, 59 FOOD & DRUG L.J. 1 (2004). Notably, both the Vodra and Levine and the King and Walsh articles use "disgorgement" in discussing *Universal I* and *II*, even though the district court clearly declined to award disgorgement, instead ordering restitution. *See id.*; King & Walsh, *supra* note 260.

E. False Claims Act and Qui Tam Actions

The False Claims Act (“FCA”)²⁶² has become one of the government’s most effective tools for recovering monies paid to fraudulent purveyors of goods and services. Originally enacted in response to rampant fraud during the Civil War, the FCA aims to harness private citizens’ knowledge of actions bilking the government out of money.²⁶³ Since the last major overhaul by Congress in 1986,²⁶⁴ the FCA has been used with increasing frequency: in 1987, only thirty qui tam suits were filed, while in 2012, there were six hundred and forty-seven.²⁶⁵ In the first nine months of 2012, over \$3.3 billion was recovered through qui tam suits.²⁶⁶ Of this, over \$2.5 billion was recovered on behalf of the Department of Health and Human Services,²⁶⁷ making recovery of health care expenses—mainly Medicare payments—the most remunerative application of the FCA for the government.

The FCA makes it an offense to “(A) knowingly present[], or cause[] to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly make[], use[], or cause[] to be made or used, a false record or statement material to a false or fraudulent claim.”²⁶⁸ Thus, a device manufacturer who sought payment for a device it knew to function below the standards established by the FDA could face liability under the FCA.²⁶⁹ Although the FCA provides for civil penalties between \$5,000 and \$10,000 for each violation,²⁷⁰ the real heart of the Act is that it allows for recovery of treble damages sustained by the government.²⁷¹ To encourage private citizens to come forth, the Act allows a private citizen—the “relator”—to file suit under the government’s name and to keep 15 to 30 percent of all money recovered.²⁷² The government must investigate all claims filed under the Act²⁷³ and may either choose to join the action (in which case it has the primary responsibility

262. 31 U.S.C. §§ 3729–3733 (2012).

263. HENRY SCAMMELL, *GIANTKILLERS: THE TEAM AND THE LAW THAT HELP WHISTLE-BLOWERS RECOVER AMERICA’S STOLEN BILLIONS* 36 (2004).

264. False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (1986) (amending 31 U.S.C. §§ 3729–3733).

265. U.S. DEP’T OF JUSTICE, *FRAUD STATISTICS - OVERVIEW: OCTOBER 1, 1987–SEPTEMBER 30, 2013*, at 2 (2013), http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf.

266. *Id.* The total for 2012 was \$4.9 billion. Press Release, Office of Pub. Affairs, U.S. Dep’t of Justice, *Justice Department Recovers Nearly \$5 Billion in False Claims Act Cases in Fiscal Year 2012* (Dec. 4, 2012) (updated Oct. 22, 2014), <http://www.justice.gov/opa/pr/2012/December/12-ag-1439.html>.

267. U.S. DEP’T OF JUSTICE, *supra* note 265, at 4.

268. 31 U.S.C. § 3729(a)(1)(A)–(1)(B).

269. *See* 31 U.S.C. § 3729(b)(2)(A) (defining “claim” as “any request or demand, whether under a contract or otherwise, for money . . . that—(i) is presented to an officer, employee, or agent of the United States . . .”).

270. 31 U.S.C. § 3729(a)(1).

271. *Id.*

272. *Id.* § 3730(d)(1)–(d)(2).

273. *Id.* § 3730(a).

for prosecuting the action) or to decline to join, leaving the relator to pursue the claim independently.²⁷⁴

The FCA has features that make it the closest approximation to the recovery mechanisms created by the MSP. The FCA and its qui tam mechanism allow the government or a private relator to bring a single action concerning all devices implicated in a given failure. Unlike recovery measures based on fines and measures based solely on the amount that Medicare paid for a medical device, the government's recovery under the FCA is based on the totality of the damages sustained by the government. However, because actions under the FCA must be based on a violation of the Act itself,²⁷⁵ these actions are limited to failure to warn claims, where the manufacturer knew or should have known about a device defect. Thus, claims under the FCA could not extend to the other aspects of product liability, notably strict liability claims of defective design.²⁷⁶

* * *

Unfortunately, none of these means of recovery are ideal for at least two reasons. First, many of these tools depend on criminal activity, fraud, and other actions that are often lacking when the problem is a defective device. Thus, these tools may not be available to the government in the event of a costly medical device failure. Second, none of these tools is adequately tailored to recover the proper amount. To satisfy the goals of the MSP, the amount recovered should represent the total sum paid on behalf of a beneficiary attributable to the device failure.²⁷⁷ Some of the available means, such as settlement of criminal cases, may result in payments to the government far in excess of Medicare's costs. And other means, such as civil fines and court-ordered disgorgement, may undercompensate the government for payments made on behalf of Medicare beneficiaries.

