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# Raich, Health Care, and the Commerce Clause

Alex Kreit

Aaron Marcus

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**RAICH, HEALTH CARE, AND THE COMMERCE CLAUSE**Alex Kreit<sup>†</sup> and Aaron Marcus<sup>††</sup>

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† J.D. 2004, University of Pennsylvania Law School; B.A. 2001 Hampshire College. Law Clerk to the Honorable M. Blane Michael, Circuit Judge, United States Court of Appeals for the Fourth Circuit. I thank my co-author, with whom I have had the great fortune and pleasure to work on a number of projects; I hope for many more to come. I also thank Steph Sherer, whose creative and dedicated work has informed my thoughts on this subject.

†† J.D. 2004, University of Minnesota Law School; B.A. 2001 Hampshire College. Aaron Marcus is serving a two-year term with the Staff Attorney's Office for the United States Court of Appeals for the Third Circuit. He was Editor-in-Chief of Volume XXII, *Law and Inequality: A Journal of Theory and Practice*. He also served on the Board of Directors for Students for Sensible Drug Policy. He would like to thank Professor Eric Janus for his trust and support as well as this article's co-author, Alex Kreit, whose insight and passion have pushed the limits of the drug policy debate.

## I. INTRODUCTION

Like much of the debate over medical marijuana, the popular response to the Ninth Circuit's recent decision in *Raich v. Ashcroft*<sup>1</sup> has focused largely on drug policy and criminal justice issues.<sup>2</sup> Meanwhile, the discussion among legal academics revolves around broad Commerce Clause questions such as the role of the "broader regulatory scheme" doctrine, the meaning of *Wickard* after *Lopez*, and the place of the traditional state interest inquiry in Commerce Clause jurisprudence.<sup>3</sup> The Supreme Court's consideration of the Ninth Circuit's opinion in *Raich*, which held unconstitutional the Controlled Substances Act as applied to four medical marijuana patients and caregivers, will undoubtedly have the most immediate and dramatic impact in these two areas. But the case also frames an important and more specific question about the relationship between federal and state powers over health care: the extent to which health care activity should be regulated by state and local, rather than federal, government.

This article considers to what extent health care may be viewed as a traditional area of state concern in the context of the Supreme Court's revival of federalism principles, in particular limits on Congress' Commerce Clause power, and what effect *Raich v. Ashcroft*, heard by the Court in the fall 2004 term,<sup>4</sup> might have on these issues. Addressing these questions will necessarily involve exploration of medical marijuana policy as well as the role of the "traditional state interest" principle within the Commerce Clause. However, the central focus of this article is not what impact *Raich* may have on the Commerce Clause or our nation's drug laws, but what effect it might have on health care issues.

We start by briefly examining medical marijuana in Part II: the debate over its efficacy, regulatory history, and current trends in both cultural and legal spheres.<sup>5</sup> We then review the Court's recent Commerce Clause jurisprudence, with a focus on the role of the

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1. 352 F.3d 1222 (9th Cir. 2003), *cert. granted*, 124 S. Ct. 2909 (U.S. June 28, 2004) (No. 03-1454).

2. *See, e.g.*, Patrick Hoge, *2 Moms who Need Marijuana Await Supreme Court Ruling - Forced to Challenge Feds to Keep Their Healing Remedy*, S.F. CHRON., Aug. 19, 2004, at B1.

3. *See, e.g.*, Marcus Green, Note, *Guns, Drugs, and Federalism: Rethinking Commerce-Enabled Regulation of Mere Possession*, 72 FORDHAM L. REV. 2543 (2004).

4. *Raich v. Ashcroft*, 352 F.3d 1222 (9th Cir. 2003), *cert. granted*, 124 S. Ct. 2909 (U.S. June 28, 2004) (No. 03-1454).

5. *See infra* Part II.

traditional state interest factor in the analysis, and provide an overview of *Raich*.<sup>6</sup> In Part IV, we provide a historical look at the traditional role of states in regulating health care and compare that with the more recent expansion of federal health care regulation.<sup>7</sup> Part V then provides an overview and examples of how the traditional state interest issue may impact future health care regulation in four different fields.<sup>8</sup>

## II. MEDICAL MARIJUANA

In the wake of California's 1996 medical marijuana ballot initiative, the issue has enjoyed a resurgence in mainstream news coverage. Similar ballot initiatives have appeared regularly since 1996. In 2004, Montana voters became the latest to pass a medical marijuana initiative.<sup>9</sup> Although the interest in medical marijuana is recent, marijuana has been used as a medicine in the United States since at least the middle of the 1800s.<sup>10</sup> In parts of Asia and Africa, the plant has been used medicinally for thousands of years, to treat ailments from malaria to headaches.<sup>11</sup>

Today, medical marijuana proponents cite evidence that it is effective in treating patients who suffer from a number of conditions, including HIV/AIDS, multiple sclerosis, cancer, and glaucoma.<sup>12</sup> Medical marijuana helps these patients by effectively treating pain, nausea and wasting, muscle spasms, and seizures.<sup>13</sup> Because it is nearly impossible for non-government researchers to conduct studies of marijuana's efficacy as a medicine,<sup>14</sup> anecdotal

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6. See *infra* Part III.

7. See *infra* Part IV.

8. See *infra* Part V.

9. Medical Marijuana Act, Montana Laws Init. Meas. 148 (2004) (passed Nov. 2, 2004, effective Jan. 1, 2005).

10. See LESTER GRINSPOON & JAMES B. BAKALAR, MARIHUANA, THE FORBIDDEN MEDICINE 4-7 (1997) (discussing the early studies in the United States of marijuana as a medicine).

11. *Id.* at 3.

12. Brief of The Leukemia & Lymphoma Society, Pain Relief Network, California Medical Association, AIDS Action Council, Compassion in Dying Federation, End-of-Life Choices, National Women's Health Network, Global Lawyers and Physicians, and Autonomy, Inc. as Amici Curiae in Support of Respondents at 10-17, *Ashcroft v. Raich*, 124 S. Ct. 2909 (2004) (No. 03-1454) [hereinafter *Lymphoma Society Brief*].

13. *Id.*

14. See, e.g., Marcella Bombardieri & Jenna Russell, *Pot Project Wins Support*, BOSTON GLOBE, Nov. 2, 2003, at A.28 (showing the resolution of a research request from a professor at the University of Massachusetts was still unclear despite

evidence necessarily provides the basis for some of these claims.<sup>15</sup> But, recent comprehensive studies commissioned by the United States and the Great Britain House of Lords both support the conclusion that marijuana is a useful medicine for at least some patients.

