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BODY OF PREEMPTION:

HEALTH LAW TRADITIONS AND THE PRESUMPTION AGAINST PREEMPTION

*Elizabeth Y. McCuskey**

Preemption plays a prominent role in health law, establishing the contours of coexistence for federal and state regulatory authorities over health topics as varied as medical malpractice, insurance coverage, drug safety, and privacy. When courts adjudicate crucial preemption questions, they must divine Congress's intent by applying substantive canons of statutory interpretation, including presumptions against preemption.

This Article makes three main contributions to health law and preemption doctrine. First, it identifies a variant of the presumption against preemption that applies to health laws—referred to throughout as the “tradition presumption.” Unlike the general presumption against preemption on federalism grounds, courts base this tradition presumption on a notion of “state primacy” that is rooted in tradition and unique to health regulation. Therefore, courts assume it is unlikely in most cases that Congress intended to preempt state health laws.

Second, this Article explores the tradition presumption's accuracy as a description of health laws' history and its utility as a gauge of congressional intent. Investigation reveals that it is unexamined, inaccurately broad, and subjective. Further, its rote perpetuation risks deterring meaningful inquiry into the context of federal health regulations. Even when courts invoke the tradition presumption to save worthy reform efforts from elimination by preemption, this blunt tool's unstable construction has made it particularly vulnerable to critique.

Third, to remedy these infirmities, this Article proposes a “scalpel approach” to health law preemption analysis; it is designed to identify distinct regulatory traditions and reflect the heterogeneity of regulatory topics within the body of “health law.” The scalpel approach promotes a more accurate preemption analysis and a more coherent health law jurisprudence, while reserving the tradition presumption as a tiebreaker for indeterminate cases. By encouraging courts to relinquish monolithic notions of tradition in health law, the scalpel approach enables health law preemption analysis to accommodate the frequent departures

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from tradition.

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INTRODUCTION

Preemption generally describes the displacement of state law by federal law.¹ State and federal law generously overlap in regulating health, frequently implicating preemption doctrine.² The history of health law tracks the state-

1. See, e.g., *Preemption*, BLACK'S LAW DICTIONARY (10th ed. 2014) ("The principle (derived from the Supremacy Clause) that a federal law can supersede or supplant any inconsistent state law or regulation."); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 225 n.3 (2000) (using "preemption" to "refer to the displacement of state law by federal statutes (or by courts seeking to fill gaps in federal statutes)"); see also Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 768 (1994). See generally Mark Pertschuk et al., *Assessing the Impact of Federal and State Preemption in Public Health: A Framework for Decision Makers*, 19 J. PUB. HEALTH MGMT. & PRAC. 213 (2013).

2. See Nelson, *supra* note 1, at 225 ("The powers of the federal government and the powers of the states overlap enormously.").

federal push and pull over regulatory power in several major categories: provider and facility regulation, public health, food and drugs, insurance, and data privacy. And Congress largely determines the scope of federal oversight through its Supremacy Clause power.³

As the volume and role of health regulation have expanded over the past century,⁴ preemption doctrine has become increasingly relevant.⁵ Recently, for example, the Supreme Court held that failure-to-warn and design defect claims against generic drug manufacturers were preempted, while the same claims could proceed against the brand-name drug manufacturers due to different wording in two federal statutes.⁶ Then, in *Gobeille v. Liberty Mutual Insurance Co.*,⁷ the Court held that the Employee Retirement Income Security Act (ERISA) preempted Vermont's efforts to collect health insurance data to guide state health policy because ERISA displaces state regulation that "relates to" employer-sponsored benefits.⁸ Preemption has had longstanding relevance in health law, with ERISA preemption alone generating an enormous volume of case law on health insurance since passage of the Act in 1974.⁹

The ascendance of vast, concurrent federal and state regulatory efforts has given preemption doctrine a forceful but quotidian role. "[I]n those many statutory cases where courts interpret the mass of technical detail that is the ordinary diet of the law," preemption implements federalism on a microscale.¹⁰ Since the New Deal era, Congress has steadily expanded the reach of federal law, relying on its constitutionally enumerated powers from the Commerce and Spending Clauses to legislate in areas concurrently regulated by states.¹¹ More overlap calls for more frequent employment of preemption analysis to manage

3. U.S. CONST. art. VI, cl. 2.

4. See, e.g., Abbe R. Gluck, *Symposium Issue Introduction: The Law of Medicare and Medicaid at Fifty*, 15 YALE J. HEALTH POL'Y, L. & ETHICS 1, 1 (2015) [hereinafter Gluck, *Medicare and Medicaid*] (describing "the transformation of health law from a field of local and private law . . . to the field of federal, statutory, public law that it now undoubtedly has become, even if it is rarely described as such").

5. Nelson, *supra* note 1, at 225; see also Gardbaum, *supra* note 1, at 768 ("[P]reemption . . . is almost certainly the most frequently used doctrine of constitutional law in practice.").

6. Compare *Wyeth v. Levine*, 555 U.S. 555, 558–59 (2009) (holding that claims against a branded drug were not preempted), with *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 610–11 (2011) (holding that failure-to-warn claims against a generic drug were preempted), and *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2466–67 (2013) (holding that design defect claims against a generic drug were preempted). See also *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (holding that claims for injury or death by vaccines were preempted).

7. 136 S. Ct. 936 (2016).

8. *Gobeille*, 136 S. Ct. at 947.

9. A recent Westlaw search of all state and federal cases for the terms "ERISA! /s preempt! & health!" returned 10,000 cases.

10. *Egelhoff v. Egelhoff*, 532 U.S. 141, 160–61 (2001) (Breyer, J., dissenting).

11. See Robert A. Schapiro, *From Dualism to Polyphony*, in *PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION* 33, 41 (William W. Buzbee ed., 2009) [hereinafter *PREEMPTION CHOICE*] (noting that since 1937, there has been an overlap between state and federal regulation).

the regulatory scheme that impacts folks' lives on a daily basis.¹²

Preemption has played a particularly prominent role in the evolution of health law as regulatory authorities grapple with problems of treatment, access, finance, and community health. For example, preemption has protected the Medicaid program from state laws and attempts at state enforcement that would undermine access.¹³ On the other hand, ERISA has preempted many state efforts at expanding access to health insurance¹⁴ and collecting health insurance data.¹⁵ For drug- and treatment-related injuries, preemption also cuts both ways: it can establish a national floor of protection,¹⁶ but it can leave serious injuries without remedy if it imposes a ceiling of compliance.¹⁷ Falling in the middle of this spectrum, the strong preemption scheme in the National Childhood Vaccine Injury Act of 1986 establishes certainty and centrality with a no-fault system for injury claims against vaccine makers.¹⁸ It supports the low-cost supply of vaccines essential for public health but does so potentially at the expense of undercompensating some victims of injury.¹⁹ Preemption jurisprudence thus has enormous consequences for health care access, regulation, and remedy.

This Article investigates the health law applications of a central feature in preemption jurisprudence: the presumption against preemption. Supreme Court jurisprudence has developed two distinct but related presumptions. The first is applied to all valid exercises of state regulatory power and flows from the language of the Supremacy Clause; thus, it is referred to here as the "constitutional presumption."²⁰ The second presumption applies only to police power regulations and is based on a tradition of state regulatory primacy; it is referred to here as the "tradition presumption" or the "*Rice* presumption" after

12. See Garrick B. Pursley, *Preemption in Congress*, 71 OHIO ST. L.J. 511, 513 (2010) (noting that preemption can reduce a state's ability to provide benefits to its citizens); Ernest A. Young, "*The Ordinary Diet of the Law*": *The Presumption Against Preemption in the Roberts Court*, 2011 SUP. CT. REV. 253, 254–55 [hereinafter Young, *The Ordinary Diet of the Law*] (asserting that, because of the increasing concurrence of national and state authority, preemption cases are the "functional heart" of modern federalism).

13. See, e.g., *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011); *Ark. Dep't of Health & Human Servs. v. Ahlborn*, 547 U.S. 268, 292 (2006). *But cf.* *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 644 (2003) (holding that state efforts at achieving cost savings by subjecting drugs without negotiated prices to prior authorization were not preempted).

14. E.g., *Retail Indus. Leaders Ass'n v. Fielder*, 475 F.3d 180, 195–97 (4th Cir. 2007).

15. E.g., *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 939 (2016).

16. See *Wyeth v. Levine*, 555 U.S. 555, 555 (2009).

17. See, e.g., *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 610–11 (2011) (holding that federal law preempts state law that imposes a duty on manufacturers to change a drug label on generic drugs); *Aetna Health, Inc. v. Davila*, 542 U.S. 200, 201 (2004) (holding that ERISA preempted a state law claim authorizing remedies beyond the scope of ERISA).

18. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-1–300aa-33 (2012)); see also *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995) ("For injuries and deaths traceable to vaccinations, the Act establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system.").

19. See *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 229 (2011) (noting that the Act gives manufacturers significant tort-liability protections in exchange for the no-fault system).

20. Nelson, *supra* note 1, at 293.

the Supreme Court opinion that solidified it.²¹

Commentators and jurists often conflate the two presumptions,²² but I outline below the salient differences in theory, foundation, and operation. The constitutional presumption interprets the Supremacy Clause as requiring courts to harmonize state and federal law to the greatest extent possible and to presume that Congress intended no conflict.²³ The tradition presumption assumes that states have traditionally regulated a particular field, then infers that Congress did not intend to disturb that tradition. Courts have applied the tradition presumption with particular force²⁴ to health law cases across an array of issues from finance to products liability.²⁵

While stacks of opinions have relied on these presumptions as preemption's analytic framework, some recent Supreme Court opinions have suggested that the presumptions' days are numbered.²⁶ The presumptions against preemption, as applied to health law, rest on two shaky legs. The constitutional leg, scholars have pointed out, is hamstrung by the language and historical context of the Supremacy Clause, which makes duly enacted federal statutes the law of the land, effectively disregarding conflicting state law.²⁷ The constitutional presumption's applicability remains a live issue in the debate over substantive canons of statutory interpretation.²⁸

The focus of this Article, however, is the tradition presumption and its application to health law. The tradition presumption colors how courts interpret congressional intent for health legislation based on a factual assumption about the regulatory context—namely that there exists a tradition of state primacy in regulating health.²⁹ The tradition justifying this presumption has remained largely unexamined by scholars and jurists.

Investigation reveals that the blunt supposition of a tradition of state primacy in all areas of health law is, in some aspects, inaccurate, as well as unstable. Historically, state governments claimed that state police powers covered matters of health, safety, welfare, and morals.³⁰ But the extent of states'

21. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

22. *See, e.g., PLIVA, Inc.*, 564 U.S. at 633–34 (Sotomayor, J., dissenting).

23. Nelson, *supra* note 1, at 292.

24. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484–86 (1996); *Rice*, 331 U.S. at 230.

25. *See, e.g., De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997); *Medtronic, Inc.*, 518 U.S. at 484–86.

26. *See, e.g., Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 946 (2016) (expressing agnosticism about the utility of “[a]ny presumption against pre-emption, whatever its force in other instances”); *PLIVA, Inc.*, 564 U.S. at 621–22 (citing Nelson, *supra* note 1, at 238–42, with favor to support rejection of the presumption); *see also* Young, *The Ordinary Diet of the Law*, *supra* note 12, at 278, 307–08.

27. *See* Nelson, *supra* note 1, at 232 (noting that the Supremacy Clause results in courts not having to harmonize federal statutes with prior law).

28. *See, e.g.,* Young, *The Ordinary Diet of the Law*, *supra* note 12, at 307–08 (noting that the *Rice* presumption is applied inconsistently).

29. *See Rice*, 331 U.S. at 230 (noting that “the assumption that the historic police powers of the States were not to be superseded . . . unless that was the clear and manifest purpose of Congress”).

30. *See* D. Benjamin Barros, *The Police Power and the Taking Clause*, 58 U. MIAMI L. REV. 471, 484–88 (2004).

use of that power has varied widely over time, by topic, and by state. The Constitution empowers Congress to regulate police power, concurrently with states, within its Article I legislative authority (usually the Commerce or Spending Clauses).³¹ Health law covers a uniquely heterogeneous array of regulatory areas, including provider liability, facility regulation, insurance, product safety, public health, and privacy. While states have established themselves as the primary regulators in some areas, like provider licensing and liability, the regulatory balance in other areas, like food and drugs and health care business transactions, have been more evenly distributed.³²

Further, the notion of tradition itself is malleable and unrestrained by legal definition. Health law today increasingly is recognized as federal and statutory, despite significant roles of state and local governments.³³ But if such a strong state tradition ever existed, at what point did the balance tip to its current ratio? And how long must the federal statutory character remain dominant until it becomes the new tradition? As a matter of jurisprudence, the presumption against health law preemption depends on the accuracy of historical characterizations and a notion of tradition.

Ultimately, this Article advocates a surgical approach to determining preemptive intent in health law. Rather than the blanket presumption against preemption, whose rote repetition has diluted its interpretive force, the scalpel approach that I propose analyzes the regulatory context on a topic-by-topic basis. The scalpel approach could, for example, support a presumption that Congress does not intend to preempt state law on provider liability or public health measures, based on the strong and enduring tradition of state primacy of regulation over those issues. A proponent of preemption would then need to rebut that presumption with clear and convincing evidence of preemptive intent. By contrast, a question about health information privacy might proceed as a straight question of preemptive intent, without a rebuttable presumption, because the regulatory tradition in that area is not lopsided enough to support the tradition presumption. However, under the scalpel approach, the presumption favoring state law might still be deployed as a tiebreaker in cases where congressional intent is truly indeterminate.

By developing more accurate and topic-sensitive notions of regulatory tradition, the scalpel approach aims to preserve the efficiency of a presumption, while encouraging a more precise consideration of each law's context and intended effects. The scalpel approach has the potential to strengthen health law jurisprudence by building a more nuanced analytic framework to examine state regulation and congressional intent in each contributing area. Nuance and precise treatment will be particularly useful in the near future, as the Affordable Care Act's (ACA) system-wide reforms continue to recast the relationship

31. U.S. CONST. art. I, § 8 cls. 1, 3.

32. See, e.g., Ole Salthe, *State Food, Drug and Cosmetic Legislation and Its Administration*, 6 LAW & CONTEMP. PROBS. 165, 167-74 (1939).

33. See, e.g., Gluck, *Medicare and Medicaid*, *supra* note 4, at 1-2 (highlighting the federalization and "statutorification" of health law in the past fifty years).

between federal and state laws. Through examining the regulatory context of discrete health law issues, the scalpel approach to health law preemption jurisprudence may even reveal a more robust basis for preserving state laws that bolster health policy.

My analysis unfolds in three parts. Section I situates the presumptions within preemption doctrine, summarizing their origins and functions as interpretive canons—and illuminating the tradition presumption as applied to health law. Section II then investigates the health law regulatory tradition, analyzing discrete health law categories as well as the historical interplay of federal and state regulations. This investigation reveals significant heterogeneity among health law categories and their corresponding regulatory traditions. Section III proposes jurisprudential reforms, including the scalpel approach, and treats the presumption as a tiebreaker, rather than a framing concept. The proposed reforms reflect the descriptive and normative concerns highlighted throughout the investigation.

I. THUMB ON THE SCALE: THE PRESUMPTIONS AGAINST PREEMPTION

This Article questions the foundation and utility of a presumption against preemption for health law and begins by placing *preemption* and *presumptions* in their doctrinal contexts. In short, preemption turns on congressional intent.³⁴ The presumptions against preemption establish a default judicial position of *no* congressional intent to preempt, then require evidence of “clear and manifest purpose” to rebut it.³⁵ By placing this thumb on the interpretive scale,³⁶ presumptions color preemption analysis, which strongly impacts health law jurisprudence.

A. Preemption

Preemption functions as a choice of law doctrine, determining which regulation controls if two or more bodies have regulated an issue. However, preemption does not start from a presumption that the choice is among equal sovereigns.³⁷ The Supremacy Clause gives federal law the “supreme”—or preemptive—position, as long as it falls within Congress’s constitutional power.³⁸

34. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992).

35. *See id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

36. *See* Robert R.M. Verchick & Nina Mendelson, *Preemption and Theories of Federalism*, in *PREEMPTION CHOICE*, *supra* note 11, at 13, 22 (debating whether a presumption against preemption is “the right choice or an inappropriate ‘thumb on the scale’”); Daniel J. Meltzer, *Preemption and Textualism*, 112 MICH. L. REV. 1, 54 (2013) (articulating reasons for “placing the thumb on the scale that the presumption against preemption provides”).

37. *See* Louise Weinberg, *The Federal-State Conflict of Laws: “Actual” Conflicts*, 70 TEX. L. REV. 1743, 1744–48 (1992).

38. U.S. CONST. art. VI, cl. 2; *see* Gardbaum, *supra* note 1, at 769 (examining the nature of the connection between the Supremacy Clause and preemption); Nelson, *supra* note 1, at 234 n.32 (explaining that the Supremacy Clause gives federal statutes the power to preempt state statutes, as long as the statutes are “authorized (whether implicitly or explicitly) by something else in the Constitution”).

Thus, preemption can be a powerful force displacing state and local law with federal law.

Preemption doctrine determines which authority or authorities (federal, state, local, or concurrent) control an issue. The doctrine polices the federal-state regulatory lines set by the Supremacy Clause.³⁹ The Supremacy Clause makes federal law “the supreme law of the [l]and” and binds “the Judges in every State” to apply it.⁴⁰ Because states retain concurrent authority to regulate in almost every area, federal law frequently overlaps.⁴¹ When state and federal laws cover the same topic, the Supremacy Clause, applied by way of preemption doctrine, determines which law controls.⁴²

Federal law may displace all state regulation on a particular topic, or it may displace only regulations with conflicting requirements.⁴³ For example, a federal law stating that health insurance navigators *may* offer advice on consumers’ choice of plans preempts a state law stating that navigators may *not* offer advice.⁴⁴ But when a federal law requires cigarette manufacturers to include particular warnings on packaging, how does that requirement affect state law products liability claims challenging the adequacy of those warnings?⁴⁵ The answer depends on congressional intent, the touchstone of preemption.⁴⁶

In pursuit of gleaning congressional intent, the Supreme Court has developed varying categories of preemption to identify the source, severity, and outcome of an analysis.⁴⁷ First, Congress either expresses its preemptive intent or simply implies it. In express preemption, Congress includes in the statute a statement “explicitly withdrawing specified powers from the states.”⁴⁸ However, even explicit clauses often leave their meaning and scope open for interpretation.⁴⁹ On the other hand, Congress may express its intent *not* to preempt certain types of state laws by including a so-called “savings” clause in the statute.⁵⁰

39. See Nelson, *supra* note 1, at 234.

40. U.S. CONST. art. VI, cl. 2.

41. Nelson, *supra* note 1, at 225.

42. See *id.* at 226–28 (discussing express, implied, and conflict preemption of state statutes by federal statutes).

43. See *id.* at 227–28.

44. See, e.g., *St. Louis Effort for AIDS v. Huff*, 782 F.3d 1016, 1022 (8th Cir. 2015) (interpreting the ACA’s health insurance “navigator” provision and regulations as invalidating a Missouri law that prohibited navigators from offering advice).

45. Nelson, *supra* note 1, at 226; see, e.g., *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 504–05 (1992) (holding that the Public Health Cigarette Smoking Act of 1969 displaces some state claims, but not others).

46. See *Cipollone*, 505 U.S. at 505 (noting that the broad language of the Act extended its preemptive reach).

47. See generally Christopher H. Schroeder, *Supreme Court Preemption Doctrine*, in *PREEMPTION CHOICE*, *supra* note 11, at 119 (detailing the development of this taxonomy in Supreme Court opinions).

48. Nelson, *supra* note 1, at 226.

49. *Id.* at 227.

50. See Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 738

Even without an explicit statement from Congress, federal law (via legislation or regulatory action) preempts state law if Congress's intent to do so may fairly be implied.⁵¹ Implied preemption has two variants: conflict preemption and field preemption.⁵² In conflict preemption, the most prevalent,⁵³ the Supremacy Clause creates federal law supremacy where there is a conflict with state law.⁵⁴ Conflict preemption arises where it is impossible to comply with both federal and state laws or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"⁵⁵ (also known as "obstacle preemption").

In field preemption, a rarer form,⁵⁶ the implication of intent flows from a federal regulatory scheme "so pervasive . . . that Congress left no room for the States to supplement it,"⁵⁷ or from a federal interest "so dominant" that federal law is "assumed to preclude enforcement of state law" in that field.⁵⁸ Both "field" and "conflict" preemptions most frequently arise as implied preemption, though they can be explicit.⁵⁹

The most conclusive, and rarest,⁶⁰ form of preemption, "complete preemption," applies when "a federal statute's preemptive force [is] so extraordinary and all-encompassing that it converts an ordinary state-common-law complaint into one stating a federal claim for purposes of the well-pleaded-complaint rule."⁶¹ Under complete preemption, "a federal statute wholly displaces [any] state-law cause of action" for the same alleged harm and confers federal question jurisdiction over the claim.⁶² The Supreme Court has recognized complete preemption only in the context of a few statutes: the Labor Management Relations Act, National Bank Act, and ERISA.⁶³

(2008) (referring to a savings clause as "a clause that disclaims some or all displacement" of state law).

51. See *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 883–86 (2000).

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

53. See *Nelson*, *supra* note 1, at 227–28 (stating that conflict preemption is "ubiquitous").

54. *English*, 496 U.S. at 79 ("[S]tate law is pre-empted to the extent that it actually conflicts with federal law.").

55. *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)); *Animal Legal Def. Fund v. Otter*, 44 F. Supp. 3d 1009, 1026 (D. Idaho 2014).

56. *Nelson*, *supra* note 1, at 227 (noting that courts are reluctant "to read implicit field-preemption clauses into federal statutes").

57. *English*, 496 U.S. at 79 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

58. *Rice*, 331 U.S. at 230.

59. *But see* *Cal. Div. of Labor Standards Enft v. Dillingham Constr., Inc.*, 519 U.S. 316, 336 (1997) (Scalia, J., concurring, joined by Ginsburg, J.) (suggesting that ERISA's express preemption may be identified as field preemption, preempting state regulation in the "field" of laws regulating employee benefit plans); *Egelhoff v. Egelhoff*, 532 U.S. 141, 153 (2001) (espousing "normal" conflict and field preemption analysis for ERISA).

60. See Gil Seinfeld, *The Puzzle of Complete Preemption*, 155 U. PA. L. REV. 537, 548 (2007). ("[T]he jurisprudence of complete preemption remains, as it has always been, significantly undertheorized. Indeed, if one consults the text of the relevant Supreme Court opinions, it is fair to say that it is entirely untheorized.").

61. *Complete-Preemption Doctrine*, BLACK'S LAW DICTIONARY (10th ed. 2014).

62. *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003).