The ineffectiveness of existing government tools highlights the tension between the MDA and the MSP created by the broad application of federal preemption. The effects of § 360k, the express preemption clause of the MDA, and the trio of MDA preemption cases—*Lohr*, *Riegel*, and *Buckman*—have generated much writing, most of it critical. I will not attempt to thoroughly canvass this rich literature; rather, in Part IV, I will examine some of the proposed alternatives to a world in which regulation and recovery through state tort systems is barred.

274. *Id.* § 3730(b)(4).

275. The FCA establishes the requirement of knowingly presenting a false or fraudulent claim as the basis of an FCA claim. *Id.* § 3729(a)(1).

276. Because the FCA includes a scienter requirement, *see id.* § 3729(b)(1)(A), strict liability products defect claims, which contain no scienter requirement, should not be able to serve as the basis for FCA claims. *See United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 743 (7th Cir. 2007), *overruled on other grounds by Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009); *United States ex rel. Crenshaw v. Degayner*, 622 F. Supp. 2d 1258, 1274–75 (M.D. Fla. 2008).

277. This, of course, can be disputed based on the double-recovery provision of the MSP.

IV.

PROPOSALS TO AVOID THE BAR ON RECOVERY UNDER EXISTING FEDERAL
PREEMPTION DOCTRINE: REPEAL, NARROWING, AND COMPENSATION

The most far-reaching approach to the conflict of preemption under the MDA and recovery under the MSP would be simply to repeal the express preemption clause and legislatively reverse the Supreme Court's relevant implied preemption doctrine. The proposed Medical Device Safety Act of 2009 ("MDSA") attempted just that—it would have modified the MDA's express preemption clause by adding that "[n]othing 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."²⁷⁸ Testifying in support of the MDSA, Professor Thomas McGarity reasoned that, in addition to the compensatory and deterrent benefits of subjecting manufacturers to state tort liability, reversing the course on federal preemption of medical device defect suits would be unlikely to lead to a conflict with an important federal policy.²⁷⁹ Instead, McGarity noted that "[t]o the extent that the device fails to comply with [f]ederal requirements, allowing common law claims to proceed would simply reinforce the primary purpose of the Medical Device Amendments, which is to protect patients from poorly designed and manufactured medical devices."²⁸⁰ Addressing the concern that exposing manufacturers to state tort liability could adversely impact the MDA's purpose of assuring access to cutting-edge technology, McGarity stated that "[a]lthough think tank reports and op-ed pages are filled with claims that the American civil justice system is depriving citizens of useful technologies, I have seen very little hard empirical support for such claims in the context of either drugs or medical devices."²⁸¹ In contrast, testifying in opposition to the MDSA, former Chief Council for the FDA, Peter Barton Hutt, focused on the need for national uniformity to preserve the FDA's authority over medical devices and on the superiority of the FDA's institutional expertise compared with state judges and juries.²⁸²

The MDSA was referred to the Senate Health, Education, Labor, and Pensions Committee, where it died.²⁸³ Given that the MDSA would have completely abandoned preemption, this outcome is likely favorable. Without empirical evidence of the effects of subjecting manufacturers to multiple regulatory regimes, the concern over the impact of tort litigation on new product development is significant in many contexts. For example, where a

278. Medical Device Safety Act of 2009, S. 540, 111th Cong. (2009).

279. See *Protecting Patients From Defective Medical Devices: Testimony on S. 540 Before the S. Comm. on Health, Education, Labor, and Pensions*, 111th Cong. 5 (2009) (statement of Thomas McGarity).

280. *Id.* at 25–26.

281. *Id.* at 22.