The United States report was commissioned in 1997, largely in response to California's medical marijuana law, and was conducted by the National Institute of Medicine of the National Academy of Sciences (IOM).<sup>16</sup> The resulting year-long study of relevant scientific literature, in consultation with experts from a variety of fields, gave a qualified recommendation of medical marijuana, concluding that "[s]cientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, and appetite stimulation."<sup>17</sup> The House of Lords study concluded that marijuana had "genuine medical applications" in treating similar problems.<sup>18</sup> In addition to being an effective treatment for a number of conditions, marijuana is a relatively safe and "benign" medicine in terms of side effects and potential toxicity.<sup>19</sup>

Marijuana was widely thought to have value as a medicine even when the first anti-marijuana laws were passed. The American Medical Association (AMA) cautioned against passage of the first federal regulation of marijuana, the Marihuana Tax Act of 1937,<sup>20</sup> because it believed the Act would make impossible research into and use of marijuana as a medicine.<sup>21</sup> The AMA's position was not

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receiving support from both of Massachusetts' senators).

15. See generally GRINSPOON & BAKALAR, *supra* note 10 (including stories from individual patients in addressing the potential benefits of marijuana as a medicine).

16. INSTITUTE OF MEDICINE, MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE 1 (1999), available at <http://www.nap.edu/books/0309071550/html>.

17. *Id.* at 4.

18. SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY NINTH REPORT, CANNABIS: THE SCIENTIFIC AND MEDICAL EVIDENCE (Nov. 4, 1998), available at <http://www.publications.parliament.uk/pa/ld199798/ldselect/ldsctech/151/15101.htm>.

19. GRINSPOON & BAKALAR, *supra* note 10, at 137-54.

20. Marihuana Tax Act of 1937, Pub. L. No. 75-238, Ch. 553, 50 Stat. 551, *repealed by* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 1101, 84 Stat. 1236, 1292.

21. See RICHARD J. BONNIE & CHARLES H. WHITEBREAD II, THE MARIHUANA CONVICTION: A HISTORY OF MARIHUANA PROHIBITION IN THE UNITED STATES 164-73 (1974) (discussing the congressional testimony of an AMA representative during consideration of the Marihuana Tax Act of 1937).

surprising, given that at the time marijuana was included in the *United States Pharmacopeia*, a comprehensive list of medicinal substances recognized in the United States.<sup>22</sup> The Act distinguished between medical and non-medical uses of marijuana,<sup>23</sup> but the distinction was irrelevant as a practical matter because the Act functioned in such a way as to “effectively criminaliz[e] the possession of marijuana throughout the United States.”<sup>24</sup> The Marihuana Tax Act, which was declared unconstitutional in 1969,<sup>25</sup> had the effect of eliminating any use of marijuana as a medicine for thirty years,<sup>26</sup> and knowledge of marijuana’s value as a medicine slipped from public and professional consciousness.

By 1970, when Congress passed the Controlled Substance Act (CSA),<sup>27</sup> marijuana was thought of as a symbol of the youth counter-culture,<sup>28</sup> not a medicine. The CSA organized drugs by Schedule, I-IV: Schedule I substances have a high potential for abuse and no accepted medical use, while Schedule IV substances have a low potential for abuse, an accepted medical use, and are unlikely to cause addiction.<sup>29</sup> Marijuana was provisionally placed in Schedule I, pending recommendations and findings from a Presidential Commission created by the Act.<sup>30</sup> The Commission ultimately urged that marijuana be decriminalized, with penalties removed for all personal marijuana-related activity.<sup>31</sup> President Nixon rejected the recommendation, leaving marijuana a Schedule

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22. Marijuana was listed in the *Pharmacopeia* until 1941. GRINSPOON & BAKALAR, *supra* note 10, at 8.

23. Marihuana Tax Act of 1937, Pub. L. No. 75-238, § 7(a)(2), 50 Stat. at 554.

24. ERIC SCHLOSSER, REEFER MADNESS: SEX, DRUGS, AND CHEAPER LABOR IN THE AMERICAN BLACK MARKET 20 (2003); *see also* GRINSPOON & BAKALAR, *supra* note 10, at 8 (discussing the difficulties physicians who wished to use medical marijuana in treating patients faced under the Act); *Leary v. United States*, 395 U.S. 6 (1969) (discussing in some detail the structure of the Marihuana Tax Act in the context of recreational use of marijuana and holding the Act unconstitutional as violative of the Fifth Amendment).

25. *Leary*, 395 U.S. 6.

26. BONNIE & WHITEBREAD, *supra* note 21, at 165.

27. Controlled Substance Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242 (codified as amended at 21 U.S.C. § 801-904) (2000).

28. *See* DAN BAUM, SMOKE AND MIRRORS: THE WAR ON DRUGS AND THE POLITICS OF FAILURE 7-8 (1997) (discussing marijuana as a symbol of the counter-culture). The CSA passed in a politically charged atmosphere as part of President Nixon’s effort to crack down on crime and lawlessness. *Id.* at 13-17.

29. BONNIE & WHITEBREAD, *supra* note 21, at 245.

30. *Id.* at 246-47.

31. *Id.* at 270.

I drug.<sup>32</sup>

Independent of the increased federal effort against drug use, the idea of marijuana as a medicine began to gain traction again in the mid-1960s and early 1970s as the increase in recreational use led some users to accidentally stumble upon marijuana's medicinal value.<sup>33</sup> At the same time, marijuana reform activists began to seize on the prohibition of medicinal use of marijuana as an example of the excesses of the drug war.<sup>34</sup> In the late 1970s and early 1980s, the new interest in medical marijuana translated into passage of medical marijuana laws in thirty-three states.<sup>35</sup> These early medical marijuana laws were quite different from the recent efforts: instead of expressly permitting medical marijuana use and distribution under state law in violation of the CSA, most established programs allow use only when approved by the federal government as part of the FDA's Investigative New Drug (IND) program.<sup>36</sup> INDs were generally used by pharmaceutical companies for research projects but, due to pressure from medical marijuana patients, the federal government allowed limited medical marijuana use under a "Compassionate IND" program.<sup>37</sup>

The Compassionate IND program stopped permitting new applications in 1992 with thirteen qualified patients.<sup>38</sup> Those patients were grandfathered in and the remaining patients still receive medical marijuana from the federal government, but the end of the program signaled to activists that medical marijuana efforts at the federal level had hit a wall.<sup>39</sup> In 1996, modern state

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32. *Id.* at 273.