63. See generally Seinfeld, *supra* note 60, at 549–53.

All preemption's species in this taxonomy share a common doctrinal trait: congressional intent is the touchstone of the analysis,⁶⁴ its alpha and omega. Although the Supremacy Clause dictates that federal law reigns supreme, courts have nonetheless employed interpretive presumptions against preemption in divining congressional intent. A presumption against preemption places a thumb on the *intent* scale. The presumption "can be overcome [only] where . . . Congress has made clear its desire for pre-emption."⁶⁵ The presumption has become integral to preemption precedent and applies even to interpretation of express preemption provisions.⁶⁶

B. Presumptions Against Preemption

Law is peppered with presumptions.⁶⁷ Functionally, a presumption establishes that something is true in advance of any proof; a rebuttable presumption then shifts the burden of proof to the party seeking to overcome the presumption, while a conclusive or irrebuttable presumption ends the inquiry entirely.⁶⁸ Presumptions may serve policy or reflect probability. Policy presumptions further substantive goals, even where the issue presumed is unlikely. For example, the law presumes undue influence whenever a lawyer names herself as a beneficiary in a will she drafts.⁶⁹ This presumption reflects a policy of establishing trust and confidence in lawyers, rather than a probability

64. *E.g.* *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978); *Retail Clerks Int'l Ass'n, Local 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963).

65. *Egelhoff v. Egelhoff*, 532 U.S. 141, 151 (2001).

66. *See* *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518 (1992) (instructing a narrow reading disfavoring preemption, even for express preemption provisions); Nelson, *supra* note 1, at 291.

67. *See* Antonio E. Bernardo, Eric Talley & Ivo Welch, *A Theory of Legal Presumptions*, 16 J. L., ECON. & ORG. 1, 1 (2000) ("Few features of American jurisprudence are as fundamental as legal presumptions."); *see, e.g.*, FED. R. EVID. 301 ("[T]he party against whom a presumption is directed has the burden of producing evidence to rebut the presumption."); CAL. FAM. CODE § 7540 (West 1994) ("[T]he child of a wife cohabiting with her husband, who is not impotent or sterile, is conclusively presumed to be a child of the marriage."); *Shamrock Oil & Gas Corp. v. Sheets*, 313 U.S. 100, 108–09 (1941) (holding that there is a presumption against federal removal jurisdiction); *Coffin v. United States*, 156 U.S. 432, 453 (1895) (holding that in criminal proceedings, there is a presumption of innocence); *Connor v. Statewide Grievance Comm.*, 797 A.2d 1081, 1086 (Conn. 2002) (holding that there is a presumption favoring state court subject matter jurisdiction).

68. William N. Eskridge, Jr. & Philip P. Frickey, *Quasi-Constitutional Law: Clear Statement Rules As Constitutional Lawmaking*, 45 VAND. L. REV. 593, 595 n.4 (1992) [hereinafter Eskridge & Frickey, *Quasi-Constitutional Law*]. Additionally, some legal rules are inaccurately referred to as "presumptions." These "conclusive presumptions" strangely "cannot be overcome by any additional evidence or argument because [they are] accepted as irrefutable proof that establish[] a fact beyond dispute." *Conclusive presumption*, BLACK'S LAW DICTIONARY (10th ed. 2014). I have excluded these "conclusive presumptions" from the analysis here because they amount to legal fictions and, because they are irrebuttable, function as rules of substantive law. *See* JOHN H. WIGMORE, A STUDENTS' TEXTBOOK OF THE LAW OF EVIDENCE 454 (1935) ("'Conclusive presumptions' or 'irrebuttable presumptions' are usually mere fictions, to disguise a rule of substantive law[,] . . . and when they are not fictions, they are usually repudiated by modern courts.").

69. *See, e.g., In re Disbrow's Estate*, 24 N.W. 624, 630 n.2 (Mich. 1885).

that such gifts actually are products of undue influence.⁷⁰

Probability presumptions, by contrast, establish “[s]omething that is thought to be true because it is highly probable,” such as the presumption of death after a certain number of years missing.⁷¹ A probability presumption promotes efficiency by substituting probability for proof. Such presumptions thus resemble a court’s taking judicial notice of “legislative facts”—facts of general “relevance to legal reasoning and the lawmaking process”⁷² or truths universally acknowledged that “do not change from case to case” or litigant to litigant.⁷³

Where an issue is debatable, rebuttable presumptions can frame the exchange, particularly over tricky issues of intent.⁷⁴ In this way, rebuttable presumptions feature prominently in the substantive canons of statutory interpretation, guiding inquiry into the often ambiguous intent of Congress.⁷⁵ The presumptions supply “general policies the Court will ‘presume’ Congress intends to incorporate into statutes.”⁷⁶ They may be rebutted with argument or evidence, including statutory text, legislative history, legislative purpose, or some combination thereof.⁷⁷

Rebuttable presumptions thus set the level of clarity with which Congress must express its intent, usually requiring some form of “clear statement” to overcome an established interpretive presumption.⁷⁸ The rebuttable presumption against preemption embodies these interpretive rules.⁷⁹ Preemption

70. See, e.g., Joseph W. deFuria, Jr., *Testamentary Gifts from Client to the Attorney-Draftsman: From Probate Presumption to Ethical Prohibition*, 66 NEB. L. REV. 695, 722 (1987) (“[C]ourts began to view such conduct as an ethical problem rather than a probate issue.”).

71. *Presumption*, BLACK’S LAW DICTIONARY (10th ed. 2014). For example, the presumption of death for missing persons after seven years historically “is based on two elements. First, the natural mortality of man in the lapse of time. . . . Second, the probability of continued communication from any one who is not dead.” *Presumptions—Presumption of Death from Seven Years’ Absence Without News—Substitution of Actuarial Table*, 30 HARV. L. REV. 642, 654 (1917) (citation omitted).

72. FED. R. EVID. 201(a) advisory committee’s note. (arguing that notice of legislative facts should “leave open the possibility of introducing evidence through regular channels in appropriate situations” and it would be “inappropriate” to limit such notice with “indisputability”).

73. *United States v. Gould*, 536 F.2d 216, 220 (8th Cir. 1976).

74. See generally Edna Ullman-Margalit, *On Presumption*, 80 J. PHIL. 143 (1983) (surveying the role of presumption in philosophy, and exploring presumption as a basis for deliberation).

75. See HENRY M. HART, JR. & ALBERT M. SACKS, *THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW* 1124–25 (1994) (“An essential part of the context of every statute is its purpose. . . . Deciding what purpose ought to be attributed to a statute is often difficult.”); see also Abbe R. Gluck & Lisa Schultz Bressman, *Statutory Interpretation from the Inside—An Empirical Study of Congressional Drafting, Delegation, and the Canons: Part I*, 65 STAN. L. REV. 901, 940 (2013) (classifying presumptions against preemption as “substantive canons” of interpretation).

76. Eskridge & Frickey, *Quasi-Constitutional Law*, *supra* note 68, at 595 n.4.

77. *Id.*

78. See *id.* (comparing “clear statement rules” of statutory interpretation with “super-strong clear statement rules,” which “seem to require very specifically targeted ‘clear statements’ on the face of the statute to rebut a policy presumption”) (citing *Gregory v. Ashcroft*, 501 U.S. 452, 470 (1991)).

79. See Garrick B. Pursley, *Defeasible Federalism*, 63 ALA. L. REV. 801, 803 (2012) (“The presumption against preemption, for example, is a rule of statutory interpretation that courts periodically use to determine the preemptive scope of federal law. It instructs courts not to construe statutes to preempt state law absent clear evidence of congressional intent.”).

analysis, like many other principles of statutory interpretation, sets "[t]he purpose of Congress [as] the ultimate touchstone."⁸⁰ The presumption against preemption establishes the intent *not* to preempt, then requires proof of a "clear and manifest" statement from Congress to rebut that presumed intent.⁸¹

The presumption against preemption has developed two branches, one a policy presumption and the other a probability presumption. The first branch, what I refer to as the constitutional presumption, is a federalism policy presumption against preempting any state laws enacted pursuant to Tenth Amendment reserved powers. The second branch—the focal point of this Article—is the tradition presumption, which assumes that a tradition of state regulatory primacy existed at the time of legislation and that Congress intended not to disturb it. The tradition presumption, I argue below, is a probability presumption because it provides an inference of congressional intent based on a presumed historical context.

1. The Constitutional Presumption

The generally applied constitutional presumption against preemption begins with the Supremacy Clause's statement that duly enacted federal law is the supreme law of the land and is binding on state judges "any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."⁸² The Supreme Court and numerous commentators interpreted this "notwithstanding" phrase to oblige judges to harmonize state and federal law to the greatest extent possible to avoid preempting state law.⁸³ This judicial harmonization requirement narrows the construction of federal law and acts as a headwind against preemption in debatable cases.⁸⁴

Caleb Nelson's landmark article, *Preemption*, unearthed "historical materials," which he argued undermined the presumption's supposed constitutional and structural foundations.⁸⁵ Nelson explained that the "notwithstanding" language, in eighteenth century legal parlance, was known as a *non obstante* provision.⁸⁶ A *non obstante* provision was at that time included in legislation specifically to "tell[] courts that the [then-existing] general presumption against implied repeals does not apply."⁸⁷ Because the Supremacy Clause's *non obstante* provision tells courts "that the general presumption

80. See, e.g., *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (first alteration in original) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 96 (1992) (first alteration in original) (quoting *Malone*, 435 U.S. at 504).

81. See *Cipollone*, 505 U.S. at 516 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

82. U.S. CONST. art. VI, cl. 2.

83. Nelson, *supra* note 1, at 292.

84. See *id.* at 231 ("[C]ommentators have proposed finding a conflict between state and federal law *only* if it is physically impossible to comply with both—a proposal that would dramatically reduce the preemptive scope of federal statutes.").

85. *Id.*

86. *Id.* at 232.

87. *Id.* at 294.

against implied repeals does not apply in preemption cases, . . . it suggests that courts should *not* automatically seek narrowing constructions of express preemption clauses”⁸⁸ and that courts must “reject[] a general presumption that federal law does not contradict state law.”⁸⁹

This structural criticism has prompted debate about the presumption’s continued viability. As Ernest A. Young has argued, “[t]he ubiquity of [federalism presumptions], and the decades of precedent behind many of them, emphasizes the radical change that a broad reading of Nelson’s argument would impose on the federal law of statutory construction.”⁹⁰ More fundamentally, Daniel J. Meltzer has argued that the constitutional presumption “serves a useful role in protecting legal continuity,” preserving federalism relationships, and in resolving the innumerable and inevitable interpretive questions about the applications of ambiguous text.⁹¹ Yet, as Louise Weinberg has argued, the “presumption in favor of state law” should not automatically “operate[] in cases of identified ‘actual’ federal-state conflict” because “[i]dentification of a federal-state conflict-in-fact is, precisely, what overcomes the presumption.”⁹²

Currently, the embrace of the constitutional presumption, or rejection of it, varies among Supreme Court Justices. Justice Thomas’s opinion in *PLIVA, Inc. v. Mensing*⁹³ specifically rejected the presumption on the *non obstante* reading, joined by Chief Justice Roberts and Justices Alito and Scalia.⁹⁴ In their dissent, Justices Sotomayor, Ginsburg, Breyer, and Kagan directly supported the constitutional presumption.⁹⁵ Justice Kennedy joined all parts of Justice Thomas’s opinion *except* the section rejecting the constitutional preemption.⁹⁶

88. *Id.* (emphasis added).

89. *Id.* at 293; accord Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2092 (2000) (“[A]s a matter of constitutional structure, there should be no general systematic presumption against or in favor of preemption.”).

90. Young, *The Ordinary Diet of the Law*, *supra* note 12, at 320 (“One might thus apply the canon of avoidance to Nelson’s argument itself, preferring a more modest reading that would leave this pervasive and traditional judicial function intact.”); see also Ernest A. Young, *Two Cheers for Process Federalism*, 46 VILL. L. REV. 1349, 1385 (2001) (arguing that the presumption against preemption reinforces “institutional checks” on federalism).

91. Meltzer, *supra* note 36, at 55, 46–56.

92. Weinberg, *supra* note 37, at 1756; accord Young, *The Ordinary Diet of the Law*, *supra* note 12, at 318 (“One can agree with Nelson that courts should not distort the meaning of federal statutes in order to avoid preemption without accepting that the Framers of the Supremacy Clause meant courts to abandon this basic function.”); see also Robert S. Peck, *A Separation-of-Powers Defense of the “Presumption Against Preemption”*, 84 TUL. L. REV. 1185, 1201 (2010) (“The presumption against preemption serves the diffusion of power both vertically and horizontally.”).

93. 564 U.S. 604 (2011).

94. See *PLIVA, Inc.*, 564 U.S. at 621–22 (citing Nelson, *supra* note 1, with favor).

95. *Id.* at 626 (Sotomayor, J., dissenting). But cf. *DirecTV v. Imburgia*, 136 S. Ct. 463, 475–76 (2015) (Ginsburg, J., dissenting) (rejecting the use of an “arbitration-favoring presumption” in preemption analysis).

96. *PLIVA, Inc.*, 564 U.S. at 2572. Justice Kennedy wrote the majority opinion in *Gobeille*, reasoning that “[a]ny presumption against pre-emption, whatever its force in other instances,” could not save the state law at issue because it directly contradicted ERISA’s purpose. *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 946 (2016).

As a substantive canon, the constitutional presumption against preemption suffers from the same inconsistency as other substantive canons, varying from court to court and even from jurist to jurist within each court.⁹⁷ More than a decade ago, some expressed concern that the presumption was waning,⁹⁸ but more recently it “seems fair to say that the legitimacy, strength, and scope of the presumption against preemption remains a live issue.”⁹⁹ The Supreme Court has not formally rejected the constitutional presumption, and, importantly, federal and state courts still apply it regularly.¹⁰⁰

2. The Tradition Presumption

Courts have a distinct presumption against preemption for topics covered by state police powers, based on an ostensible tradition of state regulatory primacy over those topics.¹⁰¹ This “tradition” branch of presumption is a purely interpretive canon, rather than a structural command from the Supremacy Clause.¹⁰²

While congressional intent is the “ultimate touchstone” for preemption analysis,¹⁰³ the tradition presumption puts a thumb on the interpretive scale for any federal legislation “in [a] field which the States have traditionally occupied.”¹⁰⁴ Analysis of congressional intent for legislation in these fields “start[s] with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”¹⁰⁵ This tradition presumption recently has been cited as a

97. See Meltzer, *supra* note 36, at 52 (describing the variability in the presumption's application); Karl N. Llewellyn, *Remarks on the Theory of Appellate Decision and the Rules or Canons About How Statutes Are to Be Construed*, 3 VAND. L. REV. 395, 401–06 (1950) (posing that countercanons exist for every canon of interpretation); see also Eskridge & Frickey, *Quasi-Constitutional Law*, *supra* note 68, at 595.

98. Calvin Massey, “*Joltin’ Joe Has Left and Gone Away*”: *The Vanishing Presumption Against Preemption*, 66 ALB. L. REV. 759, 759 (2003). Massey argues that the Supreme Court “continues to simultaneously repeat and ignore the presumption against preemption.” *Id.* at 764.

99. Young, *The Ordinary Diet of the Law*, *supra* note 12, at 278.

100. Cf. *Graham v. R.J. Reynolds Tobacco Co.*, 782 F.3d 1261, 1275–76 n.13 (11th Cir. 2015) (noting that the “presumption against preemption has been hotly debated . . . in cases involving express preemption,” but that “the presumption appears to rest on less contested ground” in implied preemption), *vacated* 811 F.3d 434 (11th Cir. 2016).

101. See, e.g., *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518 (1992).

102. See Dinh, *supra* note 89, at 2092–93 (“Positing that the federal structure does not support a general preemption presumption does not mean the Court cannot rely on specific interpretive canons based on core federalism principles. But, these presumptions operate as rapiers, not broadswords, and their substantive justification is more subtle than a casual invocation of the federal structure.”).

103. See *Cipollone*, 505 U.S. at 516 (alteration in original) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)); *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 96 (1992) (quoting *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 208 (1985)).

104. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

105. *Id.*; see also *Hillsborough Cty. v. Automated Med. Lab., Inc.*, 471 U.S. 707, 715–16 (1985) (stating the “presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause”); *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 22 (1987) (holding that a state labor law was not preempted by the NLRB because it was a “valid and

“cornerstone” of Supreme Court preemption jurisprudence.¹⁰⁶

Courts have applied the tradition presumption especially strongly and consistently when the police power over health is involved.¹⁰⁷ For example, the majority opinion in *Medtronic, Inc. v. Lohr*¹⁰⁸ acknowledged a special presumption that applies “particularly” to federal statutes covering “a field which the States have traditionally occupied,” namely “matters of *health* and *safety*.”¹⁰⁹

Police powers and tradition had been suggested as bases for a presumption as early as the turn of the twentieth century.¹¹⁰ But most courts and many scholars trace the tradition presumption against preemption to *Rice v. Santa Fe Elevator Corp.*¹¹¹ and commonly refer to the *Rice* presumption.¹¹² In *Rice*, the Court considered a grain dealer’s challenge to the rates grain warehousemen charged for storage. The dealer claimed that the warehousemen (who were also competing dealers) charged discriminatory rates favoring themselves and the federal government, in violation of the state Public Utilities Act and Grain Warehouse Act.¹¹³ Plaintiff addressed his complaint to the Illinois Commerce Commission, requesting, among other remedies, that the state agency set uniform grain storage rates, establish a state warehousing service, prohibit discriminatory pricing, and assess penalties for violations of the state statutes.¹¹⁴ Defendant warehousemen countered that the United States Warehouse Act

unexceptional exercise of the [State’s] police power” (alteration in original) (quoting *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 758 (1985))).

106. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009); cf. Mary J. Davis, *The “New” Presumption Against Preemption*, 61 HASTINGS L.J. 1217, 1247 (2010) [hereinafter Davis, *The “New” Presumption*] (“The Court [after *Wyeth*] has made it clear that the presumption against preemption of historic state police powers continues to operate in cases of both express and implied preemption. Only clear and manifest intent of Congress to the contrary will defeat the presumption.”).

107. See, e.g., *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995); *Cipollone*, 505 U.S. at 516; *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 740–41 (1985); *Rice*, 331 U.S. at 230; *Napier v. Atl. Coast Line R.R. Co.*, 272 U.S. 605, 611–12 (1926).

108. 518 U.S. 470 (1996).

109. *Medtronic, Inc.*, 518 U.S. at 485 (emphasis added) (quoting *Rice*, 331 U.S. at 230).

110. E.g., *Reid v. Colorado*, 187 U.S. 137, 148 (1902) (“It should never be held that Congress intends to supersede, or by its legislation suspend, the exercise of the police powers of the states, even when it may do so, unless its purpose to effect that result is clearly manifested.”).

111. 331 U.S. 218 (1947).

112. E.g., Young, *The Ordinary Diet of the Law*, *supra* note 12, at 307.

113. *Rice*, 331 U.S. at 219–20. In an amusing coincidence, the grain dealer serving as lead plaintiff was named Daniel Rice. See *id.* at 218. The *Rice* analysis sprouted from prior opinions. See, e.g., *Napier v. Atl. Coast Line R.R. Co.*, 272 U.S. 605, 610–11 (1926) (assuming (1) that state regulation aimed “primarily to promote the health and comfort of engineers and firemen” was “a proper exercise of its police power,” and (2) that “there is no physical conflict between the devices required by the state and those specifically prescribed by Congress,” the Court held that “[t]he intention of Congress to exclude states from exerting their police power must be clearly manifested”); *Reid*, 187 U.S. at 147–48; *Savage v. Jones*, 225 U.S. 501, 533 (1912).

114. *Rice*, 331 U.S. at 221–22.

preempted such state regulation.¹¹⁵

In its analysis, the Court first noted that “Congress legislated here in a field which the States have traditionally occupied. So we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”¹¹⁶ But, carefully dissecting the Act and its history, the Court held that some aspects of state regulation indeed were preempted and some were not.¹¹⁷ And, where the state attempts to regulate in an area where federal regulation already exists, “the federal scheme prevails though it is a more modest, less pervasive regulatory plan than that of the State.”¹¹⁸

Since *Rice*, preemption precedent has proceeded from an “assumption that the historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress.”¹¹⁹ Because the presumption is rebuttable, many opinions spend more time analyzing the evidence offered in rebuttal than on the presumption itself.¹²⁰ The invocation of the presumption frames the analysis, even when the evidence and outcome nonetheless tilt heavily toward preemption.¹²¹

As with the constitutional presumption, the Supreme Court and other courts have inconsistently applied the tradition presumption.¹²² And among scholars, the *Rice* presumption has its champions¹²³ and its detractors.¹²⁴ This

115. *Id.* at 222.

116. *Id.* at 230 (citations omitted).

117. *Id.* at 236–37.

118. *Id.* at 236.

119. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

120. *See, e.g.,* *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617–20 (2011); *Rice*, 331 U.S. at 221–22.

121. *E.g.,* *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347–48 (2001); *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

122. *See* Davis, *The “New” Presumption*, *supra* note 106, at 1220 (“In the one hundred plus years that the Supreme Court has addressed preemption issues, it has been inconsistent about the role that the presumption against preemption plays.”); Max N. Helveston, *Preemption Without Borders: The Modern Conflation of Tort and Contract Liabilities*, 48 GA. L. REV. 1085, 1132 (2014) (noting that, in light of *Mutual Pharmaceutical Co. v. Bartlett*, “[t]he status of the presumption against preemption remains somewhat uncertain”); Young, *The Ordinary Diet of the Law*, *supra* note 12, at 312 (noting that “[t]he problem” in the Supreme Court’s recent preemption opinions “is that *Rice* is overlooked, not over-read”). The Supreme Court very recently granted a petition for certiorari to address “an increasing disagreement” among the courts “over when to apply the presumption against preemption”—specifically on the question whether federal law preempts health insurers’ subrogation suits against tort victims. *See* Brief for Respondent at 14, *Coventry Health Care of Missouri, Inc. v. Nevils*, No. 16-149 (U.S. Oct. 3, 2016), 2016 WL 5864497; Petition for Writ of Certiorari at 17–19, *Coventry Health Care of Missouri, Inc. v. Nevils*, No. 16-149 (U.S. Aug. 1, 2016), 2016 WL 4088378 (identifying circuit split); *Coventry Health Care of Missouri, Inc. v. Nevils*, No. 16-149 (U.S. Nov. 4, 2016), 2016 WL 4095218 (granting certiorari).

123. *See, e.g.,* Gardbaum, *supra* note 1, at 767; Ernest A. Young, *The Rehnquist Court’s Two Federalisms*, 83 TEX. L. REV. 1, 130–34 (2004); *cf.* Davis, *The “New” Presumption*, *supra* note 106, at 1247.

124. *See* Richard A. Epstein & Michael S. Greve, *Conclusion: Preemption Doctrine and Its Limits*, in *FEDERAL PREEMPTION: STATES’ POWERS, NATIONAL INTERESTS* 315 (Richard A. Epstein & Michael S. Greve eds., 2007) (opining that *Rice* “was not a true preemption case at all: it was a case

Article questions not the presumption's constitutionality or status, but rather the accuracy and wisdom of the "tradition" used to justify it—and its application to health laws under the umbrella of police powers.