282. See *id.* at 5–6 (statement of Peter Barton Hutt).

283. *S. 540 (111th): Medical Device Safety Act of 2009*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/111/s540> (last visited June 5, 2015).

device has not been recalled, allowing states to impose their own requirements through jury verdicts may lead to a manufacturer's removal of the device from those states' markets, resulting in an uneven patchwork of access and safety. Further, where the FDA has not recalled a device, these state-level requirements may limit manufacturers' future design options, since the requirements would impact technological features that manufacturers might still wish to employ. Because of these concerns and the lack of empirical data on the beneficial effects of national regulatory uniformity on device makers, I do not advocate the wholesale repeal of § 360k. Instead, I claim that preemption must be applied on a more granular basis in the context of recalled devices.

A second approach urges courts to apply a narrow reading to the Supreme Court's implied preemption decisions in order to widen the narrow gap through which parallel claims may fit.²⁸⁴ Circuit courts have split over how to define parallel claims, which the Supreme Court in *Riegel* indicated could survive preemption.²⁸⁵ Some courts, including the Eighth Circuit, have so broadly read the implied preemption cases that although some cases may theoretically escape express or implied preemption, the gap is so small that no cases have yet fit.²⁸⁶ Others, including the Fifth, Seventh, and Ninth Circuits, have applied a narrow reading of the Court's implied preemption decisions that have permitted some plaintiff's failure to warn cases to avoid preemption.²⁸⁷ Thus far, the Supreme Court has been unwilling to settle this split among the circuit courts.²⁸⁸ And even if the Court were to settle the split in favor of allowing parallel failure to warn claims in the implied preemption circumstances that have arisen thus far, such a holding would not address the underlying problem of an overbroad application of federal preemption.

A third approach accepts preemption as a given and seeks to provide compensation for patients who have received defective medical devices through a no-fault system modeled on the National Vaccine Injury Compensation Program.²⁸⁹ This proposal would eliminate the need for lengthy

284. See, e.g., Elliot Sheppard Tarloff, *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).

285. See *Riegel v. Medtronic, Inc.*, 552 U.S. 313, 330 (2008) (stating in dicta that “§ 360k does not prevent a state from providing a damages remedy for claims premised on violation of FDA regulations” because “states duties in such a case ‘parallel,’ rather than add to, federal requirements”).

286. See *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010).

287. See *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) (en banc); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 775–76 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546, 556–58 (7th Cir. 2010).

288. The Court recently declined to review the latest parallel claims case. See *Medtronic, Inc. v. Stengel*, 134 S. Ct. 2839 (2014) (denying cert.).

289. See Malika Kanodia, Comment, *The Fate of the Injured Patient in the Wake of Riegel v. Medtronic: Should Congress Interject?*, 32 HAMLIN L. REV. 791 (2009).

and costly litigation and would subject claims to adjudication by the most institutionally competent party, the FDA.²⁹⁰ This system would not directly impose liability on device manufacturers, therefore eliminating concerns about stifling technological advances and the availability of cutting-edge devices. This approach would not, however, afford Medicare recovery of its payments to the device manufacturers and would not provide efficient incentives to manufacturers to assure device safety.

The proposals discussed above, while effective in some areas, do not directly address the problem that federal preemption poses as an obstacle to Medicare's recovery of its payments to the manufacturers of defective medical devices. The next and final Part of this Comment offers a more direct solution.

V.

A FINER APPROACH TO THE PREEMPTION PROBLEM: WHOLESALE RECOVERY IN THE POST-RECALL CONTEXT

Most scholarly attention to governmental actions taken under the MSP has focused on what might be called the "retail level": the hundreds of actions taken every day to recover Medicare payments made on behalf of individual beneficiaries for whom another payer either made payment or was responsible for making payment.²⁹¹ In addition, a plethora of practitioner-oriented pieces have been published, focusing largely on the threat to beneficiaries and their attorneys posed by aggressive government recovery actions under the MSP.²⁹²

What has received less attention is another level at which Medicare might recover conditional payments, which I call the "wholesale level." In the wholesale recovery cases that have already been decided (including the breast implant litigation), a class of plaintiffs has either reached a settlement with or won a damages award against a medical device manufacturer under a products liability theory. After the plaintiffs won, the government exercised its rights of subrogation or direction action under the MSP to recover its share of the settlement or award.²⁹³ For this approach to be widely applicable, the breadth of preemption under the MDA must be narrowed to allow Medicare beneficiaries to sue the manufacturers of PMA-approved devices placed under recall by the FDA in a single consolidated action. Consolidating these cases into one action would enable Medicare to invoke its rights of subrogation and direct action against device manufacturers and their liability insurers.