33. GRINSPOON & BAKALAR, *supra* note 10, at 13.

34. *See, e.g.*, PATRICK ANDERSON, *HIGH IN AMERICA: THE TRUE STORY BEHIND NORML AND THE POLITICS OF MARIJUANA*, 236-248 (1981) (discussing medical marijuana patients involvement in the marijuana law reform movement).

35. GRINSPOON & BAKALAR, *supra* note 10, at 17.

36. *See* Nicole Dogwill, Comment, *The Burning Question: How Will the United States Deal with the Medical-Marijuana Debate?*, 1998 DET. C.L. REV. 247, 256-67 (1997).

37. *See generally* ROBERT C. RANDALL & ALICE M. O'LEARY, *MARIJUANA RX: THE PATIENTS' FIGHT FOR MEDICINAL POT* 104-12 (1998) (discussing the origins of the Compassionate IND program).

38. *See* GRINSPOON & BAKALAR, *supra* note 10, at 20-23.

39. An unsuccessful twenty-two year-long effort to have marijuana rescheduled through an administrative rule-making procedure also contributed to the belief among medical marijuana activists that they should turn their attention to the states. *See Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994) (denying a petition for review of the Administrator's final order maintaining classification of marijuana as narcotic drug under Schedule I).

law medical marijuana reform efforts began with the passage of Proposition 215, California's Compassionate Use Act,<sup>40</sup> and a similar ballot initiative in Arizona.<sup>41</sup>

Although a total of eleven states have passed medical marijuana laws since 1996,<sup>42</sup> California's law has been at the center of most of the medical marijuana-related publicity and legal activity, in part because of the structure of California's law and in part because local officials have been so direct in embracing and assisting patients who use marijuana. In addition to permitting use and possession of marijuana by qualified patients, California's law allows designated caregivers to grow marijuana for patients.<sup>43</sup> Although California state courts have held that this provision does not allow for operation of medical marijuana dispensaries,<sup>44</sup> custom and support from state and local officials have allowed such businesses and non-profit collectives to operate legally and openly under state law.<sup>45</sup>

Many California cities have gone further than tacit approval of medical marijuana dispensaries to outright and vocal support. In Santa Cruz, for example, city officials organized an event to distribute marijuana on the steps of city hall in response to a DEA raid of a local medical marijuana hospice in September 2002.<sup>46</sup> Oakland has implemented a system to officially approve and regulate its medical marijuana clubs after a large number of clubs sprang up in an area of downtown Oakland that many began referring to it as "Oaksterdam" in reference to Amsterdam, where

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40. Compassionate Use Act of 1996 § 1, CAL. HEALTH & SAFETY CODE § 11362.5 (West Supp. 2003).

41. See Elvia Diaz, *Medical Marijuana Debate Flares*, ARIZ. REPUBLIC, Oct. 20, 2002, at 7B (discussing the Arizona measure and the state legislature's subsequent efforts to repeal it).

42. See National Organization for Reform of Marijuana Laws, State by State Laws, at [http://www.norml.org/index.cfm?Group\\_ID=4516](http://www.norml.org/index.cfm?Group_ID=4516) (last visited Feb. 12, 2005) (Alaska, Arizona, California, Colorado, Hawaii, Maine, Maryland, Montana, Nevada, Oregon, and Washington).

43. Compassionate Use Act of 1996 § 1, CAL. HEALTH & SAFETY CODE § 11362.5(d).

44. *People ex rel. Lungren v. Peron*, 70 Cal. Rptr. 2d 20, 31 (Ct. App. 1997).

45. See, e.g., Jason Hoppin, *Pot Clubs Find a New Venue*, THE RECORDER, June 7, 2002, at 1 (noting that San Francisco Supervisor Mark Leno urged local law enforcement officials not to cooperate with federal law enforcement agencies enforcing federal drug laws).

46. Maria Alicia Gaura & Matthew B. Stannard, *Santa Cruz Officials to Defy Feds, Hand out Medical Pot at City Hall*, S.F. CHRON., Sept. 13, 2002 at A23.



marijuana is legal.<sup>47</sup>

The city of Oakland also supported the Oakland Cannabis Buyer's Cooperative (OCBC) as it litigated the first medical marijuana case to reach the Supreme Court. When the federal government first sought to close OCBC down, Oakland declared a city-wide health emergency in response.<sup>48</sup> The government attempted to shut down OCBC by requesting an injunction from a United States District Court, which subsequently granted the motion.<sup>49</sup> The Ninth Circuit reversed, holding that a medical necessity defense would likely apply to protect OCBC's activity.<sup>50</sup> The Supreme Court, however, reversed and held that medical necessity was not a valid defense to the manufacture and distribution of marijuana.<sup>51</sup> The Court explicitly reserved the issue of "whether the Controlled Substances Act exceeds Congress' power under the Commerce Clause."<sup>52</sup>

#### A. *State Interest and the Commerce Clause*

The Ninth Circuit reached its decision in *Raich* because of two Supreme Court cases that fundamentally changed Commerce Clause jurisprudence: *United States v. Lopez*<sup>53</sup> and *United States v. Morrison*.<sup>54</sup> The last time the Supreme Court held a federal action unconstitutional under the Commerce Clause before *Lopez*, was 1936.<sup>55</sup> At the time, a majority of the Court adhered to a restrictive approach focused on whether an activity had "direct" or "indirect" effects on interstate commerce.<sup>56</sup> Under the "direct-indirect" test, the Court struck down a number of important pieces of President Roosevelt's New Deal. Roosevelt considered the issue so problematic that he threatened a court-packing plan to gain a

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47. See, e.g., Henry K. Lee, *OAKLAND, Closed Pot Club Sues City, Council Broke up Cluster of Clubs in "Oaksterdam,"* S.F. CHRON., Aug. 25, 2004, at B5.

48. *United States v. Oakland Cannabis Buyers' Coop.*, 190 F.3d 1109, 1114 (9th Cir. 1999) (per curiam), *rev'd*, 532 U.S. 483 (2001).

49. *United States v. Cannabis Cultivators Club*, 5 F. Supp. 2d 1086, 1106 (N.C. Cal. 1998).