This Article analyzes the "tradition" basis for the presumption and questions its application both descriptively and normatively.¹²⁵ Section II outlines the police power origins of health law and surveys the evolving ratio of federal and state health laws, suggesting that state dominance in health regulation is, in some respects, more of a historical artifact than an ongoing tradition. Section III argues that, normatively, reliance on a shifting notion of tradition in delegating regulatory power makes for unstable doctrine and undesirably formalistic jurisprudence.

Before embarking on those explorations, however, a few uneasy thoughts about presumption's relationship to health law demand attention.

C. *The Presumption's Functions in Health Law*

Preemption can be a politically charged issue. It deals with the authority to regulate and the "distribution of power between the federal and state governments."¹²⁶ One's view of preemption's appropriateness may shift according to one's view of the underlying law or lawmaker.¹²⁷ Further, one's feelings about the presumption against preemption reflect one's views of preemption itself: an obstacle to a worthy goal of uniform law, or a safeguard against corruption under the guise of uniformity.

Preemption has played a particularly prominent role in shaping health law.¹²⁸ The full spectrum of preemptions—complete, express, field, and conflict—exist in health law and work to support and/or thwart public health goals. Preemption can bolster health, safety, and access regulation by allowing for the establishment of federal minimum protections and additional local protections.¹²⁹ It can promote national uniformity to spur innovation and access. And preemption can aid the distribution of regulatory authority, carving out spheres of uniform federal protections with important state variations. Yet

about *exclusive jurisdiction*"); Dinh, *supra* note 89, at 2087–88, 2092; Alan Untereiner, *The Defense of Preemption: A View from the Trenches*, 84 TULANE L. REV. 1257, 1265–68 (2010); cf. Brief of the Chamber of Commerce of the United States of America as Amicus Curiae in Support of Petitioner at 27–28, *Wyeth v. Levine*, 555 U.S. 555 (2009) (No. 06-1249) (arguing that the federal courts should not apply a presumption against preemption).

125. See generally Davis, *The "New" Presumption*, *supra* note 106, at 1247–55 (providing a general description of a renaissance in the Supreme Court's use of the presumption against preemption).

126. Verchick & Mendelson, *supra* note 36, at 13.

127. See *id.* at 32 (stating that preemption "will inevitably pit your principles against a desired outcome"); Scott L. Greer & Peter D. Jacobson, *Health Care Reform and Federalism*, 35 J. HEALTH POL., POL'Y & L. 203, 220 (2010); Untereiner, *supra* note 124, at 1265–66.

128. See *infra* Part II.B for a discussion of how preemption has shaped a body of health law and a regulatory framework.

129. See Verchick & Mendelson, *supra* note 36, at 19 (noting that federal law may be a "'floor' of minimum protection but [one] that states remain free" to supplement with "more protective" standards and tort claims).

preemption also can undercut health reform efforts and valuable experimentation at the state level.¹³⁰

The presumption against preemption thus has both undermined some important federal efforts and saved some important state efforts. So it is with great trepidation that this Article wades into a critique of that presumption, which lately has been invoked to support worthy reform efforts,¹³¹ including to preserve state initiatives aimed at expanding access to insurance despite ERISA.¹³² By contrast, the presumption also has been invoked unsuccessfully by states attempting to frustrate implementation of the ACA's insurance mandates and coverage reforms¹³³ and to circumvent coverage and access requirements under Medicaid.¹³⁴

This Article challenges a jurisprudential tool that has had conflicting applications to health law—in some cases, the presumption can contribute to the preservation of beneficial state laws, and, in others, it can help resist efforts to establish a nationally uniform regulatory floor on important issues like access to health care, safety, and quality of treatments. This Article mounts this challenge in an effort to strengthen the presumption's most salutary uses in health law. Ultimately, the investigation below reveals heterogeneous regulatory traditions within health law that may exhibit stronger and more nuanced traditions of state law for some topics than the blanket presumption suggests. Critiquing the presumption's underlying traditions bolsters its utility.

II. THE CORPUS OF HEALTH LAW: REGULATORY TRADITIONS IN A BODY OF LAWS

This Section sketches the historical arc of federalism in health law and questions whether the blanket tradition of state law primacy is accurate. Primacy has a dual meaning, describing either the *first* or the *most important*.¹³⁵ Tradition, in its common usage, describes “past customs . . . that influence or govern present acts or practices.”¹³⁶ With these terms in mind, this Section highlights how the history of state and federal health law regulation has contributed to the structure and governance of the health care system.

130. See, e.g., Kristen Madison, *Building a Better Laboratory: The Federal Role in Promoting Health System Experimentation*, 41 PEPP. L. REV. 765, 801–02 (2014).

131. See, e.g., *St. Louis Effort for AIDS v. Huff*, 782 F.3d 1016, 1021–23 (8th Cir. 2015).

132. E.g., *Golden Gate Rest. Ass'n v. San Francisco*, 546 F.3d 639, 648 (9th Cir. 2008).

133. E.g., *Coons v. Lew*, 762 F.3d 891, 901–02 (9th Cir. 2014), *cert. denied*, 135 S. Ct. 1699 (2015) (holding that the ACA impliedly preempted an Arizona statute providing that its citizens may forego minimum health insurance coverage without paying any penalties).

134. See, e.g., *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113–14 (2011); *Ark. Dep't of Health & Human Servs. v. Ahlborn*, 547 U.S. 268, 292 (2006); cf. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 668 (2003) (holding that state efforts at achieving cost savings by subjecting drugs without negotiated prices to prior authorization not preempted).

135. See *Primacy*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/primacy> (last visited Nov. 14, 2016) [<https://perma.cc/QD8H-SM8R>] (“[T]he state of being first (as in importance, order, or rank).”).

136. *Tradition*, BLACK'S LAW DICTIONARY (10th ed. 2014).

Ultimately, this brief investigation concludes that, while state law does have a strong tradition of regulatory dominance in discrete *types* of health law and a modest predominance overall, the broader *body* of health law does not reflect the homogenous tradition of state primacy. While states have long regulated health using their police powers, Congress has a long, steady history of setting overlapping policy and regulation via its Article I enumerated powers. The evolution of health law displays a dynamic interaction of federal and state regulations, all in step with advances in medical and scientific knowledge.

A. *Conception: The Origins of Health Law*

I begin this overview of state and federal health regulatory traditions with their respective origin stories, which frame their future interactions. States regulate health matters pursuant to the common law concept of police powers, occasionally enshrined in state constitutions.¹³⁷ Congress regulates health matters under its Article I, Section 8 enumerated powers, usually through the Commerce Clause or Spending Clause.¹³⁸ This discussion starts with the basis for state regulatory authority over health, the basis for the tradition presumption. It then covers the federal regulatory authority.¹³⁹

1. State Police Powers

States' police powers authorize them to regulate the health, safety, welfare, and morals of their citizens,¹⁴⁰ as well as innumerable other aspects of society.¹⁴¹ The foundations and parameters of the term *police power* are subject to considerable debate, as one might expect from such a broadly applicable regulatory power, tracing back to the common law.¹⁴² Whatever outer limits one

137. See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (discussing the use of state police powers to legislate). See generally Jorge E. Galva et al., *Public Health Strategy and the Police Powers of the State*, 120 PUB. HEALTH REP. 20, 21 (2005) (explaining police power in terms of history and application); Elizabeth Weeks Leonard, *State Constitutionalism and the Right to Health Care*, 12 U. PA. J. CONST. L. 1325, 1347 (2010) [hereinafter Leonard, *State Constitutionalism*] (noting that thirteen state constitutions mention health).

138. KATHLEEN S. SWENDIMAN, CONGRESSIONAL RESEARCH SERVICE, R40846, HEALTH CARE: CONSTITUTIONAL RIGHTS AND LEGISLATIVE POWERS 6–7 (2012) (noting these two clauses as “the primary sources of constitutional authority for most health care legislation”).

139. *Rice*, 331 U.S. at 230.

140. See LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 91–92 (2d ed. 2008) [hereinafter GOSTIN, PUBLIC HEALTH LAW]; ERNST FREUND, *Preface* to THE POLICE POWER: PUBLIC POLICY AND CONSTITUTIONAL RIGHTS, v (1904); Galva et al., *supra* note 137, at 20; Jana K. Strain & Eleanor D. Kinney, *The Road Paved with Good Intentions: Problems and Potential for Employer-Sponsored Health Insurance Under ERISA*, 31 LOY. U. CHI. L.J. 29, 33 (1999) (noting that states' inherent police powers include the authority to regulate insurance); cf. ROBERT I. FIELD, HEALTH CARE REGULATION IN AMERICA: COMPLEXITY, CONFRONTATION, AND COMPROMISE 4 (2007) [hereinafter FIELD, HEALTH CARE REGULATION] (describing the past century of health care regulation as organized around three main objectives: quality, cost, and access).

141. See generally Barros, *supra* note 30, at 475 (arguing that police power simply describes all states' sovereign powers).

142. See, e.g., *id.* (positing that police power be understood as all the states' reserved powers);

attaches to police power, scholars,¹⁴³ courts,¹⁴⁴ and legislatures¹⁴⁵ agree that health, along with safety and welfare, fall within them.

The doctrine of police power as we now know it arose in the mid-nineteenth century, though the ideological seeds had been planted earlier.¹⁴⁶ The Tenth Amendment, ratified in 1789, reserved for the states all powers neither delegated to the newly established federal government nor foreclosed from the states.¹⁴⁷ After its ratification, a handful of cases testing the constitutionality of state laws invoked concepts analogous to police power but did not yet identify them as such.¹⁴⁸

Then, in 1827, Chief Justice Marshall first used the phrase “police power” to describe states’ residual authority under the Constitution, particularly to regulate “infectious or unsound articles.”¹⁴⁹ Other opinions from federal and state courts and other commentary on the newly minted phrase followed, slowly at first.¹⁵⁰

Stephen R. Miller, *Community Rights and the Municipal Police Power*, 55 SANTA CLARA L. REV. 675, 679 (2015) (tracing the history of the police power and disagreement over its meaning).

143. See, e.g., GOSTIN, *PUBLIC HEALTH LAW*, *supra* note 140, at 91–92; Barros, *supra* note 30, at 484–88 (listing “health, safety, and morals” as the early “acknowledged legitimate ends” of police power, but debating the list as a limitation).

144. See, e.g., *City of Erie v. Pap’s A.M.*, 529 U.S. 277, 296 (2000) (“[H]ealth and safety are clearly within the city’s police powers.”); *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) (stating that police powers cover regulations for the benefit of “public health and the public safety”); *Hannibal & St. J.R. Co. v. Husen*, 95 U.S. 465, 470–71 (1877) (listing “domestic order, morals, health, and safety”); *Mooney v. Vill. of Orchard Lake*, 53 N.W.2d 308, 309 (Mich. 1952) (stating that police powers are exercised for “public health, safety, morals or the general welfare”). *But see* *Berman v. Parker*, 348 U.S. 26, 32 (1954) (“An attempt to define [police powers] reach or trace its outer limits is fruitless, for each case must turn on its own facts.”).

145. See, e.g., 43 U.S.C. § 315n (2012) (expressing intent not to “impair[] or restrict[]” the “police power of the respective States” to enact and enforce laws in “regards [to] public health or public welfare”); 52 PA. STAT. AND CONS. STAT. ANN. § 3302 (West 2016) (deeming the statute “to be an exercise of the police powers of the Commonwealth for the general welfare of the people of this Commonwealth,” used for various conservation goals, as well as “to prevent and eliminate hazards to health and safety”).

146. See, e.g., *Smith v. Turner*, 48 U.S. 283, 319 (1849) (using the phrase, “pauper law,” to describe a New York statute); FREUND, *supra* note 140, at v (explaining that in 1904 “[t]he law of the police power is practically a growth of the last thirty or forty years, and much of it remains unsettled”); CHRISTOPHER G. TIEDEMAN, *A TREATISE ON THE LIMITATIONS OF POLICE POWER IN THE UNITED STATES* 1–5 (1886); see generally Barros, *supra* note 30, at 478–82 (tracing early development of police power jurisprudence).

147. U.S. CONST. amend. X; see also THE FEDERALIST No. 17 (Alexander Hamilton) (promoting the idea that the Constitution left the states with “residuary authorities” untrammelled by the new federal government).

148. See, e.g., *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 208 (1824) (recognizing state power “to regulate its police, its domestic trade, and to govern its own citizens”); *Tr. of Dartmouth Coll. v. Woodward*, 17 U.S. (12 Wheat.) 518, 629 (1819) (holding that the Constitution was not intended to hamper states’ “regulation of their civil institutions, adopted for internal government”); see also Barros, *supra* note 30, at 474–75 (collecting and explaining cases).

149. *Brown v. Maryland*, 25 U.S. (12 Wheat.) 419, 444 (1827) (explaining that removal of gunpowder is a police power).

150. See, e.g., *The License Cases*, 46 U.S. (5 How.) 504, 526–28 (1847); *New York v. Miln*, 36 U.S. 102, 102 (1837); see generally Barros, *supra* note 30, at 475–77 (discussing how courts slowly began

Over time, industrialization expanded states' opportunities to use police powers.¹⁵¹ And the judicial concept of police power coalesced around states' powers to regulate health, safety, welfare, and morals.¹⁵²

The inclusion of health among states' police powers appeared early in courts' development of the doctrine.¹⁵³ Further, a few state constitutions in this early period expressly mentioned "health."¹⁵⁴ Beginning in the early 1800s, state legislatures were the earliest regulators of public health, passing laws on sanitation and vaccination, prompted by burgeoning scientific knowledge about germs and contagion.¹⁵⁵ By 1905, when Ernest Freund's exhaustive treatise on police power went to press, "legislation in the interest of safety and health" already was "so extensive" that the treatise could not catalog the laws in that category.¹⁵⁶

Also in 1905, the seminal public health case, *Jacobson v. Massachusetts*,¹⁵⁷ upheld state and local mandatory vaccination laws as constitutional, expressing the distinctiveness of state power over health matters:

Although this court has refrained from any attempt to define the limits of that [police] power, yet it has *distinctly recognized* the authority of a State to enact quarantine laws and "*health laws of every description*;" According to settled principles the police power of a State must be held to embrace, *at least*, such reasonable regulations established directly by legislative enactment as will protect the *public health* and the public safety.¹⁵⁸

Thus, the idea of health as a police power traces back to the 1820s, and the

to discuss police powers).

151. See generally MICHAEL WILLRICH, *POX: AN AMERICAN HISTORY* 302–06 (2011) (explaining how Reconstruction and industrialization altered the legal landscape for challenging state public health regulations and concluding that "[i]ndustrialization had a greater immediate impact upon the police power and its constitutional status than did the Civil War").

152. See FREUND, *supra* note 140, at v. See generally RUTH LOCKE ROETTINGER, *THE SUPREME COURT AND STATE POLICE POWER: A STUDY IN FEDERALISM* (1957).

153. See, e.g., *The License Cases*, 46 U.S. (5 How.) at 517 (explaining that police powers include "safety, health, or morals"); *Brown*, 25 U.S. (12 Wheat.) at 443–44 (discussing the power to remove gunpowder as it relates to public health); *Thorpe v. Rutland & Burlington R.R. Co.*, 27 Vt. 140, 150 (1855) (noting that the police power has its foundation in the right and duty of the Government to "secure the general comfort, health, and prosperity of the state"); see also Paul Fuller, *Is There a Federal Police Power?*, 4 COLUM. L. REV. 563, 563 (1904); Galva et al., *supra* note 137, at 21 (tracing the origins of police power to quarantine measures taken to control yellow fever in Philadelphia after the Revolution).

154. See Leonard, *State Constitutionalism*, *supra* note 137, at 1347–68 (noting that thirteen state constitutions expressly mention health, as well as others that imply the topic, and describing seven in detail).

155. See FIELD, *HEALTH CARE REGULATION*, *supra* note 140, at 5, 17; see, e.g., W.T. Eckley, *The Germ-Theory of Disease and Antiseptic Treatment*, 10 J. AM MED. ASS'N 131 (1888) (providing one scientific understanding of germs).

156. FREUND, *supra* note 140, at 110.

157. 197 U.S. 11 (1905).

158. *Jacobson*, 197 U.S. at 24–28 (emphasis added) (upholding local laws against constitutional challenge); see also WILLRICH, *supra* note 151, at 285–336 (describing the circumstances of *Jacobson*, "[t]he seminal case in modern American public health law").

idea of health's unique status among such powers back to the late 1800s. Police power health legislation has, of course, continued unabated into the modern age. In 2006—a century after *Jacobson*—Massachusetts exercised the same police power to enact its comprehensive state health insurance reform law, which became the model for the ACA.¹⁵⁹

In summary, the constitutional basis of states' reserved general powers dates back to 1789 (the ratification of the Tenth Amendment), though states' regulatory powers predate the Constitution.¹⁶⁰ Judicial recognition that health is among states' police powers traces back to the 1820s (roughly 200 years ago).¹⁶¹ And the notion that health has unique force among police powers emerged not long after.¹⁶² Simply because states *could* regulate health, however, does not mean that *only* they could—or that *only* they did.

2. Federal Spending and Commerce Clause Powers

Congress may legislate, despite states' police powers, where justified by an Article I enumerated power.¹⁶³ When the concept of state police power emerged in the late nineteenth century and gained traction at the turn of the twentieth century, courts and theorists recognized Congress's concurrent authority to regulate police power topics through its enumerated powers.¹⁶⁴ In crafting federal health laws, Congress's go-to enumerated powers have been the Commerce Clause and the Spending Clause.¹⁶⁵ The conventional view is that

159. See generally Mary Ann Chirba Martin, *Universal Health Care in Massachusetts: Setting the Standard for National Reform*, 35 FORDHAM URBAN L.J. 409 (2008).

160. See 2 J. STORY, COMMENTARIES ON THE CONSTITUTION OF THE UNITED STATES § 259, at 240 (Boston, Hilliard, Shattuck, and Co., 1833) (explaining that, under the Articles of Confederation, each state exercised its police powers “according to its estimate of its own interests, the importance of its own products, and the local advantages and disadvantages of its position in a political or commercial view,” leading to disunity), quoted in Julian N. Eule, *Laying the Dormant Commerce Clause to Rest*, 91 YALE L.J. 425, 430 (1982); Eule, *supra* (highlighting that the Dormant Commerce Clause was enacted because “America under the Articles of Confederation was marked by commercial warfare between the states” through exercise of their police powers).

161. *Brown v. Maryland*, 25 U.S. (12 Wheat.) 419, 444 (1827) (explaining that removal of gunpowder is a police power, related to health and safety).

162. See Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 446–48 (2015) [hereinafter Zettler, *Toward Coherent Federal Oversight*].

163. See FREUND, *supra* note 140, at 62 (“The federal exercise of the police power through positive legislation rests upon the enumerated powers of Congress under the constitution.”); Fuller, *supra* note 153, at 564; Nelson, *supra* note 1, at 227.

164. See, e.g., *Leisy v. Hardin*, 135 U.S. 100, 108 (1890) (“The [federal] power to regulate commerce among the States is a unit, but . . . the States may legislate in regard to them with a view to local needs and circumstances,” including health laws within reserved powers, but only “until congress otherwise directs.”); FREUND, *supra* note 140, at 62 (“The federal exercise of the police power through positive legislation rests upon the enumerated powers of Congress under the constitution.”); Fuller, *supra* note 153, at 588 (“In the execution of the powers over commerce . . . Congress may enact laws which regulate internal affairs of States that are in any way dependent upon or connected with communication with the exterior;—such as the introduction into the State of any articles of food, drugs, . . . [and] the protection of health by quarantine laws.”).

165. SWENDIMAN, *supra* note 138, at 6.

Congress may use any means that is “fairly adapted” to carrying out an express power and that does not violate any prohibition in the Constitution.¹⁶⁶ Congressional actions pursuant to these enumerated powers have built a body of federal health law that regulates both preemptively and concurrently with state law.

The Commerce Clause enabled some of the earliest federal health laws, aimed at protecting public health from contagion and dangerous products.¹⁶⁷ The early federal health laws quarantined diseased livestock and people,¹⁶⁸ and regulated drugs and food products posing health concerns.¹⁶⁹ Although Congress had entertained widespread national food regulation in the late 1800s and passed individual laws regulating biologics and aspects of drug marketing,¹⁷⁰ it did not pass its first comprehensive set of national health regulations until the Pure Food and Drug Act of 1906, an exercise of its Commerce Clause power.¹⁷¹

The Commerce Clause’s health law application has expanded exponentially as health care and treatment innovations became more expensive, complex, and widespread. Over the past century, the Commerce Clause has enabled enormous expansion of federal regulation of food and medical products,¹⁷² public health and disease control,¹⁷³ and numerous blockbuster laws across a wide spectrum of

166. U.S. CONST. art. I, § 8; *Buckley v. Valeo*, 424 U.S. 1, 90 (1975) (“[The Spending Clause] is . . . a grant of power, the scope of which is quite expansive, particularly in view of the enlargement of power by the Necessary and Proper Clause.”); see generally Robert J. Reinstein, *The Limits of Congressional Power*, 89 TEMP. L. REV. 1 (2016) (examining the scope of the Necessary and Proper Clause).

167. See FIELD, HEALTH CARE REGULATION, *supra* note 140, at 17.

168. In 1796 and 1799, Congress passed federal quarantine acts aimed at quarantining people, seizing foreign ships with insanitary conditions—particularly plague and smallpox infections—and detaining passengers in quarantined hospital wards. See Act of Feb. 25, 1799, ch. 12, 1 Stat. 619; Act of May 17, 1796, ch. 31, 1 Stat. 474; see also *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 205 (1824).

169. E.g., Oleomargarine Act of 1886, ch. 840, 24 Stat. 209; Act of May 29, 1884, ch. 60, § 3, 23 Stat. 31; Drug Importation Act of 1848, ch. 70, 9 Stat. 237; see Fuller, *supra* note 153, at 588; *Significant Dates in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN. (Dec. 19, 2014), <http://www.fda.gov/About>

FDA/WhatWeDo/History/Milestones/ucm128305.htm [<https://perma.cc/68XW-B9U9>].

170. E.g., Biologics Control Act of 1902, Pub. L. No. 57-244, 32 Stat. 328; see also FIELD, HEALTH CARE REGULATION, *supra* note 140, at 17 (describing drug laws of the 1840s). See Wallace F. Janssen, *The Story of the Laws Behind the Labels*, U.S. FOOD & DRUG ADMINISTRATION (March 11, 2014), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm> [<https://perma.cc/ZC2M-CTYM>] (describing early efforts to regulate food and drug manufacturing); Jillian London, *Tragedy, Transformation, and Triumph: Comparing the Factors and Forces That Led to the Adoption of the 1860 Adulteration Act in England and the 1906 Pure Food and Drug Act in the United States*, 69 FOOD & DRUG L.J. 315, 328 (2014) (“[G]iving the federal government the power to inspect and regulate companies selling biologic agents in interstate or foreign commerce.”).

171. See Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938); see also FIELD, HEALTH CARE REGULATION, *supra* note 140, at 5 (describing the 1906 act as the “first significant federal effort” in regulating health).