290. *See id.* at 834.

291. *See, e.g.*, Eric Helland & Fred Kipperman, *supra* note 114.

292. *See, e.g.*, Jason D. Lazarus, *Medicare Myths: What Every Trial Lawyer Should Know About the MSP & Liability Medicare Set Asides*, 84 FLA. BAR J. 46 (Nov. 2010) (revised Feb. 10, 2012).

293. *See United States v. Baxter Int'l, Inc.*, 345 F.3d 866 (11th Cir. 2003).

The viability of the wholesale recovery approach is evidenced in the Eleventh Circuit's decision in *United States v. Baxter International*.²⁹⁴ Following the settlement reached between representatives of a class of over four hundred thousand women and five manufacturers of silicone breast implants, the manufacturers established two funds designed to pay up to \$4.2 billion in damages.²⁹⁵ The government brought claims under its subrogation rights established by subsection (b)(2)(B)(iv) of the MSP, as well as under its direct right of action under subsection (b)(2)(B)(iii).²⁹⁶ The Eleventh Circuit held that the government could invoke its rights in wholesale fashion, rejecting the argument that the government had to name each beneficiary at the outset.²⁹⁷

Baxter highlights a number of points salient to my wholesale recovery proposal. First, the Eleventh Circuit interpreted the MSP as establishing the government's right to pursue not only the tortfeasors but also the tortfeasors' insurers.²⁹⁸ Thus, the court explicitly included the fourth player that I discussed in my examination of the purposes of subrogation that underlie the government's right of direct action²⁹⁹ and confirmed that even if equitable subrogation does not typically encompass a direct right of action against a tortfeasor's insurer, the statutory scheme established by the MSP includes this right. The MSP therefore can prevent a device manufacturer's liability insurer from being unjustly enriched at Medicare's expense. Second, the court held that the term "insurer" is to be interpreted broadly to refer not just to contractual general liability insurers but also to companies that self-insure or use a combination of self-insured retention and outside insurers.³⁰⁰ Thus, the wholesale recovery mechanism could apply to all manufacturers.

And third, the court held that the government could proceed at the wholesale level. Whereas the district court had accepted Baxter's argument that governmental action under the MSP could only proceed on a plaintiff-by-plaintiff basis,³⁰¹ the Eleventh Circuit rejected this argument, finding that where "an intervenor bring[s] a claim on the basis of injury to a large group of others, the identities of whom the intervenor claims cannot be determined without discovery[,] it is sufficient that the intervenor "generally give the defendant notice of the nature and scope of the plaintiffs' claims."³⁰² The Eleventh Circuit ultimately allowed the government's actions under both the subrogation and direct action clauses of the MSP.³⁰³ The court's decision

294. *Id.*

295. *Id.* at 872–74.

296. *Id.* at 876 (note that the provisions discussed in the case have been re-codified; this Article uses the current statutory structure).

297. *Id.* at 908–09.

298. *Id.* at 889.

299. *See supra* Part I.D.2.

300. *Id.* at 893–97.

301. *Id.* at 881.

302. *Id.* at 882.

303. *Id.*

makes clear that a wholesale approach to recovery of conditional Medicare payments is viable, at least in circuits that embrace such a capacious interpretation of the MSP.

Decisions in some other circuit courts and in some district courts outside of the Eleventh Circuit reflect disagreement about the government's ability to recover conditional payments using a wholesale approach. In *Thompson v. Goetzmann* ("Goetzman II"), the Fifth Circuit refused to call device manufacturers self-insured unless they "engage[d] in the same sorts of underwriting procedures that insurance companies employ; estimat[e] likely losses . . . [and] set[] up a mechanism for creating sufficient reserves" ³⁰⁴ Although *Goetzmann II* concerned a "retail" action by the government, in which it sought reimbursement of its payments from a settlement reached by a single beneficiary with a medical device manufacturer, ³⁰⁵ the logic of the decision also appears to limit government attempts at wholesale recovery if the manufacturer had no explicit self-insurance program.