50. *Oakland Cannabis Buyers' Coop.*, 190 F.3d at 1114.

51. *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 493 (2001).

52. *Id.* at 495 n.7.

53. 514 U.S. 549 (1995).

54. 529 U.S. 598 (2000).

55. *Carter v. Carter Coal Co.*, 298 U.S. 238 (1936).

56. See, e.g., *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 548-49 (1935).

majority of Justices who believed the Constitution permitted a broader federal regulatory power.<sup>57</sup>

In this setting, the Supreme Court dramatically changed course in 1937 and again in 1942. Although the 1937 case, *NLRB v. Jones & Laughlin Steel Corp.*,<sup>58</sup> marked the shift, the 1942 case, *Wickard v. Filburn*,<sup>59</sup> famously demonstrated the extent to which the Court would allow Congress to regulate activity under the Commerce Clause. In *Wickard*, the Court allowed the regulation of a wheat farmer who exceeded his acreage allotment for personal uses under the Agricultural Adjustment Act of 1938, which aimed to stabilize the price of wheat.<sup>60</sup> The Court reasoned that although the wheat farmer's individual impact on commerce was insignificant, the effect of all such farmers' level of growth was dramatic in the aggregate.<sup>61</sup> The aggregation principle seemed so sweeping that most regarded commerce power limits as nonexistent.<sup>62</sup>

Both *Lopez* and *Morrison*, by a five Justice majority, placed new constraints on congressional commerce power by holding respectively unconstitutional a law that criminalized gun possession in a school zone and a law that provided a private cause of action under federal law for victims of gender-motivated violent acts.<sup>63</sup> Together, these two cases announced a new framework for analyzing Commerce Clause challenges based on "three broad categories of activity that Congress may regulate under its commerce power:"<sup>64</sup> "the use of the channels of interstate commerce," "the instrumentalities of interstate commerce," and "those activities that substantially affect interstate commerce."<sup>65</sup> *Lopez*, *Morrison*, and most subsequent lower court cases, including

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57. See generally Alpheus Thomas Mason, *Harlan Fiske Stone and FDR's Court Plan*, 61 YALE L.J. 791 (1952) (discussing the court-packing plan).

58. 301 U.S. 1 (1937) (holding congressional power to regulate under the Commerce Clause extends to labor relations).

59. 317 U.S. 111 (1942) (holding commerce power extends to intrastate farming activities).

60. *Id.* at 114.

61. *Id.* at 127-28 (consuming homegrown wheat causes variable factor in maintenance of government regulation of commodity).

62. See, e.g., Deborah Jones Merritt, *Commerce!*, 94 MICH. L. REV. 674, 691 (1995) (referring to the Court's pre-*Lopez* approach to the Commerce Clause as an "intellectual joke").

63. 514 U.S. at 549; 529 U.S. at 598.

64. *Lopez*, 514 U.S. at 558.

65. *Id.* at 558-59.

*Raich*, have involved the substantial effects category, which covers activity that may technically be intrastate but nonetheless has a substantial impact on interstate commerce.<sup>66</sup> In *Lopez*, the Court identified *Wickard* as an example of a case that pushed the limits of the substantial effects category.<sup>67</sup>

The central consideration in determining the constitutionality of a regulation or governmental action within the substantial effects category is whether the activity regulated is commercial (economic) or noncommercial (noneconomic) in nature.<sup>68</sup> This was the primary basis that the Court used to distinguish *Wickard* from *Lopez*. The Court argued that the Gun Free School Zones Act (GFSZA) at issue in *Lopez* was not a proper exercise of Congress' commerce power because the Act "by its terms has nothing to do with 'commerce' or any sort of economic enterprise, however broadly one might define those terms."<sup>69</sup> In *Morrison*, the Court went on to establish a controlling four-factor test.<sup>70</sup> In addition to the commercial factor, the test considers whether the effect of the activity on commerce is attenuated; whether the statute contains an express jurisdictional element that limits its reach; and whether there are any Congressional findings on the relationship between the activity and interstate commerce contained in the statute or its legislative history.<sup>71</sup>

Although *Morrison*'s four-factor test is indisputably the proper method for resolving challenges to congressional commerce power, it is also deceptively simple in glossing over some of the fundamental problems the Court left unanswered in *Lopez* and *Morrison*. For example, the test does not account for the "broader regulatory scheme" doctrine mentioned in *Lopez*<sup>72</sup> and is neutral on

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66. See *id.* at 558-59 (providing an overview of the three categories of activity).

67. *Id.* at 559-60 (discussing *Wickard*, *Hodel*, *McClung*, and *Heart of Atlanta Motel* as examples "[w]here economic activity substantially affects interstate commerce").

68. *Id.* at 559-61.

69. *Id.* at 561.

70. 529 U.S. at 598.

71. *Id.* at 610-12.

72. See Adrian Vermeule, *Does Commerce Clause Review Have Perverse Effects?*, 46 VILL. L. REV. 1325 (2001) (arguing that the broader scheme doctrine may create perverse incentives for Congress to regulate more, not less, broadly); Alex Kreit, *Why is Congress Still Regulating Noncommercial Activity?*, 28 HARV. J. L. & PUB. POL'Y 169 (2004) (noting that the Court left unresolved the meaning of the broader scheme doctrine in *Lopez* and *Morrison* and proposing an interpretation of it based on the enterprise concept).

even the most fundamental question of whether as-applied Commerce Clause challenges are allowed at all.<sup>73</sup> Similarly, the four-factor test does not directly account for perhaps the most important guiding principle in both *Lopez* and *Morrison*: federal encroachment on “traditional state interests.”<sup>74</sup> For our purposes, the potential for *Raich* to impact health care law lies in the “traditional state interest” consideration.<sup>75</sup> In addition to issues strictly related to Commerce Clause jurisprudence, such as how the traditional state interest analysis relates to the *Morrison* test, *Raich* presents the Court with questions about the extent to which health care is a traditional state interest and what that classification may mean as a practical matter.