172. See, e.g., FIELD, HEALTH CARE REGULATION, *supra* note 140, at 115–16 (describing drug laws of the 1840s).

173. Galva et al., *supra* note 137, at 23–24; James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J. L. & HEALTH 309, 335–36 (1998).

topics, including health insurance,¹⁷⁴ information privacy,¹⁷⁵ and provider quality.¹⁷⁶

Reliance on the Commerce Clause to regulate health proceeded apace until the Supreme Court's 2012 opinion in *National Federation of Independent Business v. Sebelius* (*NFIB*),¹⁷⁷ challenging the ACA's individual mandate provision, which required individuals to either purchase health insurance or pay a tax.¹⁷⁸ While the *NFIB* majority noted that the Commerce Clause empowered Congress to regulate the health insurance industry and that the individual mandate was *necessary* to effectuate those reforms, it held that the mandate was not a *proper* exercise of Commerce Clause power.¹⁷⁹ Of course, this finding did not wipe out the individual mandate—the Supreme Court upheld the provision as an exercise of Congress's other go-to health law power, the Spending Clause.¹⁸⁰

The Spending Clause gives Congress the "Power To lay and collect Taxes, . . . [to] . . . provide for the . . . general Welfare of the United States."¹⁸¹ Its power is broad.¹⁸² Courts have unquestioningly deferred to congressional judgment on which topics concern the general welfare,¹⁸³ and health care has long been such a topic. As health care spending has ballooned, so has use of the Spending Clause power.¹⁸⁴

174. See, e.g., Employee Retirement Income Security Act (ERISA) of 1974, 29 U.S.C. § 1001b (2012); Patient Protection and Affordable Care Act, 42 U.S.C. §§ 300gg, 300gg-63, 300gg-91, 300gg-92 (2010) (authorizing promulgation of health insurance market regulations); Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985, Pub. L. No. 99-272, 100 Stat. 82 (1986) (codified as amended in scattered sections of 29 U.S.C.); 45 C.F.R. § 147 (2012).

175. Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, § 264, 110 Stat. 1936, 2033 (codified at 42 U.S.C. § 1320d-2) (2012)).

176. Health Care Quality Improvement Act of 1986, 42 U.S.C. § 11101 (2012).

177. 132 S. Ct. 2566 (2012).

178. *NFIB*, 132 S. Ct. at 2566.

179. *Id.* at 2592.

180. *Id.* at 2593–600.

181. U.S. CONST. art. I, § 8.

182. See *Buckley v. Valeo*, 424 U.S. 1, 90 (1976) ("It is . . . a grant of power, the scope of which is quite expansive, particularly in view of the enlargement of power by the Necessary and Proper Clause."); *Steward Mach. Co. v. Davis*, 301 U.S. 548, 581–82 (1937) ("The subject matter of taxation open to the power of the Congress is as comprehensive as that open to the power of the states."); *United States v. Doremus*, 249 U.S. 86, 93 (1919) ("If the legislation enacted has some reasonable relation to the exercise of the taxing authority conferred by the Constitution, it cannot be invalidated because of the supposed motives which induced it."); cf. *NFIB*, 132 S. Ct. at 2596 ("That [the individual mandate] seeks to shape decisions about whether to buy health insurance does not mean that it cannot be a valid exercise of the taxing power."). See generally Eloise Pasachoff, *Agency Enforcement of Spending Clause Statutes: A Defense of the Funding Cut-Off*, 124 YALE L.J. 248 (2014); Terry Jean Seligmann, *Muddy Waters: The Supreme Court and the Clear Statement Rule for Spending Clause Legislation*, 84 TUL. L. REV. 1067 (2010).

183. See *Buckley*, 424 U.S. at 90–91 ("It is for Congress to decide which expenditures will promote the general welfare."); *Steward Mach. Co.*, 301 U.S. at 548 (upholding the Social Security Act's target of relieving unemployment strain as a legitimate issue of general welfare).

184. See Zettler, *Toward Coherent Federal Oversight*, *supra* note 162, at 470 ("Because the federal government pays almost half of all health care expenses in the United States, Congress's

Through its Spending Clause powers, Congress established the United States Marine Hospital Services (MHS) in 1798,¹⁸⁵ catalyzed the construction of health care facilities after World War II,¹⁸⁶ and created federal health insurance programs including Medicare¹⁸⁷ and Medicaid.¹⁸⁸ These landmark federal Spending Clause statutes begat further legislation tied to federal purse strings, including many of the most prominent health laws regulating providers and hospitals: Emergency Medical Treatment and Active Labor Act (EMTALA),¹⁸⁹ the Stark Law,¹⁹⁰ and the Anti-Kickback Statute.¹⁹¹

The Spending Clause also enabled numerous ACA provisions, enacted as modifications of the Medicare and Medicaid programs or as federal grants for innovations in health care quality, access, and cost control.¹⁹² Only one ACA provision has been challenged successfully on Spending Clause grounds: the expansion of Medicaid to cover all adults below a uniform income threshold.¹⁹³ Although the Supreme Court held in *NFIB* that tying states' acceptance of the Medicaid expansion to funding for existing Medicaid programs was unduly coercive, the expansion survived as an optional feature for state Medicaid programs.¹⁹⁴

Thus, federal power to regulate health originates in 1788 with Article I, to the extent that a health issue impacts interstate commerce or the "general welfare" of citizens.¹⁹⁵ Congress almost immediately began exercising those powers, and the ascendance of both interstate commerce and professional medicine accelerated the reach of federal health laws at the turn of the twentieth century.¹⁹⁶ Additionally, Spending Clause programs and the regulations they impose "have transformed American health care and effectively created the structure that exists today."¹⁹⁷

spending powers provide an avenue for regulating a significant amount of medical practice: selectively funding medical services and placing conditions on those who receive payments." (footnote omitted)).

185. An Act for the Relief of Sick and Disabled Seamen, ch. 77, 1 Stat. 605 (1798).

186. Hospital Survey and Construction (Hill-Burton) Act, ch. 958, 60 Stat. 1040 (1946) (codified as amended at 42 U.S.C. §§ 291–291o (2012)).

187. Health Insurance for the Aged Act (Medicare Act), Pub. L. No. 89-97, 79 Stat. 290 (1965) (codified as amended at 42 U.S.C. § 1395 (2012)).

188. 79 Stat. 343 (codified as amended at 42 U.S.C. § 1396 (2012)).

189. 42 U.S.C. § 1395dd (2012).

190. 42 U.S.C. § 1395nn (2012).

191. Anti-Kickback Statute, 42 U.S.C. § 1320a-7(g) (2012). This statute also applies to Department of Defense health programs.

192. See Nat'l Fed'n of Indep. Bus. v. Sebelius (*NFIB*), 132 S. Ct. 2566, 2571 (2012); Pasachoff, *supra* note 182, at 251–53, 262.

193. *Id.* at 2607.

194. *Id.* at 2608. The remainder of the ACA survived, intact, under the statute's severability clause. *Id.*

195. U.S. CONST. art. I, § 8.

196. See FIELD, HEALTH CARE REGULATION, *supra* note 140, at 19–23. (explaining the history of licensure of medical professionals).

197. Robert I. Field, *A Taxonomy of American Health Care Regulation: Implications for Health Reform*, 17 TEMP. POL. & C.R. L. REV. 605, 621 (2008) [hereinafter Field, *A Taxonomy*].

B. Anatomy and Physiology: Describing the Body of Health Law

From these origins of state and federal authority to regulate health, this Article proceeds to examine *how* those authorities have been exercised to create a body of health law and establish its regulatory customs. A supposedly strong tradition of state primacy forms the basis for the presumption against preemption.¹⁹⁸ Thus, the presumption raises definitional questions: which laws constitute *health law* to invoke the presumption, and do those laws demonstrate the *tradition* of state primacy upon which the presumption is based?

The definitional questions have no stock answer. The breadth of state police power and the versatility of the Spending and Commerce Clause powers have engendered a complex and frequently overlapping array of laws impacting health. When police power was conceptualized in the early 1800s, there was no definition of health regulation, and society generated comparatively little health activity.¹⁹⁹ As science and regulation advanced, the concept of health law grew to encompass regulation within a health care *system*, or at least a complex set of interlocking parts.²⁰⁰ That complex system has grown to consume over seventeen percent of America's gross domestic product, while the role of interstate commerce and government spending programs have grown concurrently.²⁰¹ This evolution has produced a vast and complex regulatory apparatus and body of health law directed at far more activity than simply the delivery of medical treatment.²⁰²

Courts have not defined what constitutes health law, but they have nonetheless applied the tradition presumption to a wide array of legislation on a case-by-case basis.²⁰³ Practitioners and scholars, perhaps seeking coherence,

198. See, e.g., *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

199. See generally PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 30–59 (1982) (tracing the medical profession in the pre-Civil War era, when doctors carried black bags and made house calls and hospitals and surgeries were rare); George B. Moseley III, *The U.S. Health Care Non-System, 1908–2008*, 10 AM. MED. ASS'N J. ETHICS 324, 324–331 (2008) (noting that insurers did not cover health events at all in this period).

200. See, e.g., *Cnty. Psychiatric Ctrs. of Oregon, Inc. v. Grant*, 664 F.2d 1148, 1152 (9th Cir. 1981) (“The health care provider is one of the most important participants in any health care delivery system.” (quoting National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300k(a)(5) (2012))); FIELD, *HEALTH CARE REGULATION*, *supra* note 140, at 17; *THE FRAGMENTATION OF U.S. HEALTH CARE: CAUSES AND SOLUTIONS* 90–96 (Einer R. Elhauge ed., 2010); STARR, *supra* note 199, at 348; Moseley, *supra* note 199, at 325 (highlighting that at least as early as the 1970s, courts referred to “systems” in health care).

201. See ABE DUNN ET AL., BUREAU OF ECONOMIC AFFAIRS, *INTRODUCING THE NEW BEA HEALTH CARE SATELLITE ACCOUNT 1* (2015), https://www.bea.gov/scb/pdf/2015/01%20January/0115_bea_health_care_satellite_account.pdf [<https://perma.cc/9H26-2BZ7>] (“Total health care spending reached 17.4 percent of gross domestic product (GDP) in 2013 . . .”).

202. See Field, *A Taxonomy*, *supra* note 197, at 605–06 (describing the U.S. health care system as “one of America’s largest industries and . . . among the most highly regulated” by a “regulatory system of almost bewildering complexity” controlling a “broad range of activities”).

203. See, e.g., *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 646 (2003) (involving a “statute designed to foster public health” in the context of Medicaid prescription drug purchasing regulations); *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997) (discussing state revenue regulation operating on hospitals); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475

have defined health law by its component parts: provider liability, facility regulation, public health, food and drugs, insurance and finance, and information and privacy.²⁰⁴ Debate exists over whether and to what extent this list coheres into a unified body, but most agree generally on these component parts²⁰⁵—the *anatomy* in the analogy pursued here.²⁰⁶

Policy concerns of quality, cost, and access course through all parts of health law.²⁰⁷ The interactions of state and federal regulation supply some unifying and ordering principles.²⁰⁸ Robert I. Field has proposed three paradigms of health

(1996) (exploring regulations of food, drugs, and devices); *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719–20 (1985) (discussing municipal public health ordinance on blood donation); see FREUND, *supra* note 140, at 109–10 (noting that “legislation in the interest of safety and health” was in 1905 “so extensive” that it defied inclusion principles); cf. *Gade v. Nat’l Solid Wastes Mgmt Ass’n*, 505 U.S. 88, 96–97 (1992) (discussing Occupational Safety and Health Act as health and safety regulation).

204. See FIELD, *HEALTH CARE REGULATION*, *supra* note 140, at viii, 18 (focusing its discussion on “every significant kind of regulation that is directly targeted to the provision or financing of health care,” including these categories, as well as “health care business relationships,” and “funding research”); BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* xviii–xix (2d ed. 1987); Mark A. Hall, *The History and Future of Health Care Law: An Essentialist View*, 41 WAKE FOREST L. REV. 347, 352 (2006) [hereinafter Hall, *The History and Future*] (including “malpractice liability, bioethics, insurance financing, and corporate regulation,” but describing the inclusion of public health as “uncertain” because it is not “restricted to medical care delivery”); AMERICAN HEALTH LAWYERS ASSOCIATION, *THE AHLA HEALTH LAW CURRICULUM MANUAL* 12–14 (2014), https://www.healthlawyers.org/hlresources/PI/Documents/HLC_Toolkit/HLC_Full.pdf [<https://perma.cc/Q58P-L7LM>] (outlining the major topics in “health law” based on extensive practitioner survey data).

205. See, e.g., FIELD, *HEALTH CARE REGULATION*, *supra* note 140, at vii (explaining that it is nearly “impossible to cover every regulatory program that relates to health care”); M. Gregg Bloche, *The Emergent Logic of Health Law*, 82 S. CAL. L. REV. 389, 394–95 (2009); Einer R. Elhauge, *Can Health Law Become a Coherent Field of Law*, 41 WAKE FOREST L. REV. 365, 365–67 (2006); Hall, *The History and Future*, *supra* note 204, at 355–56 (“In a nutshell, health law in the United States coalesced intellectually and academically roughly twenty-five years ago as the doctrinal and public policy study of law that applies to the health care industry.”); Mark A. Hall & Carl E. Schneider, *Where Is the “There” in Health Law?: Can It Become a Coherent Field?*, 14 HEALTH MATRIX 101, 103–04 (2004) (describing the field as a law of “relational webs”); Theodore W. Ruger, *Health Law’s Coherence Anxiety*, 96 GEO. L.J. 625, 627 (2008).

206. See *Anatomy*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/anatomy> (last visited Nov. 14, 2016) [<https://perma.cc/WGD8-KGP7>] (defining anatomy as “the parts that form a living thing;” “the art of separating the parts of an organism in order to ascertain their position, relations, structure, and function;” and “dissection”).

207. See FIELD, *HEALTH CARE REGULATION*, *supra* note 140, at 4 (noting these unifying policy themes).

208. See Field, *A Taxonomy*, *supra* note 197, at 605 (discussing the emergence of a paradigms framework); Abbe R. Gluck, *Federalism from Federal Statutes: Health Reform, Medicaid, and the Old-Fashioned Federalists’ Gamble*, 81 FORDHAM L. REV. 1749, 1752 (2013) [hereinafter Gluck, *Federalism from Federal Statutes*] (presenting states as implementers in “a legal world dominated by federal statutes”); Abbe R. Gluck, *Intrastatutory Federalism and Statutory Interpretation: State Implementation of Federal Law in Health Reform and Beyond*, 121 YALE L.J. 534, 582–95 (2011) (outlining multiple theories of state-federal relations in the ACA’s health reforms). But see Nicole Huberfeld, *The Universality of Medicaid at Fifty*, 15 YALE J. HEALTH POL’Y, L. & ETHICS 67, 67–69 (2015) [hereinafter Huberfeld, *The Universality of Medicaid*] (describing the United States’ approach to health care as

care regulation to describe the interactions of regulations and regulators: (1) state primacy, in which the “initial locus” of regulation and many of the most basic regulatory functions remain with the states; (2) federal primacy, in which the federal government takes the lead; and (3) “federal funding with regulatory restrictions,” in which federal Spending Clause programs “facilitate private activity that achieves overarching [federal] policy.”²⁰⁹

The interactions of health law’s component topic areas within state and federal regulation supply a physiology and potential for coherence within the body of health law.²¹⁰ Each of these component parts has a distinct history and balance of regulatory authorities, and each contributes to the basis of any jurisprudential tradition for preemption analysis.

Leading observers have noted that the twenty-first century thus far is characterized by federal dominance in regulating health—both directly and indirectly, through antitrust, tax, and intellectual property laws.²¹¹ Figure 1, below, graphically represents some of the most prominent regulated issues in each area of health law and serves as a map for the investigation of regulatory traditions that follows. The chart organizes health law by category (columns) and sifts the laws in each category by the source of their authority—state police power or Article I enumerated powers. The horizontal line on each column represents a rough estimate of the current balance between state and federal regulatory authority in each category, with federal laws listed above the line, and state laws listed below the line in white font.

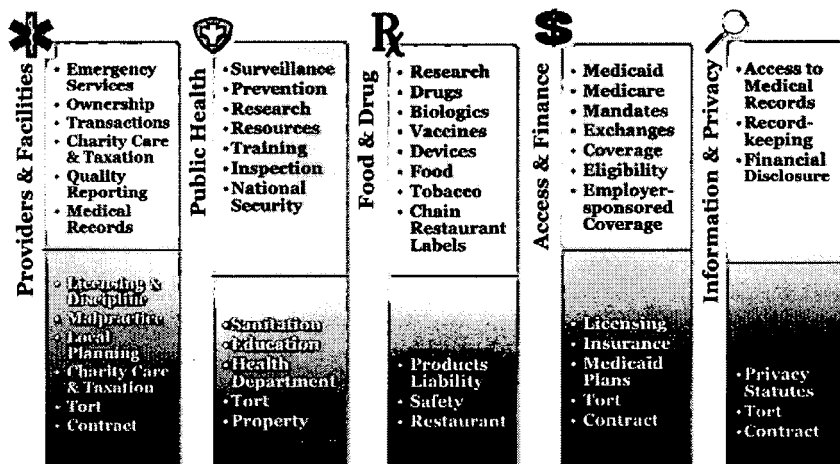
fragmented and chaotic).

209. Field, *A Taxonomy*, *supra* note 197, at 612–21.

210. See *Physiology*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/physiology> (last visited Nov. 14, 2016) [<https://perma.cc/U9HQ-SMAL>] (defining physiology as “a branch of biology that deals with the functions and activities of life or of living matter (as organs, tissues, or cells) and of the physical and chemical phenomena involved”).

211. See, e.g., FIELD, HEALTH CARE REGULATION, *supra* note 140, at 17 (“By the end of the twentieth century, the federal government had come to play a pervasive role in regulating health care that far outstripped the role of the states.”); cf. Gluck, *Federalism from Federal Statutes*, *supra* note 208, at 1749–50 (describing the current balance as an “era of federal statutory law” with state implementation).

FIGURE 1: HEALTH REGULATION BY TOPIC & AUTHORITY



This chart very roughly illustrates health law's diversity, density, and diffusion across regulatory authorities. It lists major regulatory topics as of the date of this writing and is meant to serve as an orienting tool, not a quantitative study. Placement of the federal-state balance line is entirely subjective and debatable. Here, it is informed by the historical summary that follows. Additionally, as an exercise, pin-pointing the current federal-state balance line underscores the subjectivity inherent in a regulatory relationship.

Preemption analysis is retrospective by nature, focusing on the balance that existed at the time Congress legislated and inquiring about the historical arc leading to that particular legislative moment.²¹² The tradition presumption supplants that inquiry with an assumed tradition of state primacy in health law. This Section questions that tradition, keeping in mind primacy's two potential meanings: the *first* to regulate or the one to implement the *most* regulation.²¹³ The following analysis surveys major sources of federal and state regulation in each category of health law based on the origins, customary interactions, and resilience of state law.

1. Providers and Facilities

Perhaps the most direct and visible regulation in the health care system is the regulation of health care providers and the facilities in which they work.²¹⁴ Physician regulations largely respect autonomy and expertise, deferring heavily

212. See generally Gardbaum, *supra* note 1, at 770–71.

213. See *Primacy*, *supra* note 135 (“[T]he state of being first (as in importance, order, or rank).”).

214. See FIELD, HEALTH CARE REGULATION, *supra* note 140, at 19 (“Government regulation of health care has no more fundamental role than to determine who may and may not provide services.”).

to the medical profession's private self-regulation and to tort law for remedies.²¹⁵ Facility regulation adds numerous additional layers of government supervision, but still relies on private standard-setting.²¹⁶ Providers' and facilities' voluntary participation in federal reimbursement programs, however, have invited ubiquitous federal regulations as conditions for reimbursement.²¹⁷

Deriving authority from their police power, states have regulated medical provider licensing, training, and professional discipline for nearly 150 years.²¹⁸ They have done so with minimal, if any, federal intrusion.²¹⁹ Between 1873 and 1915, every state passed some form of medical practice law, requiring a license to practice medicine, specifying the criteria for obtaining one, and setting punishments for unlicensed practice or other professional misconduct.²²⁰ This model of state-sanctioned professional licensure has historically extended to "allied health professions," such as dentists, pharmacists, and nurses.²²¹

To the extent that authorities compete in this area, the competition exists mainly between states and private professional accrediting bodies, rather than federal regulators.²²² Licensure derives from state law, but most states rely on licensing standards of private national accrediting bodies.²²³ With private professional organizations like the American Medical Association (AMA) and Federation of State Medical Boards providing for a high degree of national regulatory uniformity, federal regulation has little room to encroach.²²⁴

215. See STARR, *supra* note 199, at 351; Young, *The Ordinary Diet of the Law*, *supra* note 12, at 292–93.

216. STARR, *supra* note 199, at 351.

217. See Zettler, *Toward Coherent Federal Oversight*, *supra* note 162, at 454, 464–66 (using Medicare as an example of indirect federal regulation of medical practice).

218. See, e.g., *Dent v. West Virginia*, 129 U.S. 114, 122 (1889) (upholding a state statute requiring provider licensing); see also Nadia Sawicki, *Character, Competence, and the Principles of Medical Discipline*, 13 J. HEALTH CARE L. & POL'Y 285, 289–94 (2010) (tracing state authority to establish medical licensing boards through its history and practice). All states have exercised this regulatory power. FREUND, *supra* note 140, at 122.

219. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 21 (“[T]o this day, the basic regulation of medical practice remains with the states.”).

220. *Id.* at 20–21.

221. *Id.* at 36; see, e.g., *History of Dentistry Timeline*, AM. DENTAL ASS'N, <http://www.ada.org/en/about-the-ada/ada-history-and-presidents-of-the-ada/ada-history-of-dentistry-timeline> (last visited Nov. 14, 2016) [<https://perma.cc/V393-8QA8>] (explaining that private national organizations were formed in the mid-1800s, state licensure laws followed soon after, and a national educational accrediting body was established by the turn of the twentieth century); see Peter D. Jacobson, *The Role of ERISA Preemption in Health Reform: Opportunities and Limits*, 37 J. L. MED. & ETHICS 88, 89 (2009) [hereinafter Jacobson, *The Role of ERISA*] (“Traditionally, states are responsible for regulating health care delivery, and litigation against health care providers is resolved under state law.”).

222. See Robert I. Field, *Government as the Crucible for Free Market Health Care: Regulation, Reimbursement, and Reform*, 159 U. PA. L. REV. 1669, 1694 (2011); Field, *A Taxonomy*, *supra* note 197, at 606.

223. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 20–21.

224. *Id.* at 21–22 (explaining how the AMA successfully resisted federal practice regulations, yet achieved “nationwide regulatory uniformity” in licensure and discipline of doctors).