Some district courts have envisioned an even narrower view of the government's right to recover under the MSP. In *In re Orthopedic Bone Screw Products Liability Litigation (Bone Screw Products)*, the district court prohibited the government from recovering payments made to a class of beneficiaries because it adopted the narrow view of self-insurance described by the *Goetzmann II* court. That court held that when a liability insurer cannot be expected to pay promptly for medical care (which may predate the finding of liability by several years), Medicare's payments are not considered conditional. ³⁰⁶ Notably, the district court's decision was reversed by the Third Circuit, which found that § 405(h) of the Social Security Act deprived the federal district court of jurisdiction over claims by beneficiaries opposing administrative recovery actions. ³⁰⁷ Clearly, a Supreme Court decision clarifying the viability of wholesale recovery is needed.

One possible solution would be for courts to recognize that § 360k does not apply to devices that have been subjected to an FDA recall. Although one

304. *Thompson v. Goetzmann (Goetzmann II)*, 337 F.3d 489, 498–99 (5th Cir. 2003) (quoting 1 COUCH ON INSURANCE 10:1 (3d ed. 1997)), *modifying* *Thompson v. Goetzmann (Goetzmann I)*, 315 F.3d 457 (5th Cir. 2002). *Goetzmann II* modified *Goetzmann I* by deleting one of two alternative reasons for holding that the government had not stated a claim upon which a remedy may be provided: that only insurers who can be expected to pay promptly are covered by the MSP. *Goetzman II*, 337 F.3d at 492.

305. *See id.* at 493.

306. *In re Orthopedic Bone Screw Prods. Liab. Litig. (Bone Screw Prods.)*, 202 F.R.D. 154 (E.D. Pa. 2001), *rev'd on other grounds*, *Fanning v. United States*, 346 F.3d 386 (3d Cir. 2003). In order for Medicare to recover payments under the MSP, those payments must have been conditional—that is, made by Medicare where a primary plan had responsibility for payment. 42 U.S.C. § 1395y(b)(2)(B) (2012).

307. *Fanning*, 346 F.3d 386. The Medicare Act, 42 U.S.C. § 1395ii, makes 42 U.S.C. § 405(h) applicable to challenges to agency action under the MSP; 42 U.S.C. § 405(g) establishes the sole avenue for judicial review, which may only be accessed after all administrative procedures have been exhausted. *Id.* at 395.

can attempt to finesse the language of § 360k to argue that recalled devices are no longer “intended for human use,”³⁰⁸ the stronger argument is that none of the rationales in support of federal preemption of state tort law apply once the FDA has recalled a device; Congress did not intend to preempt state law actions against the manufacturers of recalled devices. The MDA was intended to assure device safety and efficacy.³⁰⁹ The MDA accomplished this by granting the FDA authority to establish a premarket regulatory floor.³¹⁰ Allowing device recipients to bring suit under state law *after* a device has been recalled raises no premarket issues since the device has already been removed from the market. Concerns over hampering the development of new technology by having manufacturers face multiple regulatory regimes³¹¹ are also irrelevant in the post-recall context. Given the development cycle of many medical devices,³¹² any requirements established through tort verdicts are unlikely to affect future design decisions. Permitting post-recall suits would also satisfy the equitable principles underlying subrogation relied on by the MSP by eliminating the current inequities between Medicare, device manufacturers, and the manufacturers’ liability insurers that result from preemption. Enabling Medicare to recover its payments to beneficiaries would restore the program to the position it would have been in absent the device failure, hold the device manufacturer responsible, and prevent the manufacturer’s liability carrier from being unjustly enriched at Medicare’s expense.

Narrowing the impact of preemption raises the important question of where the costs of Medicare beneficiaries’ defective medical devices should be allocated. Although a description of where the Medicare program’s costs fall under the current regime of nearly blanket preemption appears simple at first blush—on the Medicare program itself—upon closer inspection the picture is far more complex. Hospital costs, which arise from treatment of injuries due to a device defect or from surgical removal or replacement of defective devices, are paid from the HI Trust Fund.³¹³ Since payroll taxes almost entirely fund the HI Trust,³¹⁴ the costs would be expected to fall on employees and employers subject to the taxes. However, given Congress’s historic reluctance to raise the payroll tax, employees and employers have not borne these costs. In the absence of a tax increase, the costs are exacted over the long term in the form of an increased risk of insolvency of Medicare Part A and possibly further restrictions on the treatments Medicare will cover.

308. 21 U.S.C. § 360k(a) (2012). As noted above, though, recalled medical devices are often left in situ based on a weighing of the risks of leaving the device in place against the risk of surgical replacement.

309. *See supra* notes 136–138.

310. *Id.*

311. *See supra* notes 166–167.