In *Lopez*, the majority explained that when Congress improperly expands its commerce power, “it effects a ‘change in the sensitive relation between federal and state criminal jurisdiction.’”<sup>76</sup> The Court reasoned that limiting Congress’ commerce power was necessary to preserve this relationship. “Under the theories that the Government presents in support of [finding the GFSZA constitutional], it is difficult to perceive any limitation on federal power, even in areas such as criminal law enforcement or education where States historically have been sovereign.”<sup>77</sup> Justice Kennedy’s concurring opinion in *Lopez* relied even more vigorously on federalism concerns.<sup>78</sup> Kennedy argued that because the GFSZA concerned schools, which traditionally were a matter for local control, the Court had “a particular duty to ensure that the federal-state balance is not destroyed.”<sup>79</sup> Indeed, Justice Kennedy appears to view federalism as the central consideration in Commerce Clause cases: “we must inquire

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73. Compare *United States v. McCoy*, 323 F.3d 1114, 1133 (9th Cir. 2003) (Trott, J. dissenting) (concluding that the majority should not have the option of declaring a statute invalid “as applied”) with *United States v. Stewart*, 348 F.3d 1132, 1142 (9th Cir. 2003) (debating whether there can be successful as-applied Commerce Clause challenges or only facial challenges).

74. See, e.g., Peter J. Henning, *Misguided Federalism*, 68 MO. L. REV. 389, 391 (2003) (discussing *Lopez* and *Morrison* as cases in which the Court used “federalism as an independent limitation on congressional power to legislate in areas that infringe on state sovereignty” but arguing against as-applied commerce challenges).

75. See Part III *infra*.

76. *Lopez*, 514 U.S. at 561 n.3 (quoting *United States v. Emmons*, 410 U.S. 396, 411-12 (1973)).

77. *Id.* at 564.

78. *Id.* at 575 (Kennedy, J., concurring).

79. *Id.* at 581.

whether the exercise of national power seeks to intrude upon an area of traditional state concern . . . . [The GFSZA] forecloses the States from experimenting and exercising their own judgment in an area to which States lay claim by right of history and expertise.”<sup>80</sup>

In *Morrison*, the Court emphasized similar themes to explain its decision. In striking down part of the Violence Against Women Act (VAWA), the Court stated that “we can think of no better example of the police power, which the Founders denied the National Government and reposed in the States, than the suppression of violent crime and vindication of its victims.”<sup>81</sup> The *Morrison* majority argued that allowing regulation of this sort of local activity was improper because “[t]he Constitution requires a distinction between what is truly national and what is truly local . . . . [This would permit regulation of] family law and other areas of traditional state regulation since the aggregate effect of marriage, divorce, and childrearing on the national economy is undoubtedly significant.”<sup>82</sup>

The idea of protecting traditional state authority from federal intrusion in the context of *Lopez* and *Morrison* has its roots in some of the Court’s Tenth Amendment cases decided in between the 1960s and 1980s, while the Court’s Commerce Clause approach remained broadly permissive. The legal theory at issue in these cases was that the Tenth Amendment acted as an affirmative protection against federal regulation of state-run entities under the Commerce Clause. The theory was adopted only briefly in *National League of Cities v. Usery*<sup>83</sup> after being first explored in Justice Douglas’ dissenting opinion in *Maryland v. Wirtz*.<sup>84</sup> Under this theory, States were protected from the increasingly expansive scope of federal power by preventing the enforcement of otherwise constitutional regulations against state-run entities. As *Usery* explained, “the dispositive factor is that Congress has attempted to exercise its Commerce Clause authority to prescribe minimum wages and maximum hours to be paid by the States in their

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80. *Id.* at 580, 583.

81. *Morrison*, 529 U.S. at 618.

82. *Id.* at 617-18, 615-16.

83. 426 U.S. 833 (1976), *overruled by* *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528 (1985).

84. 392 U.S. 183, 201-05 (1968), *overruled by* *Nat’l League of Cities v. Usery*, 426 U.S. 833 (1976), *overruled by* *Garcia v. San Antonio Metro Transit Auth.* 469 U.S. 528 (1985).

capacities as sovereign governments.”<sup>85</sup> The Court abandoned this reading of the Tenth Amendment just ten years after *Usery*,<sup>86</sup> but the principle informs the Court’s focus on traditional state authority in its new Commerce Clause jurisprudence.

Importantly, while *Lopez* and *Morrison* draw from themes in the Tenth Amendment cases, the question of state authority functions quite differently in each setting. In the Tenth Amendment cases, it was used to provide certain state action immunity from otherwise valid federal regulation under the Commerce Clause. In the new Commerce Clause analysis, it affects the validity of the regulation itself, whether applied to a state actor or private individuals. At the same time, however, *Lopez* and *Morrison* do not carve out separate spheres of federal and state authority.<sup>87</sup>

While *Lopez* and *Morrison* noted that education and criminal law were traditional state interests as important considerations, their holdings certainly do not prevent the federal government entirely, or even largely, from regulating in those areas. This much, however, is clear: *Lopez* and *Morrison* both relied heavily on the traditional role of states to support their conclusions, though both left the counters of the traditional state interest inquiry largely undefined. Neither case specifies what role the factor should play in analyzing Commerce Clause cases even as both demonstrate it was important to the Court’s decisions.<sup>88</sup> More fundamentally, neither case explains what a traditional state interest is. Perhaps the best indication of the role the concern might play comes in the idea expressed in Justice Kennedy’s *Lopez* concurrence that protecting traditional state authority is especially important when failing to do so would foreclose experimentation by the states.<sup>89</sup> Nevertheless, the precise role the traditional state interest will play in Commerce Clause analysis generally, and in *Raich* specifically, remains unclear in many key ways. At the same time, it is the doctrinal mechanism that lies in the middle of the relationship between *Raich* and broader health care issues.

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85. *Usery*, 426 U.S. at 852.

86. *Garcia v. San Antonio Metro Transit Auth.* 469 U.S. 528 (1985).