State law historically has supplied medical malpractice remedies,²²⁵ and in the 1960s, many states shifted the benchmark for the duty of care from a “locality rule” to a national standard.²²⁶ More recently, federal regulations have addressed gaps left in the state licensure and malpractice schemes. In 1986, the federal Health Care Quality Improvement Act created a National Practitioner Data Bank (NPDB) to collect and track providers’ discipline, sanction, and malpractice verdicts and settlements.²²⁷ Hospitals, state medical boards, and malpractice insurance carriers must report specified events to the NPDB.²²⁸

With the introduction of the Medicare and Medicaid programs in the 1960s, federal regulations applied to participating providers through reimbursement criteria, program integrity laws, and regulation of the facilities in which they provide treatment.²²⁹ These programs are such a significant source of health care revenue that participation, although voluntary, is almost de facto required to sustain most medical practices.²³⁰ The Medicare and Medicaid programs set reimbursement criteria that influence the nature and structure of care delivery.²³¹ For example, a set of federal laws prohibit physicians from ordering or prescribing “designated health services” for Medicare patients from any entity in which the physician or her immediate family has a “financial relationship.”²³²

Many more of the regulations that apply to providers apply via the facilities that employ them. Most facility regulation postdates the Civil War, when hospitals started to take their modern form.²³³ While the majority of hospitals now are privately owned, states and municipalities still own and operate their own public hospitals.²³⁴ In addition, the federal government operates the

225. See, e.g., *Hammonds v. Aetna Cas. & Sur. Co.*, 237 F. Supp. 96, 102 (N.D. Ohio 1965) (holding that patient abandonment is recoverable as a tort under Ohio law); *Childs v. Weis*, 440 S.W.2d 104, 107 (Tex. Civ. App. 1969) (holding that the doctor-patient relationship is actionable under Texas law under a theory of implied contract).

226. See, e.g., *Brune v. Belinkoff*, 235 N.E.2d 793, 798 (Mass. 1968) (relinquishing the locality rule in favor of a national standard); see also Alan G. Williams, *The Cure for What Ails: A Realistic Remedy for the Medical Malpractice “Crisis”*, 23 STAN. L. & POL’Y REV. 477, 491 (2012) (stating that, although “[h]ealthcare regulation and tort law—including medical malpractice law—have traditionally been within the province of state law and regulation,” recently “scholars have advocated full federalization of medical malpractice law.”).

227. 42 U.S.C. § 11101 (2012).

228. *Id.* §§ 11131–37.

229. See FIELD, HEALTH CARE REGULATION, *supra* note 140, at 20.

230. See Zettler, *Toward Coherent Federal Oversight*, *supra* note 162, at 470–71, 464–66; E.H. Morreim, *Dumping the “Anti-Dumping” Law: Why EMTALA is (Largely) Unconstitutional and Why it Matters*, 15 MINN. J. L. SCI. & TECH. 211, 255–56 (2014) (describing the threat of the withdrawal of Medicare funding as “coercive”).

231. See *id.* at 466 (“Additionally, because private insurers often follow Medicare’s lead, the effect of the federal government’s decisions likely reach beyond Medicare patients.”).

232. 42 U.S.C. § 1395nn (2012); see also Anti-Kickback Statute, 42 U.S.C. 1320a-7b (2012).

233. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 41–42. See STARR, *supra* note 199, at 145 (“In developing from places of dreaded impurity and exiled human wreckage into awesome citadels of science and bureaucratic order, they acquired a new moral identity, as well as new purposes and patients of higher status.”).

234. See *Fast Facts on U.S. Hospitals*, AM. HOSP. ASS’N., <http://www.aha.org/research/rc/stat->

Veterans Health Administration (VA), which traces its origins to the Civil War.²³⁵ The VA expanded enormously, and now operates 152 medical centers and hundreds of nursing homes and specialty clinics in “America’s largest integrated health care system.”²³⁶

States impose licensing schemes for privately operated hospitals, just as they do for providers. While today state licensure is the primary method for overseeing hospitals’ operations,²³⁷ such laws did not proliferate until the 1950s—at least seventy-five years after provider licensing statutes.²³⁸ Much like provider licensing, state facility licensing standards are developed largely by national professional organizations.²³⁹ Many states require hospitals to obtain a certificate of need (CON) in addition to a license.²⁴⁰ These state CON laws are largely a vestige of the federal Health Planning and Services Act, launched in 1966 to help states reach underserved populations.²⁴¹ As this federal program expanded, it added Health Systems Agencies to help states with planning and required participating states to have CON programs in place.²⁴²

Once health care facilities are cleared to see patients, state tort remedies and a host of access and quality regulations guide the facilities’ provision of care.²⁴³ Since the 1950s, a pastiche of Spending Clause statutes have simultaneously directed facilities’ quality management and patient access.²⁴⁴

studies/fast-facts.shtml (last visited Nov. 14, 2016) [<https://perma.cc/M9EE-CJHS>] (providing 2016 survey data showing that more than seventy percent of registered hospitals are owned by private nonprofit and for-profit entities).

235. *History – VA History*, U.S. DEP’T VETERANS AFF., http://www.va.gov/about_va/vahistory.asp (last visited Nov. 14, 2016) [<https://perma.cc/VF9U-HLPE>] (“VHA evolved from the first federal soldiers’ facility established for Civil War Veterans of the Union Army But it was World War I that brought about the establishment of the second largest system of Veterans’ hospitals.”).

236. See *Veterans Health Administration*, U.S. DEP’T OF VETERANS AFF., www.va.gov/health (last visited Nov. 14, 2016) [<https://perma.cc/G5PZ-DN3X>]; *History – VA History*, *supra* note 235; *VA History in Brief*, U.S. DEP’T VETERANS AFF., http://www.va.gov/about_va/vahistory.asp (last visited Nov. 14, 2016) [<https://perma.cc/2CH2-Z4M6>].

237. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 43.

238. John D. Blum, *A Revisionist Model of Hospital Licensure*, 2 REG. & GOVERNANCE 48, 49 (2008) (“Unlike many core areas of state health care regulation, it was not until the 1950s that hospital licensing statutes were enacted around the country.”).

239. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 43; see also Timothy Stoltzfus Jost, *Medicare and the Joint Commission on Accreditation of Health Care Organization: A Healthy Relationship?*, 57 L. & CONTEMP. PROBLEMS 15, 16–18 (1995) (“[T]he federal government accepts [privately] accredited hospitals as Medicare providers without additional direct review.”).

240. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 58.

241. *Id.* at 57–58; see 42 U.S.C. § 246 (2012).

242. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 57. When the federal program lapsed in 1986, CON programs reverted to states’ discretion, with a majority of states opting to keep the programs in place. *Id.* at 58.

243. See generally Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381 (1994); Raymond L. Hanson & Ross E. Stromberg, *Hospital Liability for Negligence*, 21 HASTINGS L.J. 1 (1969).

244. See FIELD, HEALTH CARE REGULATION, *supra* note 140, at 42–72.

Faced with a formidable lack of access to health care facilities in rural areas,²⁴⁵ Congress passed the federal Hospital Survey and Construction Act of 1946 (Hill-Burton Act) to subsidize and expand hospital construction and renovation.²⁴⁶ The breadth and impact of the program have led some to characterize Hill-Burton as the first major federal health reform statute.²⁴⁷ The federal regulatory requirements accompanying receipt of funds included provisions for providing a minimum level of indigent care, operating an emergency room, and prohibiting discrimination against patients based on race.²⁴⁸

The National Health Planning and Resource Development Act of 1974 strengthened and consolidated health system planning, requiring, retroactively, that all Hill-Burton funded facilities participate in the Medicare and Medicaid programs.²⁴⁹ The Federal Rehabilitation Act of 1973²⁵⁰ and the Americans with Disabilities Act of 1991²⁵¹ required accessible health care facilities and stipulated that a facility may not refuse to provide services based on a patient's disease or condition.²⁵² EMTALA²⁵³ required all Medicare-participating hospitals with emergency departments to screen and stabilize all patients in active labor or with emergency medical conditions—regardless of ability to pay.²⁵⁴ EMTALA created a federal private right of action against hospitals for violations, in addition to establishing regulatory fines and penalties.²⁵⁵ But any further oversight over the quality of emergency room care remains a matter of state law.²⁵⁶

The Institute of Medicine's 2000 report on preventable errors at hospitals²⁵⁷ exposed widespread quality issues and prompted both state²⁵⁸ and federal

245. *Id.* at 56.

246. Pub. L. No. 725, 60 Stat. 1040 (codified as amended at 42 U.S.C. § 291-291o (2012)).

247. *E.g.*, Guy David, *Trends in Hospital Ownership Type and Capacity: A Decomposition Analysis*, 39 NONPROFIT & VOLUNTARY SECTOR Q. 356, 356 (2010); Andrea Park Chung et al., *Subsidies and Structure: The Lasting Impact of the Hill-Burton Program on the Hospital Industry 2* (Nat'l Bureau of Econ. Research, Working Paper No. 22037, 2012) ("The Hill-Burton program remains the largest piece of federal legislation to provide subsidies for the construction of non-profit and local governmental hospitals. From July 1947 through June 1971, \$28 billion in funds were distributed for the construction and modernization of health care institutions.").

248. *See* FIELD, HEALTH CARE REGULATION, *supra* note 140, at 56–57.

249. National Health Planning and Resources Development Act of 1974, 42 U.S.C. §§ 300k, 300l-1 (2012); *Cnty. Psychiatric Ctrs. of Oregon, Inc. v. Grant*, 664 F.2d 1148, 1149 (9th Cir. 1981).

250. 29 U.S.C. § 701 (2012).

251. 42 U.S.C. § 12101 (2012).

252. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 62–63.

253. 42 U.S.C. § 1395dd (2012).

254. *Id.*; *Gatewood v. Wash. Healthcare Corp.*, 933 F.2d 1037, 1040 (D.C. Cir. 1991); *see* David A. Hyman, *Patient Dumping and EMTALA: Past Imperfect/Future Shock*, 8 HEALTH MATRIX 29, 32–44 (1998).

255. 42 U.S.C. § 1395dd(d)(2).

256. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 55 ("Direct oversight . . . remains the province of state regulators and private accreditors.").

257. INSTITUTE OF MEDICINE, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000).

258. *E.g.*, Medical Care Availability and Reduction of Error (MCARE) Act, 2002 Pa. Legis.

regulations²⁵⁹ aimed at reducing medical errors. Medicare and Medicaid reimbursement criteria also include quality-related regulations.²⁶⁰ Numerous other laws also play vital roles in facility regulation, but they apply only indirectly to health care and have not been treated as *health law* by courts.²⁶¹

Regulation of both providers and facilities follows a basic model aptly described by Field as “regulation by the states with national coordination.”²⁶² But the “national coordination” through Spending Clause legislation has outpaced state regulation in the past fifty years.²⁶³ Ubiquitous Spending Clause regulation of providers and facilities dictates the patients they treat, the services they offer, and the way providers and facilities are paid.²⁶⁴ While state claims have supplied the primary remedies for injuries caused by providers and facilities,²⁶⁵ federal causes of action regarding quality and access have supplemented and complicated the remedial landscape.²⁶⁶

The federal laws that apply to providers and facilities through their (at least nominally) voluntary participation in federal programs (Medicare and Medicaid) rarely preempt state law.²⁶⁷ But Medicare and Medicaid laws do preempt in

Serv. 4 (West) (codified as amended at 40 PA. STAT. AND CONS. STAT. ANN. §1303.301 (West 2016)) (“ensuring patient safety” through Pennsylvania’s statutorily mandated hospital error-reporting system).

259. *E.g.*, Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, § 2(a)(5), 119 Stat. 424 (codified at 42 U.S.C. § 229b-23 (2012)) (requiring reporting of patient safety information to federal databases, quality assessment, and improvement programs as prerequisites for Medicare participation).

260. *See Quality Initiatives – General Information*, CTRS. FOR MEDICARE & MEDICAID SRVS. (Feb. 8, 2016, 3:08 PM), <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/index.html> [<https://perma.cc/7RE5-BMQQ>].

261. Ancillary laws include state and federal antitrust laws, state and federal tax laws for tax-exempt organizations, and state and local zoning and other land-use laws. *See generally* Field, *A Taxonomy*, *supra* note 197, at 616–17 (“Federal programs that directly regulate health care represent a relatively small portion of federal involvement in oversight of the industry.”).

262. FIELD, *HEALTH CARE REGULATION*, *supra* note 140, at 42.

263. *See* Abbe R. Gluck, *Why Health Lawyers Must Be Public-Law Lawyers: Health Law in the Age of the Modern Regulatory State*, 18 J. HEALTH CARE L. & POL’Y 323, 324 (2015) [hereinafter Gluck, *Public-Law Lawyers*] (noting that, although health law currently is more national than local, “states and the profession still have certain, localized areas of dominance (medical malpractice and licensing of practitioners being two important examples)”).

264. *See* Zettler, *Toward Coherent Federal Oversight*, *supra* note 162, at 454–64 (detailing examples of federal regulation of medical practice, including the Controlled Substances Act, Medicare and Medicaid, and Partial-Birth Abortion Ban Act).

265. *See generally* Jacobson, *The Role of ERISA*, *supra* note 221, at 89 (“Traditionally, states are responsible for regulating health care delivery, and litigation against health care providers is resolved under state law.”).

266. *See, e.g.*, Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. § 1395dd (2012).

267. *See* Rosemary B. Guiltinan, Note, *Enforcing a Critical Entitlement: Preemption Claims as an Alternative Way to Protect Medicaid Recipients’ Access to Healthcare*, 51 B.C. L. REV. 1583 (2010) (arguing that preemption may be a promising way to enforce access provisions in the future, but acknowledging that such is not the case yet); Michael J. Jackson, Jr., *Considerations in Medicare Reform: The Impact of Medicare Preemption on State Laws*, 13 ANNALS HEALTH L. 179, 214–21 (2004) (explaining the limited preemption of state law by ERISA, in terms of coverage).

other spheres of health law, as discussed in Part II.B.4.²⁶⁸ EMTALA, on the other hand, has a narrower scope; its' detailed statutory scheme disavows a broad preemptive effect²⁶⁹ and expressly ties damages to those recoverable under state law.²⁷⁰ Courts have, however, held that EMTALA preempts state procedural requirements directly conflicting with or standing as obstacles to the statutory scheme.²⁷¹

Provider and facility regulation thus originated with state and private authorities, which remain regulatory bulwarks against federal law, notwithstanding the voluntarily accepted federal Spending Clause programs. As federal funds have built and sustained a significant portion of the U.S. health care infrastructure, however, accompanying federal regulation has ascended in this traditionally state law category.

2. Public Health

Public health focuses on treating and preventing diseases population-wide,²⁷² through regulations regarding sanitation, quarantine, immunization, food safety, and disease.²⁷³ Contagion, disease, and scientific discovery do not respect state lines, though the care for individuals and discrete populations takes place within them. Federal and state regulations thus developed jointly as epidemiology-catalyzed public health efforts; most notably, the "germ theory" of disease developed in the 1860s and 70s.²⁷⁴

Public health laws were among the first health laws of any kind.²⁷⁵ Federal laws quarantined ships arriving at U.S. ports starting in the 1790s²⁷⁶ and created the United States Marine Hospital Services (MHS) in 1798 to care for ailing

268. See *infra* Part II.B.4 for a discussion of how Medicare and Medicaid, as insurance providers, preempt certain spheres of health law.

269. 42 U.S.C. § 1395dd(f) (2012) ("The provisions of this section do not preempt any State or local law requirement, except to the extent that the requirement directly conflicts with a requirement of this section."); *Bryan v. Rectors & Visitors of the Univ. of Va.*, 95 F.3d 349, 352 (4th Cir. 1996) ("EMTALA is quite clear that it is not intended to preempt state tort law except where absolutely necessary.").

270. § 1395dd(d)(2)(A).

271. See, e.g., *Merce v. Greenwood*, 348 F. Supp. 2d 1271, 1276 (D. Utah 2004) (collecting cases from the Second and Fourth Circuits and the District of Colorado, on notice-of-claim, statutes of limitations, and tolling provisions).

272. See FIELD, HEALTH CARE REGULATION, *supra* note 140, at 141 ("In its earliest form, health care regulation in America addressed widespread threats to the public at large.").

273. Cf. LAWRENCE O. GOSTIN & PETER D. JACOBSON, LAW AND THE HEALTH SYSTEM 1 (2006) ("We believe that the separation between health care and public health is exaggerated and that personal and population-based services are interconnected.").

274. See WILLRICH, *supra* note 151, at 34–35 ("From these new understandings of the etiology of infectious diseases arose new strategies for policing them.").

275. See GOSTIN & JACOBSON, *supra* note 273, at 12 ("Public health has deep historical, constitutional, and theoretical relationships to government."); see generally LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW AND ETHICS: A READER (2002).

276. M.S. Morgenstern, *The Role of the Federal Government in Protecting Citizens from Communicable Diseases*, 47 U. CIN. L. REV. 537, 541 (1978).

seamen.²⁷⁷ States also exercised some power over sanitation and established their own health agencies as early as 1855,²⁷⁸ to which the MHS contributed “money and manpower.”²⁷⁹ Before germ theory, however, state and federal efforts had limited effect.²⁸⁰

Germ theory, coupled with immigration in the later 1800s, led to increased reliance on the MHS and creation of the U.S. Public Health Service Commissioned Corps in 1889.²⁸¹ At the turn of the twentieth century, the federal government took the lead in promoting research, setting national policy, and funding state efforts in furtherance of scientific knowledge.²⁸²

States had controlled inspection of agricultural products within their borders since the early 1800s.²⁸³ But with the 1906 Pure Food and Drug Act, Congress intervened to prevent disease in food products shipped in interstate commerce.²⁸⁴ This extension of federal sanitation authority through the Commerce Clause launched an enormously influential chapter in federal regulation, discussed in Part II.B.3.²⁸⁵

A powerful national public health regulatory apparatus and infrastructure developed over time. In 1912, Congress expanded the MHS’s responsibilities and renamed it the Public Health Service (PHS).²⁸⁶ By 1944, Congress had reorganized the expanded PHS into the Office of the Surgeon General, the Bureau of Medical Services, the Bureau of State Services, and the National Institutes of Health (NIH).²⁸⁷ In 1946, the Communicable Disease Center was established in Atlanta, “form[ing] the hub around which public health regulation in America revolves.”²⁸⁸

Other federal agencies administer major public health initiatives, too, such as the United States Department of Agriculture’s (USDA) Supplemental Nutrition Assistance Program, which originated in the federal Food Stamp Act of 1964.²⁸⁹ Numerous other laws fall at the fringes of health law’s ambit, as they regulate social or environmental determinants of public health—for example, environmental laws.²⁹⁰ But each of these regulatory topics has a distinct

277. GOSTIN & JACOBSON, *supra* note 273 at 13.

278. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 142–43.

279. *Id.*

280. *Id.*

281. *Id.* at 143–44; *see also* STARR, *supra* note 199, at 186–97.

282. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 143–44.

283. *See id.* at 144.

284. *See infra* Part II.B.3 for a discussion of federal regulation of food traveling in interstate commerce to prevent transmission of diseases.

285. *See infra* Part II.B.3 for a discussion of the development of federal regulation of food, medical products, and other items of consumption.

286. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 143.

287. *Id.* at 146, 152.

288. *Id.* at 152.

289. *See A Short History of SNAP*, U.S. DEP’T AGRIC. FOOD & NUTRITION SERV (Nov. 20, 2014), <http://www.fns.usda.gov/snap/short-history-snap> [<https://perma.cc/NG8W-596Q>].

290. *See, e.g.*, Clean Air Act, 42 U.S.C. § 7401 (2012); Clean Water Act, 33 U.S.C. § 1251 (2012);

jurisprudence (like land use or employment law) that courts have not qualified as health law.²⁹¹

Regulatory interactions in public health law are “particularly complex.”²⁹² The federal government sets policy, funds innovation, and protects national security. Local governments carry out the day-to-day functions, with coordination from state and federal authorities.²⁹³ With communicable disease, for example, private companies produce vaccines, but the federal government contributes to the underlying research and regulates the resulting products, from safety, to supply, to remedy for injuries.²⁹⁴ State laws require vaccination, while local authorities enforce and implement those requirements.²⁹⁵

In sum, public health law involves significant federal funding and priorities, while reserving important flexibility, control, and implementation roles for state and municipal authorities.

3. Food, Drugs, and Medical Devices

Born of public health concerns and known at the turn of the twentieth century as “sanitary legislation” under state police powers, the “sanitary power” extended to “foodstuffs” and “other articles of consumption, . . . especially drugs and medicines, and candies and confections,” as well as tobacco, alcohol, and now medical devices—essentially anything meant to be ingested or used in medical treatment.²⁹⁶ Again, state tort and contract law long have supplied the *remedy* for anyone injured by food or medical products.²⁹⁷ But the *prevention* of injury through safety, efficacy, and marketing regulations has a substantial history of federal power.

At first, public health efforts addressed food regulation to eradicate

Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 (2012).

291. See, e.g., *Rapanos v. United States*, 547 U.S. 715, 738 (2006) (classifying the Clean Water Act as within “the States’ traditional and primary power over land and water use” (quoting *Solid Waste Agency v. U.S. Army Corps of Eng’rs.*, 531 U.S. 159, 174 (2001))).

292. Field, *A Taxonomy*, *supra* note 197, at 614–15 (classifying public health as within the “state primacy” paradigm, with some ambivalence); see also Galva, *supra* note 137, at 21–22; Jean C. O’Connor et al., *Preemption of Local Smoke-Free Air Ordinances: The Implications of Judicial Opinions for Meeting National Health Objectives*, 36 J. L., MED. & ETHICS 403, 404–07 (2008); Pertschuk et al., *supra* note 1, at 213–14.

293. See FIELD, *HEALTH CARE REGULATION*, *supra* note 140, at 145, 164–65 tbl.6.5 (explaining that federal grants provide the majority of public health funding). *But see* Hodge, *supra* note 173, at 331 (characterizing the federal role in public health before the New Deal as “limited”).

294. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-2 (2012).

295. See, e.g., OHIO REV. CODE ANN. § 3313.67 (West 2016).

296. FREUND, *supra* note 140, at 119–21 (noting that “Tennessee has gone so far as to prohibit the sale of cigarettes,” but that in the regulation of tobacco and alcohol, “other than purely sanitary considerations come into play”).

297. See Zettler, *Toward Coherent Federal Oversight*, *supra* note 162, at 427 (“The conventional wisdom . . . holds that states regulate medical practice . . . while the federal government regulates medical products.”); *id.* at 452 (“[M]edical malpractice liability—a creature of state law—provides a mechanism for private enforcement of medical practice standards.”).

contagion. States inspected agricultural products as early as 1819.²⁹⁸ President Lincoln formalized federal agricultural inspection by establishing the United States Department of Agriculture (USDA) in 1862.²⁹⁹ The simultaneous rise of germ theory and interstate transportation of agricultural products and livestock in the late 1800s led the USDA to call repeatedly for federal legislation to control diseases spread through food.³⁰⁰ Beginning in this period, many states enacted laws regulating the safety and purity of food and drugs.³⁰¹ And while Congress had passed limited efforts beforehand,³⁰² full-scale federal regulation arrived in 1906 with passage of the Pure Food and Drug Act and the Federal Meat Inspection Act,³⁰³ prompted by Upton Sinclair's exposé of the domestic meat packing industry's filthy conditions in his 1906 novel, *The Jungle*.³⁰⁴ Federal regulatory reach over food has consistently expanded since 1862,³⁰⁵ resulting in a web of protective federal legislation on food safety, labeling, and quality standards.³⁰⁶

Drug regulation followed a similar trajectory of federal power. As Justice Breyer observed, "[t]he pharmaceutical drug industry has been heavily regulated" by federal statute "at least since 1906," resulting in "a traditional, comprehensive regulatory regime."³⁰⁷ As early as 1848, Congress prohibited the import of adulterated drugs³⁰⁸ and soon thereafter established the functional predecessor to the Food and Drug Administration (FDA).³⁰⁹ In the early twentieth century, Congress expanded the federal regulatory scheme,³¹⁰ establishing the modern drug approval process and broadening the FDA's authority to carry it out with the 1938 Federal Food, Drug, and Cosmetic Act

298. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 144 (noting efforts as early as 1819 by New York, Massachusetts, and Georgia).