312. *See supra* Part II.D.

313. *See supra* notes 34–36 and accompanying text.

314. *See id.*

In addition to the costs that Medicare absorbs through Part A coverage of hospital expenses, there are often significant expenses incurred for outpatient care under Part B. Many device defects do not require immediate hospitalization and surgery but may require extensive outpatient consultation and periodic monitoring for impending device failure.³¹⁵ The costs of these actions are borne by the Supplemental Medical Insurance Trust Fund, which is funded largely by beneficiaries' premiums and general tax revenues.³¹⁶ Thus, the costs of outpatient evaluation and monitoring will be distributed to Part B enrollees through their premiums and to the general population through income and other taxes.

Moreover, the existing government recovery tools may be inefficient where the combined costs—those absorbed by Medicare and those paid by the manufacturer—exceed the total damages to the Medicare program. Perhaps more problematic, there is no rational relationship between the costs allocated to manufacturers and the damages sustained by Medicare.³¹⁷ Either the government decides not to pursue recovery—in which case none of the costs are allocated to the manufacturer—or the government does pursue recovery and the costs allocated to the manufacturer may range from far less to far more than those incurred by Medicare.

Channeling recovery through the MSP mechanism would alter this messy patchwork of cost allocation. Because recovery is limited to twice the program's losses, the amount imposed on device manufacturers would bear a more rational relationship to the damages that were inflicted on the program. Manufacturers would be expected to pass the costs back on to Medicare in the form of higher prices for Class III medical devices. These costs, in turn, would be borne mostly by the HI Trust Fund, since they would be paid by hospitals at the time of device implantation. Hospitals, in turn, would be paid an amount through Medicare determined by the relevant Diagnosis Related Group under the Prospective Payment System. Thus, the cost of defective medical devices would ultimately be split between hospitals, device manufacturers, and Medicare.

It could be argued that this allocation is not desirable and that the costs should be distributed more narrowly to the group who uses the medical devices or more broadly through taxes on income. As to the former, the whole point of Medicare Part A was to avoid the dramatic impact of hospital costs on the elderly,³¹⁸ so allocating the cost of device failures solely to Part A beneficiaries would seem a renunciation of the broad agreement that led to the program's

315. For example, when the Sprint Fidelis lead problem was identified, Medtronic distributed a software package—the Lead Integrity Alert system—that enabled physicians to monitor for impending lead failures by remote interrogation of patients' implanted defibrillators.

316. See *supra* notes 37–41 and accompanying text.

317. See Part III.B.

318. See MARMOR, *supra* note 53, at 11.

enactment. As to the latter, the question of how broadly to distribute the costs of health care overall is one that will only be answered over time.

CONCLUSION

Congress and the courts have inadvertently created a conflict between two sprawling statutes: the Medicare Secondary Payer Act and the Medical Device Amendments of 1976. This conflict results from an expansive interpretation of the express preemption clause of the MDA and an expansive application of implied preemption doctrine to bar state tort suits asserting negligence and product liability claims against medical device manufacturers. This bar, which applies to devices approved under the rigorous PMA process, prevents many litigants from obtaining verdicts against or bargaining to settlements with device makers. This expansive preemption doctrine, in turn, prevents Medicare from recovering payments made on behalf of its beneficiaries through its subrogation and direct action rights under the MSP. Thus, the broad powers of recovery granted by the MSP directly conflict with the broad vision of preemption under the MDA.

When the purposes of the preemption clause that Congress included in the MDA are understood, it becomes clear that the current expansive application of preemption functions like a blunt truncheon, barring Medicare from recovering hundreds of millions of dollars of payments it has made to the manufacturers of defective medical devices. The blunt force of federal preemption results in distorted incentives to medical device manufacturers to make safe devices because none of the federal government's other recovery mechanisms—civil and criminal monetary penalties, forfeiture, restitution, and disgorgement—ensures proportionality between the penalty and the cost to Medicare. The broad preemption doctrine also provides distorted incentives to the federal government to seek recovery of payment from the manufacturers of defective devices. The solution is not to abandon preemption altogether—uniformity and institutional competence are vitally important to the effective regulation of medical device makers. However, a reevaluation of existing preemption doctrine under the MDA, whether by the Supreme Court or by Congress, is overdue. And when that reevaluation occurs, it will be necessary to whittle today's blunt preemptive truncheon into a surgical tool more akin to that which Congress sought to create.