87. See Part III *infra* (exploring how authority in health care law is overlapping).

88. See *Lopez*, 514 U.S. at 549; *Morrison*, 529 U.S. at 599.

89. See *Lopez*, 514 U.S. at 568.

### B. Ashcroft v. Raich

*Raich* marks the second time in four years that the Supreme Court is faced with the issue of medical marijuana.<sup>90</sup> *Raich* comes to the Court on appeal from a 2-1 Ninth Circuit decision holding that the CSA is likely unconstitutional as applied to “the intrastate, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician and in accordance with state law.”<sup>91</sup>

The case arose in August 2002 when the DEA sent agents to the home of Diane Monson.<sup>92</sup> They were accompanied by members of the Butte County Sheriffs Department and the local district attorney.<sup>93</sup> Talks between the authorities and Monson lasted three hours before the DEA proceeded to tear down the six marijuana plants growing in her house.<sup>94</sup> Monson had been using marijuana upon the recommendation of her doctor to help treat a number of chronic illnesses.<sup>95</sup> After the raid, Monson became concerned she would not be able to obtain the strain of marijuana that best treated her pains.<sup>96</sup>

She soon located Angel McClary Raich, one of the fourteen medical marijuana patients represented by the OCBC in *United States v. Oakland Cannabis Buyers' Cooperative*.<sup>97</sup> Raich has used medicinal cannabis since 1997 for eating, muscle, and nervous system disorders.<sup>98</sup> Unlike Monson, Raich was not able to grow her

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90. In 2001, the Supreme Court found the Controlled Substance Act did not permit a medical necessity defense to marijuana possession. *United States v. Oakland Cannabis Buyers' Co-op*, 532 U.S. 483, 495 (2001). In 2003, the Court let stand a Ninth Circuit ruling that physicians have a First Amendment right to recommend marijuana to their patients. *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002), *cert. denied* 72 U.S.L.W. 3092 (Oct. 14, 2003) (No. 03-40).

91. *Raich v. Ashcroft*, 352 F.3d 1222, 1229 (9th Cir. 2003).

92. See Decl. of Diane Monson in Supp. of Mot. for Prelim. Inj., at 4 [hereinafter *Monson Decl.*], *Raich v. Ashcroft*, 248 F. Supp. 2d 918 (N.D. Cal. 2003) (No. 02-4872 EMC), *available at* <http://raich-v-ashcroft.com/raichashdiane.pdf>. None of the facts of the case are disputed by either party. See *Raich*, 352 F.3d at 1225-26.

93. *Monson Decl.*, *supra* note 92, at 4.

94. *Id.*

95. *Id.* at 3-4.

96. *Id.* at 4.

97. See generally 532 U.S. 483. See also Decl. of Angel McClary Raich in Supp. of Mot. for Prelim. Inj. at 18-19 [hereinafter *Raich Decl.*], *Raich v. Ashcroft*, 248 F. Supp. 2d 918 (N.D. Cal. 2003) (No. C 02-4872 EMC), *available at* <http://www.angeljustice.org/downloads/raichashangel.pdf>.

98. See *Raich Decl.*, *supra* note 97, at 1-17.

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own marijuana.<sup>99</sup> In 1998 she became a member of the Oakland Cannabis Buyers' Cooperative.<sup>100</sup> When the Cooperative lost its case in the Supreme Court, Raich had to find alternative sources.<sup>101</sup> She found two suppliers who generously agreed to provide her marijuana free of charge.<sup>102</sup>

Raich, Monson, and the two suppliers, who remain anonymous to protect Raich's medical supply, brought suit in the United States District Court for the Northern District of California. They sought a declaratory judgment that the CSA is unconstitutional as applied to patients using non-purchased intrastate marijuana<sup>103</sup> under California's Compassionate Use Act.<sup>104</sup> They also sought a preliminary injunction to prevent the federal government from seizing or destroying their cannabis, or from prosecuting for the use or production of marijuana for the duration of the case.<sup>105</sup>

In addition to their Commerce Clause argument, Raich and Monson made arguments based on the Fifth, Ninth, and Tenth Amendments,<sup>106</sup> but the Ninth Circuit did not reach any of these issues.<sup>107</sup> The District Court found it was unlikely the plaintiffs would succeed on the merits and refused to issue an injunction.<sup>108</sup> It found dispositive the Ninth Circuit's previous rulings that the CSA was a permissible exercise of Commerce Clause authority.<sup>109</sup> The District Court relied on two Ninth Circuit decisions that rejected Commerce Clause challenges by defendants whom were charged with marijuana possession and distribution offenses.<sup>110</sup>

On appeal, the Ninth Circuit distinguished *Visman* and *Tisor*,

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99. Raich v. Ashcroft, 352 F.3d 1222, 1225 (9th Cir. 2003).

100. Raich Decl., *supra* note 97, at 18.

101. *Id.* at 19.

102. *Id.*

103. Raich, 248 F. Supp. 2d at 922-26.

104. CAL. HEALTH & SAFETY CODE § 11362.5.

105. Complaint at 12-13, Raich v. Ashcroft, 248 F. Supp. 2d 918 (N.D. Cal. 2003) (No. 02-4872 EMC), *available at* <http://raich-v-ashcroft.com/raichashcmp.pdf>.

106. Plaintiffs' Mem. of Law in Supp. of Mot. for Prelim. Inj. at 6-24, Raich v. Ashcroft, 248 F. Supp. 2d 918 (N.D. Cal. 2003) (No. 02-4872 EMC), *available at* <http://raich-v-ashcroft.com/raichashmem.pdf>.

107. *Raich*, 352 F.3d at 1227. Although interesting arguments, it is beyond the scope of this article to deal with the other constitutional challenges. The crux of the case relates to the Commerce Clause challenge, and the Ninth Circuit ruled only upon this issue. *Id.*

108. *Raich*, 248 F. Supp. 2d at 931.

109. *Id.* at 923-26.

110. *Id.* at 924-25 (*citing* United States v. Tisor, 96 F.3d 370 (9th Cir. 1996); United States v. Visman, 919 F.2d 1390 (9th Cir. 1990)).



the two cases relied upon by the district court, on the grounds that they involved non-medical commercial activity.<sup>111</sup> The court noted that in order to properly conduct analysis under the Commerce Clause, the class of activities must be defined.<sup>112</sup> The class of activities associated with *Visman* and *Tisor* was drug trafficking, not intrastate non-commercial medical use.<sup>113</sup> The Ninth Circuit concluded that drug trafficking is an economic enterprise relating directly to the CSA's regulatory purpose of controlling the commercial marijuana market.<sup>114</sup> In contrast, the court held that the intrastate non-commercial production and personal use of marijuana upon a doctor's recommendation, and in connection with state law, is not a market-based activity.<sup>115</sup> Thus, the court stated "concern regarding users' health and safety is significantly different in the medicinal marijuana context, where the use is pursuant to a physician's recommendation."<sup>116</sup> After making this distinction, the court then analyzed the activity under the four-factor *Morrison* test.<sup>117</sup>

The Ninth Circuit found that the personal production, possession, and use of medicinal marijuana were not economic activity under *Morrison*'s first prong.<sup>118</sup> Citing Black's Law Dictionary, the court reasoned that "[l]acking sale, exchange or distribution, the activity does not possess the essential elements of commerce."<sup>119</sup> The Justice Department argued even if true, *Wickard*'s aggregation principle permitted federal involvement.<sup>120</sup> The court found *Wickard* inapplicable because, based on *Lopez* and *Morrison*, aggregation only applies to activities that are economic in character.<sup>121</sup> The majority continued to examine the other three factors and concluded that the attenuated effects and jurisdictional hook factors weighed in favor of the plaintiffs, and that the legislative history favored the government.<sup>122</sup>

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111. *Raich*, 352 F.3d at 1227-28.