299. See *FSIS History*, U.S. DEP'T AGRIC. FOOD SAFETY & INSPECTION SERV. (Mar. 24, 2015), <http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/history> [<https://perma.cc/453W-HNR7>].

300. See FIELD, HEALTH CARE REGULATION, *supra* note 140, at 144–45.

301. See Salthe, *supra* note 32, at 167–74.

302. See *FSIS History*, *supra* note 299 (describing the regulations in 1865, 1884, and 1890 relating to quarantine and removal of diseased animals and imported meat).

303. Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938); Federal Meat Inspection Act, 21 U.S.C. § 601 (2012). See generally C. C. Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 LAW & CONTEMP. PROB. 3 (1933) (noting the breadth of the 1906 Act).

304. Regier, *supra* note 303, at 9; see also *FSIS History*, *supra* note 299.

305. See, e.g., Egg Products Inspection Act, 21 U.S.C. § 1031 (2012); Poultry Products Inspection Act, 21 U.S.C. § 451 (2012).

306. See FOOD AND DRUG ADMINISTRATION, INVESTIGATIONS OPERATIONS MANUAL 104 ex. 3-1 (2016) (summarizing overlapping and distinct areas of food jurisdiction between federal agencies).

307. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 586 (2011) (Breyer, J., dissenting) (citing the Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938) and *United States v. United Foods*, 533 U.S. 405, 411 (2001)).

308. Drug Importation Act of 1848, ch. 70, 9 Stat. 237; see *Significant Dates in Food and Drug Law History*, *supra* note 169.

309. See *Significant Dates in Food and Drug Law History*, *supra* note 169.

310. See generally Regier, *supra* note 303, at 1.

(FDCA).³¹¹ Many states, in turn, have incorporated the federal standards into their own laws³¹² or adopted a parallel state version of the FDCA.³¹³

Over the course of the twentieth century, federal law “insinuated itself into almost every aspect” of the pharmaceutical industry³¹⁴—funding research through the NIH,³¹⁵ providing tax incentives,³¹⁶ protecting innovations with patents,³¹⁷ building confidence through the FDA approval process,³¹⁸ encouraging generics with eased approval processes,³¹⁹ and buying the largest share of the end products through Medicare, Medicaid, and other government insurance programs.³²⁰ The FDA oversees the testing, approval, labeling, and marketing of drugs, devices, radiation-emitting products, vaccines, blood, biologics, animal and veterinary food, drugs, cosmetics, tobacco products, and supplements.³²¹

Federal regulation of food and drugs (and other products) has therefore been a dominant part of the regulatory tradition for over a century.³²² State and local regulations, for their part, continue to implement and supplement

311. Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 301-399d (2012)). See generally David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 LAW & CONTEMP. PROB. 2 (1939) (detailing the political and social climate that led to the passage of the FDCA).

312. See Salthe, *supra* note 32, at 168–70, 173–74 (detailing state reactions to the 1906 and 1938 enactments). See, e.g., COLO. CODE REGS. § 1010-2:3-101 (2016) (incorporating federal regulations on food additives); CAL. HEALTH & SAFETY CODE § 111245 (West 2016) (incorporating federal device performance standards).

313. See Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. (forthcoming 2017) (manuscript at 19–20) [hereinafter Zettler, *Pharmaceutical Federalism*] (detailing the state regulatory efforts and the adoption of the Uniform State Food, Drug, and Cosmetic Act, paralleling federal requirements).

314. Robert I. Field, *How the Government Created and Sustains the Private Pharmaceutical Industry*, 6 ST. LOUIS U. J. HEALTH L. & POL’Y 11, 68 (2012) [hereinafter Field, *Private Pharmaceutical Industry*]; accord *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (starting with the 1906 act, “the Federal Government has played an increasingly significant role in the protection of the health of our people”).

315. Field, *Private Pharmaceutical Industry*, *supra* note 314, at 17–18.

316. *Id.* at 46–47.

317. *Id.* at 47–48.

318. *Id.* at 38.

319. *Id.* at 43–44.

320. *Id.* at 12–23.

321. See 21 U.S.C. § 393(a)–(b) (2012) (establishing the FDA’s oversight of regulated products). In 2013, federal regulations reached a last bastion of state authority: compounding pharmacies. Drug Quality and Security Act, Pub. L. No. 113-54, § 102(b), 127 Stat. 587 (2013) (codified at 21 U.S.C. § 353a-1 (2012)) (imposing on the FDA new inspection and regulation responsibilities over compounding pharmacies).

Intellectual property law exerts considerable influence over drug and device law and policy, and intellectual property has been heavily federal since its inception. Because intellectual property is ancillary to and does not directly address health, I have not included it in the tradition history here.

322. See Field, *A Taxonomy*, *supra* note 197, at 615–16 (describing food and drug safety as within the “federal primacy” paradigm).

foundational federal policies.³²³ Further, state and local power over food handling, restaurant standards, and remedies for injuries still predominate. State and local regulations also serve a vital role as policy laboratories for consumption and nutrition regulation.³²⁴

The comprehensive federal food and drug statutes have prompted numerous preemption questions.³²⁵ Several statutes have explicitly addressed preemption and intentionally displaced state laws in favor of national uniformity. The Medical Device Amendments to the FDCA, for example, explicitly established a forceful federal preemption for device regulation.³²⁶ And the National Childhood Vaccine Injury Act of 1986 established a federal regime for administering remedies for vaccine injuries that almost completely preempts state claim procedures.³²⁷

The FDCA, by contrast, did not create a federal private right of action or explicitly address preemption,³²⁸ and state remedies for injuries caused by tobacco and drugs—the primary remedies for injured consumers—have fared somewhat better against preemption.³²⁹ The “clash” between the “presumption against preemption in areas of traditional state purview” and the “mandatory

323. See Zettler, *Pharmaceutical Federalism*, *supra* note 313, (manuscript at 20) (“[T]hese [traditional] state schemes ultimately represent efforts to complement or amplify the reach of the FDA’s requirements.”); cf. Lars Noah, *State Affronts to Federal Primacy in Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 53 (2016) (“In certain circumstances, states may enjoy the authority to prohibit the sale of an FDA-approved pharmaceutical.”).

324. See, e.g., U.S. DEP’T OF AGRIC., SCIENTIFIC REPORT OF THE 2015 DIETARY GUIDELINES ADVISORY COMMITTEE, pt. D, ch. 4, at 7 (Feb. 2015) (stating that public health action to limit sugar-sweetened beverage consumption “is needed across all levels—Federal, state, and local—to create private-public partnerships and business models”); cf. Madison, *supra* note 130, at 776–84 (identifying ways in which the state laboratory model falls short of its policy potential).

325. See Zettler, *Pharmaceutical Federalism*, *supra* note 313, (manuscript at 20–50) (detailing FDA preemption of products liability claims, as well as numerous other state regulatory efforts).

326. 21 U.S.C. § 360k (2012) (expressly preempting state and local laws “relat[ing] to the safety or effectiveness of [a] device” regulated by the FDA “which is different from, or in addition to, any [FDCA] requirement”); see *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 343–44 (2001) (preempting injury claims based on allegations of fraud in the approval process); *Bates v. Dow Agrosiences LLC*, 544 U.S. 431, 444 (2005) (holding that the Federal Insecticide, Fungicide, and Rodenticide Act similarly did not preempt state law fraud, breach of warranty, and deceptive trade practices claims).

327. 42 U.S.C. §§ 300aa-1–300aa-34 (2012); see *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (holding that the Vaccine Act’s remedial scheme preempted state design defect claims); Catherine M. Sharkey, *Against Categorical Preemption: Vaccines and the Compensation Piece of the Preemption Puzzle*, 61 DEPAUL L. REV. 643, 644–45 (2012) (“[This Act] is the rare example whereby Congress provides for a federally administered compensation fund alongside its newly fashioned regulatory standards”).

328. *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 817 (1986) (stating that the FDCA does not create a private right of action expressly or impliedly). See generally Richard B. Stewart & Cass R. Sunstein, *Public Programs and Private Rights*, 95 HARV. L. REV. 1193, 1208–09 (1982) (explaining the circumstances under which private rights of action may be available).

329. See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 555 (2009) (holding claims against FDA-approved brand-name drug not preempted); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518–20 (1992) (holding that a mandatory federal Surgeon General’s warning did not preempt state law tobacco injury claim).

Chevron deference accorded to agency interpretations of ambiguous statutes,” like the FDCA, has roiled state and federal courts for years.³³⁰ Recently, additions to the FDCA approval process for generic drugs were held to preempt certain state law claims about the adequacy of warnings,³³¹ prompting Congress to consider but not enact legislative revisions to restore state remedies.³³² While a few states recently have passed distinctive drug regulation measures, they have not altered the baseline FDA regulatory requirements and remain subject to the FDCA’s well-established preemption.³³³

Regulation of medical products is thus heavily and historically federal, with an enormous, specially-devoted federal agency. State tort law continues to provide the primary remedy for injuries incurred under this regime, though federal law has encroached on the remedial power as well.

4. Insurance, Finance, and Access

Compared against provider regulation, public health regulation, and food and drug regulation, health insurance regulation seems like a fairly recent phenomenon because health insurance itself did not exist until the twentieth century.³³⁴ The business of insurance, generally, was entrusted to the states. While state police powers extended to health care well before the existence of insurance, in 1945, the federal McCarran-Ferguson Act expressly assigned to states the primary responsibility for regulating insurance.³³⁵ Acceleration in the cost and complexity of health care in the past century has spawned numerous state regulations, as well as federal Spending Clause programs to finance coverage and Commerce Clause programs to regulate it.³³⁶ State regulation of insurance may be historically *primary*, but federal regulation has become increasingly formidable.

States were first to regulate the rates of doctors and hospitals, and general rate regulation power remains within state and local control.³³⁷ But long gone

330. Catherine M. Sharkey, *Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts*, 15 J. L. & POL’Y 1013, 1019–20 (2007) [hereinafter Sharkey, *Federalism in Action*].

331. See, e.g., *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013) (holding that design defect claims about warnings against generic drug were preempted); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 604 (2011) (holding that failure-to-warn claims against generic drug were preempted); see also Katie Thomas, *In 5-4 Ruling, Justices Say Generic Makers Are Not Liable for Design of Drugs*, N.Y. TIMES (June 24, 2013), http://www.nytimes.com/2013/06/25/business/justices-rule-generic-makers-not-liable-for-drugs-design.html?_r=0 [https://perma.cc/J47W-MRZ3] (providing a brief discussion of the practical effects of these cases).

332. Patient Safety and Generic Labeling Improvement Act, S. 2295, 112th Cong. (2012).

333. See Zettler, *Pharmaceutical Federalism*, *supra* note 313 (manuscript at 55–58) (offering examples of recent state legislation and a critique of its “limited legal or practical impact”).

334. See FIELD, HEALTH CARE REGULATION, *supra* note 140, at 75 (“Regulatory attention to the financing of health care is a fairly recent phenomenon.”).

335. See *id.* at 74–85; McCarran-Ferguson Act, 15 U.S.C. §§ 1011–1015 (2012).

336. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 74–85.

337. *Id.* at 60; see, e.g., *Mass. Med. Soc’y v. Dukakis*, 815 F.2d 790, 790, 791–92 (1st Cir. 1987) (holding that the Medicare Act did not preempt a state law prohibiting balance billing).

are the days when a patient could afford to pay providers' rates with a few chickens or cash on hand.³³⁸ After World War II, the cost of medical treatment quickly outpaced inflation and necessitated third-party financing.³³⁹ Private health insurance, as well as government payment systems, brought insurance, finance, and access to the forefront of modern health law.

Since the 1960s, Americans have relied almost entirely on charity or third-party financing to pay for and guarantee access to health care.³⁴⁰ The content, source, and balance of insurance regulation varies whether the source is commercial health insurance (purchased by individuals or provided by employers as a benefit) or government health insurance (Medicare, Medicaid, and other programs).³⁴¹ Immediately prior to the ACA, "[e]mployer-sponsored insurance [was] the leading source of health insurance in America," and it remains so today.³⁴²

Commercial health insurance. Since the 1850s, states have been the primary regulators of insurance; therefore, they have supplied most laws governing private health insurance.³⁴³ Insurers did not cover health care, however, until after 1908.³⁴⁴ The first two categories of true health insurance sprung up in the early 1930s: Groups of hospitals offered prepaid services (known as "Blue Cross" model plans), and groups of physicians offered similar arrangements (known as "Blue Shield" plans).³⁴⁵ Health insurance policies were rare until after World War II, when they became ubiquitous and largely employer-sponsored because insurance offered as an employee fringe benefit was exempt from the wartime wage and price controls.³⁴⁶

338. See STARR, *supra* note 199; Moseley, *supra* note 199.

339. See VICTOR R. FUCHS, *THE HEALTH ECONOMY* 331–32 (1986). Worker's compensation systems, however, were instituted by states in the early 1900s. See FIELD, *HEALTH CARE REGULATION*, *supra* note 140, at 75–76. By setting aside funds to pay for on-the-job injuries, these programs were early forms of health insurance. See *id.*

340. See Alain C. Enthoven & Victor R. Fuchs, *Employment-Based Health Insurance: Past, Present, and Future*, 25 *HEALTH AFF.* 1538, 1539 (2006).

341. See GOSTIN, *PUBLIC HEALTH LAW*, *supra* note 140, at 345–49 (discussing the various regulatory systems in place for commercial and government health insurance).

342. KAISER FAMILY FOUND. & HEALTH RESEARCH & EDUC. TR., *EMPLOYER HEALTH BENEFITS: 2012 ANNUAL SURVEY 1* (2012), <http://kff.org/private-insurance/report/employer-health-benefits-2012-annual-survey/> [<https://perma.cc/K7PN-WS7T>]; accord MARK A. HALL ET AL., *THE LAW OF HEALTH CARE FINANCE AND REGULATION* 55 (3d ed. 2013) [hereinafter HALL ET AL., *THE LAW OF HEALTH CARE*] (stating that prior to the ACA, fifty-one percent of Americans had employer-sponsored health insurance, twenty-eight percent were covered by a government program, five percent bought commercial policies individually, and sixteen percent had no insurance).

343. See Jay Conison, *ERISA and the Language of Preemption*, 72 *WASH. U. L.Q.* 619, 644 (1994) ("[B]efore ERISA, state law was viewed as the primary source of standards for plans."); Jacobson, *The Role of ERISA*, *supra* note 221, at 89 (2009); Elizabeth Weeks Leonard, *The Rhetoric Hits the Road: State Challenges to the Affordable Care Act Implementation*, 46 *U. RICH. L. REV.* 781, 803 (2012) ("[H]ealth insurance regulation has long been the primary domain of states.").

344. Moseley, *supra* note 199.

345. See FIELD, *HEALTH CARE REGULATION*, *supra* note 140, at 76–77; Moseley, *supra* note 199, at 325.

346. See FIELD, *HEALTH CARE REGULATION*, *supra*, note 140, at 77–78; see also Enthoven &

Over their roughly 150 years of insurance regulation, states have both exercised licensing authority over insurers and have regulated issuance of policies.³⁴⁷ Since 1945 with the passage of the McCarran-Ferguson Act,³⁴⁸ some state insurance regulation has enjoyed a form of reverse preemption in which state insurance law is supreme to federal law.³⁴⁹ The Health Maintenance Organization Act of 1973³⁵⁰ “marked the first time that Congress created a direct federal role in the regulation of health insurance;” the legislation was “designed to supplement, rather than replace . . . state functions” through federal funding and qualifications.³⁵¹

State health insurance regulation thus can quite accurately be described as “primary” from its inception. The federal government, however, unintentionally assumed a major role with the passage of the ERISA³⁵² in 1974. Although passed primarily with pension benefits in mind, ERISA applies to all employer-sponsored benefits, which has come to include health insurance. ERISA’s original purposes were to safeguard employees’ pensions and to encourage the provision of pension benefits by establishing a uniform system of federal regulation.³⁵³ To promote uniformity, Congress wrote into ERISA a “terse but comprehensive”³⁵⁴ provision expressly preempting state laws that “relate to” any “benefit plan[s]”³⁵⁵ covered by the Act. ERISA thus preempts vast swaths of state initiatives aimed at increasing access to employer-sponsored health insurance.³⁵⁶

ERISA’s savings clause exempts state regulation of “the business of insurance” from preemption under the statute.³⁵⁷ The difficulty of determining when state laws “relate to” employer-sponsored health insurance (and are

Fuchs, *supra* note 340, at 1539 (describing trends in the history of insurance).

347. See FIELD, HEALTH CARE REGULATION, *supra* note 140, at 80–81.

348. McCarran-Ferguson Act, 15 U.S.C. § 1011 (2012) (though the Act was passed in 1945, both the original and current versions limit regulation of insurance to the states).

349. See Alan M. Anderson, *Insurance and Antitrust Law: The McCarran-Ferguson Act and Beyond*, 25 WM. & MARY L. REV. 81, 81–82, 88–89 (1983).

350. Pub. L. No. 93-222, 87 Stat. 914 (1973) (codified as amended at 28 U.S.C. §§ 300e–300e-14a (2012)).

351. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 83, 82.

352. Pub. L. No. 93-406, 88 Stat. 829 (1974) (codified as amended at 29 U.S.C. §§ 1001–1461 (2012)).

353. In the four decades after ERISA’s passage, employer-sponsored health insurance has eclipsed pensions and 401(k)s as the most sought-after benefit provided by employers. See generally HALLET AL., THE LAW OF HEALTH CARE, *supra* note 342. But cf. Enthoven & Fuchs, *supra* note 340, at 1538–39 (tracing the overall decline in employer-sponsored insurance since the 1980s).

354. Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 943 (2016).

355. 29 U.S.C. § 1144(a) (2012).

356. *E.g.*, Pharm. Care Mgm’t. Ass’n v. District of Columbia, 613 F.3d 179, 190 (D.C. Cir. 2010) (holding that access legislation was partially preempted); Retail Indus. Leaders Ass’n v. Fielder, 475 F.3d 180, 197 (4th Cir. 2007) (holding that play or pay was preempted).

357. Ky. Ass’n of Health Plans v. Miller, 538 U.S. 329, 339 (2003); see, e.g., *id.* at 336, 341–42 (holding that “any willing provider” laws were not preempted); Pharm. Care Mgm’t. Ass’n v. Rowe, 429 F.3d 294, 301 (1st Cir. 2005) (holding that pharmacy benefit manager legislation was saved from preemption).

preempted) versus when they relate to the “business of insurance” (and are saved from preemption) has resulted in one of the most contentious preemptions in health law—perhaps in any law, period.³⁵⁸ As the Supreme Court has noted in ERISA contexts, health insurance is a “field[] of traditional state regulation,” and Congress must not have intended ERISA to “displace general health care regulation, which historically has been a matter of local concern.”³⁵⁹ By that logic, the Supreme Court held that ERISA does not preempt a state statute requiring hospitals to collect a surcharge from commercial insurers, despite the impact on employer-sponsored insurance.³⁶⁰ On the other hand, the Court has held that ERISA does preempt state law *remedies* for health insurers’ faulty eligibility and coverage decisions, despite state law’s traditional role in supplying remedies.³⁶¹

ERISA preemption remains a very live issue. This past term, the Supreme Court decided *Gobeille*, in which state efforts to collect health insurance data for public health programming collided with ERISA preemption, as applied to a subspecies of employer-sponsored health benefits.³⁶² Vermont enacted a law requiring all health insurance claims processors to submit data to the state’s “all-payer claims database,” for use in assessing population health needs.³⁶³ Although the State argued that its data collection was “classic health care regulation” and beyond ERISA’s preemptive sweep,³⁶⁴ the Court held, 6–2, that ERISA preempted the Vermont law.³⁶⁵ While the decision has imperiled state efforts at transparency and data collection,³⁶⁶ commentators have speculated that it could spur state and federal government agencies to coordinate and consolidate their data collection.³⁶⁷

358. See *supra* Part II.A.2 for a discussion of federal health law regulation.

359. N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655, 661 (1995).

360. See *id.* at 668.

361. Aetna Health Inc. v. Davila, 542 U.S. 200, 214 (2004); cf. Pegram v. Herdrich, 530 U.S. 211, 231 (2000) (holding that medical malpractice claims against managed care organizations challenging conflicted determinations of medical necessity may not be preempted).

362. *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 940–43 (2016).

363. *Id.* at 940–41.

364. Transcript of Oral Argument at 6, 9, 11, 20, *Gobeille v. Liberty Mutual Insurance Co.*, 136 S. Ct. 936 (No. 14-181).

365. *Gobeille*, 136 S. Ct. at 947 (“ERISA’s express pre-emption clause requires invalidation of the Vermont reporting statute.”).

366. See, e.g., Erin Fuse Brown & Jaime King, *The Consequences of Gobeille v. Liberty Mutual for Health Care Cost Control*, HEALTH AFF. BLOG (Mar. 10, 2016), <http://healthaffairs.org/blog/2016/03/10/the-consequences-of-gobeille-v-liberty-mutual-for-health-care-cost-control/> [https://perma.cc/7BZB-ASRZ].

367. See, e.g., David Newman, *After Gobeille: Can Federal Regulators Save All-Payer Claims Databases?*, HEALTH AFF. BLOG (March 10, 2016), <http://healthaffairs.org/blog/2016/03/10/after-gobeille-can-federal-regulators-save-all-payer-claims-databases/> [https://perma.cc/PR32-CGAA]; William Sage, *Out of Many, One: ERISA Preemption, State All-Payer Claims Database Laws, And The Goals of Transparency*, HEALTH AFF. BLOG (March 10, 2016), <http://healthaffairs.org/blog/2016/03/10/out-of-many-one-erisa-preemption-state-all-payer-claims-database-laws-and-the-goals-of-transparency/> [https://perma.cc/3MH9-MT9K].

The content of commercial health insurance policies is primarily regulated by state law. Even after ERISA, states could still, for example, set coverage minimums. Yet, even before the ACA, federal laws had added preemptive bits and pieces to states' coverage and eligibility regulations by prohibiting discrimination based on race, religion, national origin, and disability,³⁶⁸ requiring extension after separating from employment,³⁶⁹ requiring some coverage for mental health,³⁷⁰ pediatric vaccines,³⁷¹ childbirth,³⁷² and specific treatments, as well as restricting the use of preexisting condition limitations in employment-based plans.³⁷³ To this patchwork, the ACA added a definitive set of federal coverage and eligibility provisions, regulations on the business of commercial health insurers, reforms to the insurance markets, as well as mandates for certain employers to provide insurance and for all individuals to have it.³⁷⁴ While states long enjoyed the prime spot in commercial health insurance regulation, the ACA era promises to rebalance the relationship.³⁷⁵

Government insurance programs. Commercial insurance covers a majority of the population, yet public insurance programs cover a majority of America's health care expenditures.³⁷⁶ In the early years of the Republic, the federal government directly funded certain aspects of health care, and after the Civil War, it served discrete populations of seamen and soldiers.³⁷⁷ In the first half of the twentieth century, federal legislation provided health coverage for the Department of Defense and veterans,³⁷⁸ established what became known as the

368. *E.g.*, Americans with Disabilities Act, 42 U.S.C. § 12112(a) (2012); Civil Rights Act of 1964, 42 U.S.C. §§ 2000d–2000d-7 (2012)).

369. Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985, 29 U.S.C. § 1161 (2012)).

370. Mental Health Parity Act of 1996, 29 U.S.C. § 1185a (2012).

371. 29 U.S.C. § 1169(d) (2012).

372. 29 U.S.C. § 1185 (2012).

373. Health Insurance Portability and Accountability Act (HIPPA) of 1996, 29 U.S.C. § 1181 (2012); 29 U.S.C. § 1185b (2012).

374. *See generally* *Summary of the Affordable Care Act*, KAISER FAMILY FOUND. (Apr. 25, 2013), <http://kff.org/health-reform/fact-sheet/summary-of-the-affordable-care-act/> [<https://perma.cc/Z8ZQ-BT4X>].

375. *But see* Sara Rosenbaum, *Can This Marriage Be Saved? Federalism and the Future of U.S. Health Policy Under the Affordable Care Act*, 15 MINN. J. L. SCI. & TECH. 167, 173 (2014) (“In many respects, the basic approach to the regulation of health insurance in the United States remains undisturbed under the Act.”).

376. GOSTIN & JACOBSON, *supra* note 273, at 334; Nicole Huberfeld, *Federalizing Medicaid*, 14 U. PA. J. CONST. L. 431, 473–76 (2011) [hereinafter Huberfeld, *Federalizing Medicaid*] (detailing ways in which the federal government contributes to a “large portion” of health care expenditures); Abigail R. Moncrieff, *Federalization Snowballs: The Need for National Action in Medical Malpractice Reform*, 109 COLUM. L. REV. 844, 861–62 (2009) (estimating the federal government's share of national health care expenditures at around forty percent).

377. *E.g.*, An Act for the Relief of Sick and Disabled Seamen, ch. 77, 1 Stat. 605 (1798).

378. Pub. L. No. 85-961, § 1(25)(B), 72 Stat. 1447 (1956) (codified as amended at 10 U.S.C. § 1077(a) (2012)); *see also* 10 U.S.C. §§ 1071-1110b (providing for health care of uniformed military members and dependents); 32 C.F.R. § 199.1 (detailing scope of applicability for the coverage program).

Indian Health Service, providing health care for Native Americans;³⁷⁹ provided federal grant funding for state-coordinated maternal and pediatric health care services;³⁸⁰ and expanded access by funding hospital construction.³⁸¹ Then, in the 1960s and 1970s, Congress enacted the first widespread federal health insurance programs, Medicare and Medicaid.³⁸²

As described in Part II.A.2, these Spending Clause statutes created voluntary programs with federal funding conditioned on acceptance of federal regulation and oversight of everything from rates to ownership to coordination of care.³⁸³ Submission to federal regulatory authority is theoretically a choice for providers, hospitals, and states, though Medicare and Medicaid contribute heavily to such entities' bottom lines. As conceived in 1965, Medicare was established as a federal program to cover elderly and disabled patients, and Medicaid was an income-based program to cover patients with disabilities, pregnant women, dependent children, and parents of young children.³⁸⁴ Medicaid has expanded more generally to the poor under the ACA,³⁸⁵ and the coverage and reimbursement methods for both programs are now followed by many private insurers.³⁸⁶

These federal programs—Medicare as a federal program and Medicaid as a federal-state partnership implemented by all fifty states—compliment rather than conflict with state law because “the two governments are pursuing ‘common purposes.’”³⁸⁷ This partnership model has given the presumption against preemption for these regulatory programs “special force.”³⁸⁸

Charity care. Charity care insures the remainder of the population not covered by commercial insurance or a Spending Clause program even after implementation of the ACA. State and federal laws providing tax-exempt status for facilities require or encourage them to provide free care or community

379. Snyder Act, ch. 115, 42 Stat. 208 (1921) (codified as amended at 25 U.S.C. § 13 (2012)).

380. Sheppard-Towner Maternity and Infancy Act, ch. 135, 42 Stat. 224 (1921); see Hodge, *supra* note 173, at 332 (discussing the passage of this act).

381. See *supra* Part II.B.1 for a discussion of the Hill-Burton Act.

382. See Wendy E. Parmet, *After September 11: Rethinking Public Health Federalism*, 30 J. L. MED & ETHICS, 201, 203 (2002).

383. See *supra* Part II.A.2 for a discussion of federal spending powers.

384. See generally Nicole Huberfeld et al., *Plunging into Endless Difficulties: Medicaid and Coercion in National Federation of Independent Business v. Sebelius*, 93 B.U. L. REV. 1, 13–20 (2013) [hereinafter Huberfeld et al., *Plunging into Endless Difficulties*].

385. See Huberfeld, *The Universality of Medicaid*, *supra* note 208, at 69 (discussing the impact of the ACA Medicaid expansion and universality principle).

386. See Jeffrey Clemens & Joshua D. Gottlieb, *In The Shadow Of A Giant: Medicare's Influence On Private Physician Payments* 2, 17 (Nat'l Bureau of Econ. Research, Working Paper No. 19503, 2015) (demonstrating that Medicare pricing and coverage influence the same decisions of private insurers).

387. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666 (2003) (quoting *N.Y. State Dep't of Soc. Servs. V. Dublino*, 413 U.S. 405, 421 (1973)).

388. *Id.* (citing *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715–718 (1985)). But see Jacksonis, *supra* note 267, at 180 (noting the impact of federal preemption provisions on state legislatures).

benefits.³⁸⁹ EMTALA requires emergency screening and stabilization for all patients at Medicare hospital emergency departments, regardless of ability to pay,³⁹⁰ and Medicare's "disproportionate share" payments compensate those "safety-net" hospitals that render more charity care.³⁹¹

In sum, while states exhibit primacy over health insurance regulation, the federal government has implemented some level of regulation and coverage practically since health insurance's inception.

5. Information and Privacy

Health information historically has garnered unique protections. State medical practice acts commonly require doctors to maintain confidentiality.³⁹² These statutory duties are enforced through actions including breach of contract, malpractice, and negligence. Further, states' common law privacy protections frequently treat doctors as fiduciaries with duties of confidentiality.³⁹³

Protections for health information thus have been the subject of state law. But the tradition was one of litigation through transsubstantive remedies, rather than targeted health regulation. With the rise of health insurance and computing, unfathomable volumes of health data have catapulted health information and privacy into the health law sphere.³⁹⁴ The state duty of confidentiality has become "antiquated" because "[c]onfidentiality is predicated on the existence of a physician/patient relationship," while "[m]odern data collection is based only in small part on this relationship."³⁹⁵

389. *E.g.*, 26 U.S.C. § 501(r) (2012) (requiring 501(c)(3) organizations that operate hospital facilities to provide community health needs assessment, have financial assistance policies, limit charges in certain circumstances, and have a billing and collection policy to determine whether a patient qualifies for any federal financial assistance); *see also* Cecilia M. Jardon McGregor, *The Community Benefit Standard For Non-Profit Hospitals: Which Community, And For Whose Benefit*, 23 J. CONTEMP. HEALTH L. & POL'Y 302 (2007) (reviewing the requirements placed on tax-exempt hospitals by federal, state, and local laws).

390. Pub. L. No. 99-272, § 9121, 100 Stat. 82, 164–67 (1986) (codified as amended at 42 U.S.C. § 1395dd (2012)).

391. § 9105, 100 Stat. at 158–60 (1986) (codified as amended at 42 U.S.C. § 1395ww (2012)).

392. *See* Lawrence O. Gostin, *Health Information Privacy*, 80 CORNELL L. REV. 451, 507 (1995) (explaining that state medical practice acts "frequently contain provisions limiting unauthorized disclosures of confidential patient information").

393. *Id.* at 508–09 ("Most states recognize a common-law duty of confidentiality applying to certain health care professionals," enforced through "various theories of recovery, including invasion of privacy, breach of confidentiality, breach of implied contract, and breach of fiduciary relationship."); *see also* Isaac Buck, *Furthering the Fiduciary Metaphor: The Duty of Providers to the Payers of Medicare*, 104 CAL. L. REV. (forthcoming 2016) (arguing for fiduciary principles to be instilled into the payer-provider relationship).

394. Gostin, *Health Information Privacy*, *supra* note 392, at 457 ("[T]he 34 million annual hospital admissions and 1.2 billion physician visits could generate the equivalent of 10 billion pages of medical records."); *see also* Lawrence O. Gostin et al., *Privacy and Security of Personal Information in a New Health Care System*, 270 J. AM. MED. ASS'N 2487, 2488 (1993) (examining the privacy and security goals for collecting, storing, and using information in a new health care system and the means to achieve these goals).

395. Lawrence O. Gostin et al., *The Nationalization of Health Information Privacy Protections*,

This is precisely why Congress enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA)—upending state patchwork regulation and establishing a uniform, national, and preemptive scheme of health information privacy regulations.³⁹⁶ The Health Information Technology for Education and Clinical Health Act (HITECH), as well as additions from the ACA, have expanded federal dominance in this area. HIPAA and HITECH establish a floor of privacy protection but do not preempt state laws that offer greater patient protections.³⁹⁷

In *Gobeille*, the Supreme Court examined whether insurance regulation through ERISA preempted a state health data collection statute.³⁹⁸ At oral argument, the lawyers favoring preemption classified the regulation as information regulation, while the State reiterated that the law was “classic health care regulation” and therefore under state authority.³⁹⁹ The Supreme Court majority viewed the law as information regulation that imposed competing reporting duties, which conflicted with ERISA’s desired uniformity.⁴⁰⁰

Stepping back for a moment, the above survey reveals that numerous health law topics have a strong tradition of relying on state *remedies* for injury and allowing for state *implementation* of health initiatives. But they have a varied federal and state tradition regarding *preventive* regulations. Overall, the characterization of health law’s defining tradition as state or federal is inherently subjective.

C. *Evolution: Health Law Federalism*

The historical summary just presented dismantles the notion that the entire body of health law exhibits a monolithic regulatory tradition. The ratio of state-to-federal regulation has been a moving target over the 175 years of health law jurisprudence.⁴⁰¹ The regulatory narrative in each of health law’s component parts suggests that *evolution*, rather than *tradition*, more aptly describes the state and federal regulatory relationship. Field has observed that “much of American health care regulation [reflects] a dynamic and often unstable balance of federal,

8 CONN. INS. L.J. 283, 293 (2002) [hereinafter Gostin et al., *The Nationalization*].

396. Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended, at 29 U.S.C. § 1181 (2012)). See generally Gostin et al., *The Nationalization*, *supra* note 395 at 284–85 (stating that the “two primary justifications for safeguarding health information privacy” are (1) the data is highly personal, and (2) the rapid shift to electronic records raises concerns that unwarranted disclosures of highly personal information could lead to “stigmatization and discrimination,” as well as erode patient trust in their providers).

397. 45 C.F.R. § 160.203(b) (2016); see Gostin et al., *The Nationalization*, *supra* note 395, at 304–05.

398. 136 S. Ct. 936 (2016).

399. Transcript of Oral Argument, *supra* note 364, at 6.

400. *Gobeille*, 136 S. Ct. at 939.

401. See Field, *A Taxonomy*, *supra* note 197, at 608 (“In its historical sweep, American health care regulation is a series of programs layered on top of another over the course of the past 150 years.”).

state, and local authority.”⁴⁰² To place health law’s regulatory tradition in the parlance of history: the only constant is change.

Increasing scientific knowledge, population mobility, and economics have driven this evolution toward federal policy-setting and funding, with state implementation and supervision of daily tasks and remedies. While the tradition presumption has influenced health policy in many ways, it has become “increasingly difficult to maintain,” given the increasing complexity in medicine, organizational structure, economics, and mobility.”⁴⁰³ State primacy in some areas of health law is merely vestigial. In *Gobeille*, for example, the Supreme Court simultaneously acknowledged states’ “traditional power to regulate in the area of public health” and ERISA’s intentional displacement of “substantial areas of traditional state regulation”⁴⁰⁴ with federal law and federal agency regulation.⁴⁰⁵ As many leading commentators agree, “[h]ealth law today is *national and statutory*.”⁴⁰⁶

Health law had passed its tipping point toward federal legislation (at least in volume) by the close of the twentieth century, a decade before the ACA.⁴⁰⁷ The ACA solidified this shift as it wove federal law into nearly every health law sphere, concentrating heavily on insurance and access.⁴⁰⁸ If health law ever had a tradition of state primacy, the ACA diverged from it, despite the statute’s reliance on state implementation and innovation.⁴⁰⁹ The dynamism and federalism that characterize health law’s past and future simply do not coalesce with the tradition presumption underlying health law preemption

402. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 141–42; *see also id.* at 168 (“The conflict between federal and state authority permeates American political history.”); *cf.* Huberfeld, *Federalizing Medicaid*, *supra* note 376, at 454–60 (tracing the evolution of federalism in health care cases and lamenting the lack of coherence).

403. FIELD, HEALTH CARE REGULATION, *supra* note 140, at 168 (“A tremendous amount of local health regulation can now be seen as having national dimensions.”); *see also* Zettler, *Toward Coherent Federal Oversight*, *supra* note 162, at 454–77 (explaining how federal laws have encroached on even the practice of medicine).

404. *Gobeille*, 136 S. Ct. at 946.

405. *Id.* at 944; *id.* at 949–50 (Breyer, J., concurring).

406. Gluck, *Public-Law Lawyers*, *supra* note 263, at 324; *see, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (“Despite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasingly significant role in the protection of the health of our people.”); Gluck, *Public-Law Lawyers*, *supra* note 263, at 324 (“[A]s a general matter, health law has become a field of public law Today, health law is made not through state or local law, but through . . . big, complex, federal statutes passed by Congress and then implemented by federal agencies and courts, sometimes along with other actors, such as the states.”); *see also* Gostin et al., *The Nationalization*, *supra* note 395, at 293.

407. *See* Gluck, *Intrastatutory Federalism*, *supra* note 208, at 576–95; Huberfeld et al., *Plunging into Endless Difficulties*, *supra* note 384.

408. *See* Gluck, *Public-Law Lawyers*, *supra* note 263, at 324 (noting that “[i]t is very hard to look around today and think that this private, local, non-federal narrative still accurately describes the health care landscape”).

409. *See* Huberfeld et al., *Plunging into Endless Difficulties*, *supra* note 384; *cf.* 29 U.S.C. § 1191(a)(2) (2012) (noting that ACA provisions shall not be construed to alter ERISA preemption for group health plans); 42 U.S.C. § 300gg-23(a)(2) (2012) (same).

jurisprudence.⁴¹⁰

This historical examination reveals strong regulatory traditions within each discrete category of health law. Section III will examine how this observation should factor into courts' analysis of health law preemption. The saturation of federal health statutes dilutes the notion of state primacy in the entire body of health law but supports a gestalt characterization of federal and state concurrent regulation, with states playing a seminal role in implementing and supplementing federal programs.⁴¹¹

III. THE SCALPEL APPROACH: REHABILITATING HEALTH LAW'S PREEMPTION JURISPRUDENCE

This Section returns to the tradition presumption's function as a substantive canon of interpretation for divining congressional intent.⁴¹² If the tradition presumption is to remain a probability presumption—broadly probative of Congressional intent, as opposed to a specific statement of policy preference—then the partial fiction of its underlying *tradition* seems to threaten its viability. Three sitting Supreme Court Justices have expressed a desire to shed the tradition presumption.⁴¹³ A fourth, Justice Kennedy, stopped short⁴¹⁴ but nonetheless cast doubt on the tradition presumption's future relevance.⁴¹⁵ While the Court's liberal members have spoken in support of continuing the tradition presumption,⁴¹⁶ its use and vitality in preemption doctrine remain in question.⁴¹⁷

410. See, e.g., Gluck, *Intrastatutory Federalism*, *supra* note 208, at 576–95 (detailing the multiple models of federalism involved in health reform legislation).

411. See generally FIELD, HEALTH CARE REGULATION, *supra* note 140; cf. Gluck, *Federalism from Federal Statutes*, *supra* note 208, at 1750, 1753–65 (“Since the New Deal, Congress has repeatedly invited the states to be the front-line implementers of its new federal laws—federal-statutory design decisions that are often described by legislators as respectful of ‘federalism,’ even as the new national legislation displaces traditional state dominance over a particular area of policy.”).

412. See *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 96 (1992) (“The purpose of Congress is the ultimate touchstone [of preemption].” (quoting *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 208 (1985))); see also *Coons v. Lew*, 762 F.3d 891, 902 (9th Cir. 2014) *cert denied* 135 S. Ct. 1699 (2015) (applying this concept to a preemption challenge under the ACA).

413. See *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 621–22 (2011) (rejecting the constitutional presumption in Justice Thomas’s majority opinion, which was joined by Chief Justice Roberts, Justice Alito, and the late Justice Scalia).

414. *Id.* at 2572 (Kennedy, J., concurring in the Thomas majority opinion *except* the section rejecting the presumption).

415. *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 946 (2016). Rather than beginning his analysis with the presumption, Justice Kennedy reserved it for the last portion of the opinion, acknowledging only that “[t]he Court *in the past* has ‘addressed claims of pre-emption with the starting presumption that Congress does not intend to supplant state law,’ in particular state laws regulating a subject of traditional state power,” such as insurance. *Id.* (emphasis added) (citation omitted). For his “past” example, Kennedy cited an opinion from 1995. *Id.* (citing *N.Y. State Conference Of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654–55 (1995)).

416. See *Gobeille*, 136 S. Ct. at 950–58 (Ginsburg, J., dissenting, joined by Sotomayor, J.) (emphasizing the tradition presumption’s “important role” in “framing preemption doctrine” for matters of “health and safety”); *PLIVA, Inc.*, 564 U.S. at 626–46 (Sotomayor, J., dissenting, joined by Ginsburg, Breyer, and Kagan, JJ., supporting continued use of the presumption against preemption in

Intervention is needed only if the tradition presumption is worth saving. The efficiencies of the presumption tool, as well as the strength of states' contributions to health law suggest that the tradition presumption's prognosis is not terminal. This Section examines the tradition presumption's redeeming features and proposes jurisprudential reforms to bolster those desirable attributes while also respecting the nuances of tradition discussed in Section II.

A. *Prosthetic Statutory Interpretation*

Presumptions are formalistic in that they supply a procedure for decision making, weighted toward one outcome in advance of analysis.⁴¹⁸ Presumptions weigh the decision toward the more probable outcome or toward an important policy consideration.⁴¹⁹ This theoretical distinction between probability and policy is important in determining whether a presumption has sufficient support to bear its canonical weight. Critique of a policy presumption must look to the strength of the underlying policy preference; critique of a probability presumption must look to underlying data or trends. As outlined in Section I, the health law tradition presumption against preemption most closely resembles a probability presumption, and its strength therefore depends on the prevalence of state law primacy.⁴²⁰

The history recounted in Section II reveals the subjectivity and transience of both state and federal regulatory tradition. Though used as an analytical basis for

a pharmaceutical regulation case).

417. See, e.g., *Graham v. R.J. Reynolds Tobacco Co.*, 782 F.3d 1261, 1275 n.13 (11th Cir. 2015) (noting that “[t]he presumption against preemption has been hotly debated”); Massey, *supra* note 98, at 764 (lamenting that the Supreme Court “continues to simultaneously repeat and ignore the presumption”); Young, *The Ordinary Diet of the Law*, *supra* note 12, at 278 (concluding that “the legitimacy, strength, and scope of a presumption against preemption remains a live issue”); see also Dinh, *supra* note 89, at 2092 (posing alternative justifications for the constitutional presumption based on “specific interpretive canons” rather than the “federal structure”); Sharkey, *Federalism in Action*, *supra* note 330, at 1021 (noting “[p]reemption’s grip on scholars” generally).

418. See, e.g., Thomas W. Merrill, *Preemption in Environmental Law: Formalism, Federalism Theory, and Default Rules*, in *FEDERAL PREEMPTION: STATES’ POWERS, NATIONAL INTERESTS*, *supra* note 124, at 166, 166–68; Garbbaum, *supra* note 1, at 773 n.21; Mark Seidenfeld, *A Process Failure Theory of Statutory Interpretation*, 56 WM. & MARY L. REV. 467, 502–07, 512 (2014). See generally Duncan Kennedy, *Legal Formalism*, in 13 *ENCYCLOPEDIA OF THE SOCIAL & BEHAVIORAL SCIENCES* 8634 (Neil J. Smelser & Paul B. Baltes eds., 2001) (“A system is procedurally formalist to the extent that it makes the success of a substantive legal claim depend on following procedural rules.”); Richard A. Posner, *Legal Formalism, Legal Realism, and the Interpretation of Statutes and the Constitution*, 37 CASE W. RES. L. REV. 179 (1986) (explaining the effect of formalism on cases); Frederick Schauer, *Formalism*, 97 YALE L.J. 509 (1988) (demonstrating how rules in a formalistic system constrict decisionmakers).

419. See *supra* Part I.C for a discussion of the health law presumption’s effect on policy considerations.

420. See *supra* Part I.C for a discussion of the health law presumption as a probability presumption. See also Davis, *The “New” Presumption*, *supra* note 106, at 1247 (highlighting that “[t]he question remaining” for the presumption against preemption “is what type of evidence will support that conclusion”).

the presumption, tradition is a malleable term⁴²¹ and has flexible usage in jurisprudence.⁴²² The word's common definition contains a duality, describing both patterns and beliefs about the past.⁴²³ Tradition, by definition, is not written; it is believed and recounted until it becomes "know it when you see it." Along these same lines, conceptions of tradition in health law preemption jurisprudence have become truly notional.⁴²⁴

Even where a tradition of state primacy arguably exists, that tradition does not provide particularly compelling evidence of congressional intent to preempt (or not). In certain instances, Congress legislates because of state regulatory primacy. Congress could, for example, intend to correct the failures of state regulators or to remove regulatory obstacles posed by the presence of fifty different regimes.⁴²⁵ Congress can and does legislate in spite of state regulatory primacy, in light of it, or in concurrence with it.⁴²⁶ The tradition presumption does not resolve this ambiguity; it ignores it.

Despite the congenital weaknesses in the notion of tradition, the default to it in health law has some redeeming value. First, it acknowledges the undeniably

421. See *Tradition*, BLACK'S LAW DICTIONARY (10th ed. 2014) ("1. Past customs and usages that influence or govern present acts or practices. 2. The delivery of an item or an estate.").