112. *Id.* at 1228.

113. *Id.*

114. *See id.* at 1230.

115. *Id.* at 1228, 1231.

116. *Id.* at 1230.

117. *Id.* at 1229-30.

118. *Id.* at 1229.

119. *Id.* (citing BLACK'S LAW DICTIONARY (7th ed. 1999) ("commerce")).

120. *See id.* at 1230.

121. *Id.* at 1230 (citing *United States v. Morrison*, 529 U.S. 598, 610-11 n.4 (2000); *United States v. Lopez*, 514 U.S. 549, 558 (1995)).

122. *Id.* at 1231-35.

In dissent, Judge Beam first argued that the plaintiffs lacked standing to bring the suit.<sup>123</sup> He argued that plaintiffs had made no showing whatsoever that they had particular reason to fear that federal prosecution or some other adverse action would be against them.<sup>124</sup> Beam's central disagreement over substance with the majority concerned its decision to classify the activity at issue so narrowly.<sup>125</sup> He compared the case to *Wickard* and argued the majority's classification was indefensible because the activity involved in *Wickard* could have been described as "the intrastate, noncommercial cultivation of wheat for personal food purposes."<sup>126</sup>

Although the majority and dissent did not disagree specifically about the traditional state interest factor,<sup>127</sup> the issue was intimately related to definition of the class of activity each side chose to adopt.<sup>128</sup> The potential for *Raich* to influence other areas of health care law also lies in this question. *Raich* will primarily influence general Commerce Clause jurisprudence, but the Court's treatment of the traditional state interest factor in resolving the constitutional question will also affect the relationship between states and the federal government in regulating health care.

### III. PUBLIC HEALTH AS A TRADITIONAL STATE CONCERN

#### A. *Public Health and Its Boundaries*

Chief Justice Marshall announced in *Gibbons v. Ogden*<sup>129</sup> that a state's police power encompasses the ability to enact "health laws of every description."<sup>130</sup> Eighty years after *Gibbons*, the Supreme Court again declared that a state has always retained authority to make regulations that "protect the public health and safety."<sup>131</sup> The Court has continuously repeated this pronouncement.<sup>132</sup> It has

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123. *Id.* at 1236 (Beam, J., dissenting).

124. *Id.* at 1237.

125. *See id.* at 1238-39.

126. *Id.* at 1238.

127. *See id.* at 1238-39.

128. *See id.* The court did not address this relationship directly, but California's adoption of a medically oriented statute provided the basis for narrowly classifying the activity. On the other hand, a broader classification of the activity would downplay state regulation.

129. 22 U.S. 1 (1824).

130. *Id.* at 203 (Chief Justice Marshall announcing the decision of the case).

131. *Jacobson v. Mass.*, 197 U.S. 11, 25 (1905) (citations omitted).

132. *See, e.g., City of Erie v. Pap's A.M.*, 529 U.S. 277, 296 (2000) (regarding a

even stated “a State’s power to regulate . . . for the purpose of protecting the health of its citizens . . . is at the core of its police power.”<sup>133</sup> Despite this powerful rhetoric, the Court has never clarified what the public health police power entails. The expansion of federal regulation in the field of health care since the beginning of the 1900s makes it even more difficult to discern the extent to which health care is a subject for state regulation. It is necessary to closely inspect the origins of health care as a concern for the state and recent federal involvement to understand the issues the Supreme Court will face as it decides how to classify the activity engaged in by the *Raich* plaintiffs.

### B. *Public Health and Health Care*

The term “public health” is a broad classification of activities dealing with personal and societal health. The World Health Organization has defined achieving public health as “a state of complete physical, mental, and social well being . . . .”<sup>134</sup> The Institute of Medicine has an equally broad definition: “fulfilling society’s interest in assuring conditions where people can be healthy.”<sup>135</sup> Despite their breadth, both statements seem accurate in identifying the broad swath cut by public health issues. These statements are more esoteric than practical. If these definitions guided public health practices, “the health department ought to be the biggest state agency.”<sup>136</sup>

We can find assistance in narrowing the topic by examining what modern functions are generally within the purview of public health agencies. These include the control and elimination of

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city’s inherent police powers); *Barnes v. Glen Theatre, Inc.*, 501 U.S. 560, 569 (1991) (upholding Indiana’s public nudity ban); *City of Newport v. Iacobucci*, 479 U.S. 92, 95 (1986) (citing *California v. LaRue*, 409 U.S. 109, 114 (1972)) (interpreting the Twenty-First Amendment); *Head v. New Mex. Bd. of Exam’rs in Optometry*, 374 U.S. 424, 428 (1963) (stating, “the statute here involved is a measure directly addressed to protection of the public health, and the statute thus falls within the most traditional concept of what is compendiously known as the police power.”).

133. *Sporhase v. Neb., ex rel. Douglas*, 458 U.S. 941, 956 (1982).

134. WORLD HEALTH ORG., BASIC DOCS. 1 (41st ed. 1996).

135. COMMITTEE FOR THE STUDY OF THE FUTURE OF PUBLIC HEALTH, INSTITUTE OF MEDICINE, THE FUTURE OF PUBLIC HEALTH 7 (1988) [hereinafter FUTURE OF PUBLIC HEALTH].