422. See, e.g., *United States v. Windsor*, 133 S. Ct. 2675, 2691 (2013) ("[T]he extent of the state power and authority over marriage as a matter of history and tradition."); *Washington v. Glucksberg*, 521 U.S. 702, 710 (1997) ("We begin, as we do in all due process cases, by examining our Nation's history, legal traditions, and practices."); *Morissette v. United States*, 342 U.S. 246, 263 (1952) ("[W]here Congress borrows terms of art in which are accumulated the legal tradition and meaning of centuries of practice, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken. . . ."); cf. E. Donald Elliott, *The Evolutionary Tradition in Jurisprudence*, 85 COLUM. L. REV. 38, 90-94 (1985) (explaining that jurisprudence itself has traditions); Wesley Newcomb Hohfeld, *Some Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 23 YALE L.J. 16, 21 (1913) (highlighting the confusion of legal and nonlegal conceptions through "the ambiguity and looseness of our legal terminology").

423. Compare *Tradition*, MERRIAM-WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/tradition> (last visited Nov. 14, 2016) [<https://perma.cc/VN9L-LVG3>] (defining tradition as "an inherited, established, or customary pattern of thought, action, or behavior;" "cultural continuity in social attitudes, customs, and institutions; characteristic manner, method, or style;" and "a belief or story or a body of beliefs or stories relating to the past that are commonly accepted as historical though not verifiable"), with *Tradition*, BLACK'S LAW DICTIONARY (10th ed. 2014) ("Past customs and usages that influence or govern present acts or practices.").

424. See *Notional*, MERRIAM-WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/notional> (last visited Nov. 14, 2016) [<https://perma.cc/UKR7-JUA6>] (defining notional as "theoretical, speculative;" "existing in the mind only;" "imaginary;" "given to foolish or fanciful moods or ideas;" "conceptual;" and "presenting an idea of a thing, action, or quality").

425. See generally *Gluck & Bressman*, *supra* note 75, at 974-85 (examining the use of legislative history to discern congressional intent).

426. See, e.g., *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989) ("The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to 'stand by both concepts and to tolerate whatever tension there [is] between them.'" (quoting *Silkwood v. Kerr-McGee Corp.* 464 U.S. 238, 256 (1984))); *Peck*, *supra* note 92, at 1195 ("Where state and federal regulation have coexisted for a long time, the Court is less likely to find that Congress intended to preempt state law.").

important and historic role states play in regulating health.⁴²⁷ Second, state primacy was more pervasive decades ago when many of the seminal federal health law statutes were enacted.⁴²⁸ Third, the presumption protects state law and avoids the difficulty of assessing the ratio. Preemption disrupts any regulatory effort that does not favor federal authority. So even if health law's tradition were recast as a fifty-fifty split between federal and state authority, preemption would upset that ratio in the same manner as it would a ten-ninety or thirty-seventy, just to a lesser degree.

Thus, the tradition offers guidance based on some degree of logic and sets a bulwark against the erosion of state power in health law. If the tradition presumption preserves a meaningful role for state law intended by Congress, then its rote application may actually weaken its force, making it appear more like a policy tool than a true reflection of legislative context.⁴²⁹ Some scholars have argued that, despite invoking the tradition presumption *against* preemption, Supreme Court opinions have exhibited a presumption *in favor* of preemption.⁴³⁰ Of course, canons of statutory interpretation are hardly immune to manipulation and formalist criticism.⁴³¹ But those existential questions about the canons, aside from brief acknowledgement, are beyond the scope of this Article.

Although tradition is a *notion*, it is used to support a presumption, a substantive canon of interpretation.⁴³² At their best, presumptions can enhance

427. See *supra* Part II.A.1 for a discussion of state police power to regulate health law, the origin of this power, and its tradition as it relates to federal rules and regulations.

428. See, e.g., Federal Meat Inspection Act, ch. 2907, §301, 34 Stat. 1260 (1907) (codified as amended at 21 U.S.C. § 661 (2012)) (enacting 1906 provisions on “[f]ederal and [s]tate cooperation”). For example, the Federal Meat Inspection Act of 1906 is still the law of the land, though the world thankfully looks much different than it did in Upton Sinclair’s *The Jungle*. State primacy characterized the tradition in food and drug regulation in 1906 and thus remains relevant to those provisions. See *Food Standards and the 1906 Act*, U.S. FOOD & DRUG ADMIN. (May 20, 2009), <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/ucm132666.htm> [<https://perma.cc/45JH-J35F>]; § 1, 34 Stat. 1260 (codified as amended at 21 U.S.C. § 601 (2012)).

429. See 21B CHARLES ALAN WRIGHT & KENNETH W. GRAHAM, JR., *FEDERAL PRACTICE & PROCEDURE* § 5122 (2d ed. 2005) (“Because presumptions . . . reflect substantive policies and can require unpopular results, ‘bad’ presumption opinions frequently reflect disagreement with the substantive policy rather than misunderstanding of the procedural requirements.”).

430. E.g., Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 963, 1013–16 (2002); Massey, *supra* note 98, at 764 (lamenting that the Supreme Court “continues to simultaneously repeat and ignore the presumption”).

431. See, e.g., FRANK B. CROSS, *THE THEORY AND PRACTICE OF STATUTORY INTERPRETATION* 20 (2008) (“Critics have long lamented ‘willful’ judicial decision making according to the judges’ preferences rather than the materials of the law.”); Frank H. Easterbrook, *Judicial Discretion in Statutory Interpretation*, 57 OKLA. L. REV. 1, 12 (2004) (arguing that the judge’s views were not controlled “by anything in the text, but by the generality shift”); William N. Eskridge Jr. & Philip P. Frickey, *Statutory Interpretation as Practical Reasoning*, 42 STAN. L. REV. 321, 322 (1989) (arguing that all three main theories of statutory interpretation “fail to establish an overriding and ‘objective’ foundation for interpreting statutes”).

432. See, e.g., James J. Brudney & Corey Ditslear, *Canons of Construction and the Elusive Quest for Neutral Reasoning*, 58 VAND. L. REV. 1, 12–14 (2005); Eskridge & Frickey, *Quasi-Constitutional*

efficiency, provide a stable and uniform frame for legal analysis, and play a communicative role between the legislative and judicial branches.⁴³³ At their worst, presumptions raise concerns about coherence, countermajoritarianism, and normative preferences.⁴³⁴

From an efficiency standpoint, reliance on tradition may be helpful, but probably only slightly. It is a rebuttable presumption, inviting evidence of a clear statement to the contrary.⁴³⁵ Thus, it does not circumvent all inquiry into intent. Its invocation in contested Supreme Court opinions shows that considerable analysis is still necessary to resolve ambiguity.⁴³⁶ But by framing the adjudicative process and establishing burdens of proof, presumptions help maintain legal stability.⁴³⁷

But any stabilizing effect the tradition presumption has on health law preemption doctrine would be uncertain, due to its malleability. Additionally, the use of a clear statement rule for preemptive intent could prompt Congress to state its intent more clearly, assuming Congress actually considers relevant judicial presumptions when it drafts legislation.⁴³⁸ Assuming Congress's knowledge of the tradition presumption would then suggest that Congress's use of ambiguous language is a deliberate choice to forego preemption.⁴³⁹ This hypothetical feedback loop is likely conjectural, as empirical evidence suggests that many drafters are aware that a presumption exists but have little concept of how it works.⁴⁴⁰

As formulated, the tradition presumption is not particularly enlightening; however, it has potential.⁴⁴¹ Overall, the health law tradition presumption is a

Law, *supra* note 68, at 595–97.

433. See, e.g., Bradford R. Clark, *Process-Based Preemption*, in *PREEMPTION CHOICE*, *supra* note 11, at 192, 199–213.

434. See *id.*; Eskridge & Frickey, *Quasi-Constitutional Law*, *supra* note 68, at 629–45.

435. See Eskridge & Frickey, *Quasi-Constitutional Law*, *supra* note 68, at 626 (stating that the “results [tradition] [is] perhaps best understood as creating a rebuttable presumption”).

436. See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 565–66, 575 (2011) (disagreeing on the proper methods to apply presumption); *id.* at 589 (Thomas, J., concurring) (same); *id.* at 623–24 (Alito, J., dissenting) (same); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518, 522–23, 530–32 (1992) (applying presumption using different methods in each of the Justices' opinions); *id.* at 537 (Blackman, J., concurring in part, and dissenting in part) (same); *id.* at 544–46 (Scalia, J., concurring in part, and dissenting in part) (same).

437. See Tamar Frankel, *Presumptions and Burdens of Proof as Tools for Legal Stability and Change*, 17 HARV. J. L. & PUB. POL'Y 759, 759 (1994) (“Presumptions and burdens of proof are used, among other purposes, to maintain legal stability and at the same time effect change.”). *But see* James J. Brudney & Corey Ditslear, *The Warp and Woof of Statutory Interpretation: Comparing Supreme Court Approaches in Tax Law and Workplace Law*, 58 DUKE. L.J. 1231, 1241 (2009) [hereinafter Brudney & Ditslear, *The Warp and Woof*] (“Substantive canons often lack predictive value for a related but distinct reason—judges assign them varying weights in different case-specific circumstances.”).

438. See Seidenfeld, *supra* note 418, at 492–94.

439. See *id.* at 518–21.

440. Gluck & Bressman, *supra* note 75, at 943–43; *cf.* Brudney & Ditslear, *The Warp and Woof*, *supra* note 437, at 1241 (noting that lawmakers do not take these canons into consideration).

441. This Article leaves for another day the general countermajoritarian critique of federalism

stand-in for complex inquiry. It is not a misuse of history,⁴⁴² but rather a non-use. Generally, much of preemption doctrine springs from ambiguity, requiring searching judgments about what Congress meant absent express statements.⁴⁴³ The tradition presumption, however, does little to illuminate actual intent.⁴⁴⁴ It clarifies the default outcome, rather than illuminating the most probative path to congressional intent.⁴⁴⁵

With that, there are at least three options for reforming the tradition presumption in health law.⁴⁴⁶ Option one would excise the presumption against preemption entirely. As discussed, complete abolition may reduce efficiency, stability, communication, and residual accuracy, as well as potentially affect other areas of police power not studied here.⁴⁴⁷ Option two would change the analysis of health law tradition underlying the presumption. This “scalpel approach” is explored below in Part B. Option three would transform the presumption from a standard of proof to a tiebreaker, as discussed in Part C.

Ultimately, this Article recommends combining the scalpel and tiebreaker approaches to achieve the most salutary effects on health law jurisprudence.

B. The Scalpel Approach

Rather than shedding the presumption entirely, abandoning not only its drawbacks but also its efficiency and ability to save valuable state laws, a more surgical approach would tailor the health law preemption analysis according to topic. That is, a presumption against preemption would be based on the regulatory tradition for that particular area of health law. A more specialized dissection of context and tradition could rehabilitate the presumption.

presumptions, see Clark, *supra* note 433, at 201–02; Eskridge & Frickey, *Quasi-Constitutional Law*, *supra* note 68, at 629–45, and focuses instead on the use of tradition to support presumptions in health law.

442. See Evan C. Zoldan, *The Civil Ex Post Facto Clause*, 2015 WIS. L. REV. 727, 772 (2015).

443. Even express preemption provisions can provoke interpretive ambiguities, particularly about the reach of the expressed desire to preempt. See Nelson, *supra* note 1, at 226–27.

444. Cf. Victoria F. Nourse, *A Decision Theory of Statutory Interpretation: Legislative History by the Rules*, 122 YALE L.J. 70, 140–41 (2012) (explaining how legislative procedure can elucidate congressional intent and account for the empirically driven influences on the legislative process).

445. Cf. J. Harvie Wilkinson III, *Toward A Jurisprudence of Presumptions*, 67 N.Y.U. L. REV. 907, 907 (1992) (arguing for presumption as the dominant mode of legal analysis; “[o]ne cannot understand law without first understanding that most legal principles are not inviolate—instead they are embodiments of presumptions whose rebuttal is always within the realm of the possible.”). But cf. Keener v. Exxon Co., USA, 32 F.3d 127, 134 n.* (4th Cir. 1994) (Murnaghan, J., dissenting) (recognizing “that the hard task of interpreting statutes can, in some cases, be aided by the application of judicially-created presumptions,” but finding that this was not one of those cases).

446. Note that all of these options alter the substantive canon and would apply with equal force to the questions of statutory preemption, as well as agency preemption. See Gluck, *Intrastatutory Federalism*, *supra* note 208, at 556–60 (highlighting cannons that concern agency preemption); Catherine M. Sharkey, *Inside Agency Preemption*, 110 MICH. L. REV. 521, 531–70 (2012) (providing an assessment of federal agency practice with respect to preemption).

447. For example, land use and zoning, environmental law, family law, labor law, and numerous business law topics come from states’ police powers. See generally FREUND, *supra* note 140.

In practice, the scalpel approach would identify the topic impacted by a statute, then dissect the state-federal regulatory balance for that particular area of health law,⁴⁴⁸ like providers, facilities, public health, food, medical products, insurance, and information privacy.⁴⁴⁹ Courts could therefore take notice of “legislative facts” about the tradition in that area,⁴⁵⁰ then measure statutory language against that more nuanced picture. The underlying tradition for each topic offers the actual context in which Congress acted, unlike the history-blind tradition presumption. A preemption opinion applying the scalpel approach might begin with a standard like the following:

When determining preemptive intent, the court considers the regulatory context in which Congress legislated. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). If the federal law covers an *issue* traditionally and primarily governed by state or local authority, the court will presume that Congress did not intend to preempt and will require clear indicia of preemptive intent to rebut this presumption. See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Initially, the court must identify both the discrete legal topic within health law and the regulatory tradition that existed when Congress enacted the statute. See, e.g., *Mass. Med. Soc’y v. Dukakis*, 815 F.2d 790, 791–92 (1st Cir. 1987).

Modifying the presumption in this manner would keep the burden of proving intent on the proponents of preemption but would change the evidence required to satisfy that burden based on the health law topic at issue.⁴⁵¹ Maintaining a rebuttable presumption framework preserves the potential efficiency and uniformity of a presumption based on probability. And narrowing the tradition analysis from the entire body of health law to its component parts helps ensure the veracity of that probability. Further, establishing the distinct tradition of each part of health law should be the work of future research and court opinions—and that jurisprudence could be built upon over time.

A singular tradition presumption for all health regulation is a blunt instrument. A scalpel approach would have at least two salutary effects on the development of health law.⁴⁵² First, it would encourage a deeper and more

448. Cf. Davis, *The “New” Presumption*, *supra* note 106, at 1254–55 (articulating a “new” general presumption against preemption that would increase the burden of rebutting it in implied conflict preemption analyses).

449. See *supra* Part II.B for a discussion of the wide array of health law categories.

450. E.g., FED. R. EVID. 201(a) advisory committee’s note to 1972 proposed rule (stating that notice of legislative facts is disputable with argument and evidence and should “leave open the possibility of introducing evidence through regular channels in appropriate situations.”). See *supra* Part I.B for an explanation of the relationship between probability presumptions and the judiciary taking notice of “legislative facts.”

451. Cf. Davis, *The “New” Presumption*, *supra* note 106, at 1246–48 (discussing the evidence of intent in *Wyeth v. Levine*, and proposing different evidentiary burdens for express versus implied conflict preemption analyses).

452. See, e.g., *Cal. Bankers Ass’n v. Shultz*, 416 U.S. 21, 85 (1974) (Douglas, J., dissenting) (objecting to “a sledge-hammer approach to a problem that only a delicate scalpel can manage”).

coherent jurisprudence on the legislative purposes behind health laws.⁴⁵³ Second, it would encourage a more accurate and nuanced examination of the cooperative history of federal and state regulation on particular aspects of health care.⁴⁵⁴ Crucially, the scalpel approach would more accurately capture the tradition of delegating the implementation of federal policy to state regulators, rather than assigning a binary “primacy” of one authority or the other.⁴⁵⁵

The scalpel approach has been applied in a few rare instances. The Ninth Circuit in *Golden Gate Restaurant Association v. San Francisco*⁴⁵⁶ and the First Circuit in *Massachusetts Medical Society v. Dukakis*⁴⁵⁷ both applied the tradition presumption, but they defined the health law issue narrowly and drew on historical authority.⁴⁵⁸ In *Golden Gate*, the Ninth Circuit defined the relevant “field in which the [local] Ordinance operates” not as simply health, but narrowly as “the provision of health care services to persons with low or moderate incomes.”⁴⁵⁹ The court noted that “State and local governments have traditionally provided health care services to such persons” and framed its ERISA preemption analysis accordingly.⁴⁶⁰ Similarly, in *Massachusetts Medical*, the First Circuit targeted its tradition analysis to the discrete issue of medical fees and relied on the historical strength of state and local authority over medical fee regulation.⁴⁶¹

Dissecting the varied traditions within health law using the scalpel approach may actually rehabilitate the presumption, as demonstrated by *Golden Gate* and *Massachusetts Medical*, by identifying those areas in which a strong tradition of state primacy in fact exists. While the scalpel approach cannot fully cure the complications of ERISA preemption, the strains of pharmaceutical preemption, or the endemic issues of public health, it may at least offer a more accurate and highly tailored analytic method. The scalpel approach encourages more useful health law jurisprudence by prompting courts to carefully consider regulatory tradition by topic in determining congressional intent.⁴⁶² In the diverse but

453. The impact on interbranch communications, however, seems tenuous. While the scalpel approach might clarify for Congress what issues will be construed as health laws, it is hard to see how a nuanced presumption would communicate more forcefully than a blanket one.

454. See FIELD, *A Taxonomy*, *supra* note 197, at 627 (“Historical patterns of regulation can serve as a guide to the kinds of outcomes to which reform may lead.”).

455. Cf. Gluck, *Federalism from Federal Statutes*, *supra* note 208, at 1749–54 (explaining that states obtain their power of regulation in health law from a conscious decision by Congress to delegate that power); Huberfeld et al., *Plunging into Endless Difficulties*, *supra* note 384.

456. 546 F.3d 639 (9th Cir. 2008).

457. 815 F.2d 790 (1st Cir. 1987).

458. See *Mass. Med. Soc’y*, 815 F.2d at 791–92 (citing Paul Starr’s Pulitzer Prize-winning 1982 book, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* on the issue of medical fee regulation); *Golden Gate Rest. Ass’n*, 546 F.3d at 648 (citing Starr for the history of public health and poverty regulation).

459. *Golden Gate Rest. Ass’n*, 546 F.3d at 648.

460. *Id.* (holding that ERISA did not preempt a city ordinance requiring employers to make minimum health care expenditures for employees).

461. *Mass. Med. Soc’y*, 815 F.2d at 792–93.

462. See Clark, *supra* note 433, at 209–10 (“[A]pplication of the traditional presumption against

interdependent body of modern health law, this approach could promote coherence and could help courts navigate the overlapping reforms wrought by the ACA.⁴⁶³

C. *Presumption as Tiebreaker*

A third option to rehabilitate the tradition presumption is to recast its role. As currently formulated, the tradition presumption is invoked at the outset of preemption analysis, framing the inquiry into congressional intent and the burdens required to establish it.⁴⁶⁴ The presumption, however, creates too broad a frame. But even the scalpel approach cannot guarantee certainty on intent where it is genuinely ambiguous. If the scalpel approach ends indeterminately, the presumption against preemption could break the tie in favor of state law. Transforming the overall tradition presumption from leading the analytical inquiry to concluding a tiebreaker could preserve its utility as a default preference while avoiding broad application.⁴⁶⁵

Rather than beginning the analysis with a thumb on the scale, this rearrangement encourages a context-specific analysis *before* resorting to the tiebreaker. And it offers some degree of transparency about the process of doing so. Further, relegating the presumption to a tiebreaker would minimize some of the framing effects that the presumption might have. Psychology teaches that decisionmakers react differently based on the way the choice is presented—or “framed”—at the outset.⁴⁶⁶ It follows that, in presenting state law primacy as the status quo, the tradition presumption may color the analysis as well as its results.

preemption arguably would have sufficed to ensure that . . . the political safeguards of federalism . . . make the crucial decision”); Verchick & Mendelson, *supra* note 36, at 23 (“[A] presumption against preemption promotes legislative deliberation.”); see also Evan C. Zoldan, *Congressional Dysfunction, Public Opinion, and the Battle over the Keystone XL Pipeline*, 447 LOY. U. CHI. L.J. 617, 622 (“Among the most dysfunctional of laws are those that evince a lack of deliberation or that fail to provide guidance.”).

463. Compare, e.g., 42 U.S.C. § 18041(d) (2012) (The ACA shall not “be construed to preempt any State law that does not prevent the application” of the ACA.), with 42 U.S.C. § 300gg-23(a)(2) (2012) (stating that the ACA shall not be construed to alter ERISA’s preemption of a group health plan requirement).

464. See, e.g., *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 954 (2016) (Ginsburg, J., dissenting) (describing it as a “starting presumption” for “framing preemption doctrine”); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (stating that preemption analysis “start[s] with the assumption that the historic police powers of the States were not to be superseded”); accord *State v. Stafford*, 837 A.2d 1118, 1124 (N.J. Super. Ct. App. Div. 2003) (“[A] a court *must begin* with the presumption that Congress does not intend to preempt state law.” (emphasis added)); *Taj Mahal Travel, Inc. v. Delta Airlines, Inc.*, 164 F.3d 186, 192 (3d Cir. 1998) (“[T]he interpretation of even express presumption provisions . . . *must begin* with the ‘presumption that Congress does not intend to supplant state law.’” (emphasis added) (quoting *N.Y. Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654 (1995))).

465. See Verchick & Mendelson, *supra* note 36, at 22 (“[S]ometimes courts need a ‘tiebreaker’ to resolve whether an ambiguously worded statute actually does preempt state law.”).

466. See, e.g., Chris Guthrie, Jeffrey J. Rachlinski & Andrew J. Wistrich, *Inside the Judicial Mind*, 86 CORNELL L. REV. 777, 796–99 (2001) (explaining the psychological concept of “framing,” and applying it to adjudication).

With that, and considering the above analysis, coupling the scalpel and tiebreak approaches creates the most effective balance between efficiency and cohesiveness in health law jurisprudence.

CONCLUSION

Health law is inherently innovative. Advances in medical and scientific knowledge have driven the evolution of public health and safety regulation. Likewise, powerful social and economic changes have continuously broadened health laws' impact and increased its complexity. The various areas of regulation regarding the provision, availability, and quality of health care reflect a unique heterogeneity. Consequently, the relationships among federal, state, and local authorities reflect perpetual negotiation. The only constant in health law is change.

Jurisprudential doctrines offer continuity and stability in courts' application of law, and health law is no exception. Yet, health law preemption jurisprudence, based on the presumption of a singular federalism tradition, is infirm for viewing a complex issue too simplistically. By dissecting health law's myriad traditions and history, a scalpel approach to preemption can rehabilitate the doctrine and greatly improve its prognosis. As our most pressing questions play out in health law contexts, this is an ideal moment to diagnose and treat maladies in health law preemption jurisprudence.