136. Lawrence O Gostin, Scott Burris & Zita Lazzarini, *The Law and the Public’s Health: A Study of Infectious Disease Law in the United States*, 99 COLUM. L. REV. 59, 69 (1999) (defining public health).

diseases and illness;<sup>137</sup> sewage and garbage removal;<sup>138</sup> quarantine;<sup>139</sup> water filtration, fluoridification, and treatment;<sup>140</sup> licensing of medical professionals;<sup>141</sup> disclosure of medical information;<sup>142</sup> pollution prevention;<sup>143</sup> health education;<sup>144</sup> vaccinations;<sup>145</sup> inspections of private and commercial buildings;<sup>146</sup> and regulation of food and drugs.<sup>147</sup>

Public health agencies may have the authority to reach only one or all of these issues.<sup>148</sup> Other matters that play important public health roles such as environmental regulation, policing and crime control, poverty reduction, and labor protections are typically resigned to other local, state, and federal agencies that rarely or poorly coordinate with health officials.<sup>149</sup> Occasionally, the lack of a coherent definition of public health has resulted in an inability to deal effectively with large-scale problems that affect social well-being.<sup>150</sup>

Although public health encompasses a wide range of activities and regulations, a great deal of it is outside the more particular area of health care and closely related practices. By “health care,” we refer to the region of public health that relates to the practice and development of medicine. Under our definition, health care is

137. See 39 AM. JUR. 2D *Health* § 52 (2004).

138. See *id.* § 49.

139. See *id.* §§ 59-64.

140. See *id.* § 49; 78 AM. JUR. 2D *Waterworks and Water Companies* §§ 31-39.

141. See 39 AM. JUR. 2D *Health* § 80 (2004).

142. See *id.* § 83.

143. See *id.* § 49; 61A AM. JUR. 2D *Pollution Control* § 50 (2004).

144. See, e.g., 42 U.S.C. § 247c (2004) (providing authorization for federal funding of STD education and prevention programs); MINN. STAT. § 144.05, subd. 1(e) (2004) (providing that the state Department of Health “[p]romote personal health by conducting general health education programs and disseminating health information”).

145. See 39 AM. JUR. 2D *Health* §§ 65-69 (2004).

146. See *id.* §§ 70-79 (2004).

147. See *id.* § 49.

148. See FUTURE OF PUBLIC HEALTH, *supra* note 135, at 81-83.

149. See *id.* at Appendix A (describing organization of defined public health agencies). What is not included in this assessment warrants attention. The Department of Justice, Environmental Protection Agency, and the Department of Labor are conspicuously missing despite the reach over various medical and public health activities. See, e.g., 29 C.F.R. §§ 1910.1-1910.1018 (2004) (setting out occupational health and safety standards for the Department of Labor). States likewise divide resources and oversight between similar agencies. See, e.g., MINN. STAT. §§ 116.1-116.115 (2004) (establishing a pollution control agency separate from state health agencies).

150. FUTURE OF PUBLIC HEALTH, *supra* note 135, at 81-83.

the process by which the medical profession is able to directly act to benefit public well-being. These activities relate to the physical involvement of doctors in directing and implementing personal care and healthy living. This excludes such issues as crime control, broad environmental concerns, and poverty reduction. With this in mind, we identify six categories of traditional state health care practices: (1) regulation of the practice of medicine through licensing;<sup>151</sup> (2) containment, treatment and elimination of disease including sanitation, inoculation, and quarantine;<sup>152</sup> (3) care for the mentally ill;<sup>153</sup> (4) health education;<sup>154</sup> (5) vital statistics;<sup>155</sup> (6) and medical research.<sup>156</sup> These categories may not be exclusive and a thorough examination of each is not necessary to understanding the traditional control of health care by the states, but they provide a sufficient basis to categorize most current activities quickly. The information to be gleaned from a historical summary is not what specific activities states have historically carried out, but rather the broad fundamental purposes behind these actions. Answering these questions provides a basis for applying federalism principles to current hot button issues.

### C. *A History of State Medical Regulation*

#### 1. *Colonial America*

In the early years of the colonies, private or religious groups, not community governments, often performed public services.<sup>157</sup> Health care, however, was very different. William Penn, while looking for land for what was to become Philadelphia, wanted a

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151. See 39 AM. JUR. 2D *Health* § 80 (2004).

152. See *id.* § 52.

153. See *id.* §§ 106-08.

154. See, e.g., MINN. STAT. § 144.055, subd. 1 (2004) (authorizing the commissioner of health to develop and conduct health education programs).

155. See, e.g., MINN. STAT. § 144.213, subd. 1 (2004) (authorizing the commissioner of health to maintain vital statistics).

156. See, e.g., 42 U.S.C. § 247c (2004) (providing authorization for federal funding of STD education and prevention programs); MINN. STAT. § 144.05, subd. 1(e) (2004) (providing that the state Department of Health “[p]romote personal health by conducting general health education programs and disseminating health information.”).

157. See Wendy E. Parmet, *Health Care and the Constitution: Public Health and the Role of the State in the Framing Era*, 20 HASTINGS CONST. L.Q. 267, 285-86 (1993) (discussing public health practices in the colonial and federalist periods).

location that was “navigable, high, dry, and healthy.”<sup>158</sup> He was intimately concerned with the plague and fires that decimated London and wanted a town consisting of widely spread lots so contamination and fire could not easily ravage the city.<sup>159</sup> Penn would have been disappointed to learn few public health regulations were adopted in early Philadelphia, but the northern cities quickly developed mechanisms to deal with sickness.<sup>160</sup>

Like Penn, many early settlers came to North America believing that the public health was a governmental function.<sup>161</sup> Disease was common and communities quickly responded.<sup>162</sup> With little medical knowledge, settlers implemented policies that had been used in Europe for hundreds of years.<sup>163</sup> Many of these practices arose during Europe’s constant battle with the black plague.<sup>164</sup> Those responsible for implementing health care polices shared no common backgrounds. Often, barber-surgeons, religious leaders, or community officials implemented health care measures.<sup>165</sup>

In New Amsterdam, which would become New York, no trained surgeons accompanied the first settlers.<sup>166</sup> When the first surgeon with a medical degree arrived, the Governor was notified and he soon became a member of the Council.<sup>167</sup> He was even

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158. JOSEPH E. ILLICK, *COLONIAL PENNSYLVANIA: A HISTORY* 30 (1976) (quoting William Penn).

159. *Id.* Penn was likely more concerned with potential fires than with disease. His original plan called for the distribution of large plots of land so no house or building would be close to another, thereby avoiding the spread of fire. *Id.*

160. *See generally* JOHN B. BLAKE, *PUBLIC HEALTH IN THE TOWN OF BOSTON 1630-1822* 3, 5-7 (1959) (stating how Boston settlers first relied upon other aspects of society in addition to medical knowledge and beliefs in response to sickness, and realizing they needed to train their own physicians); JOHN DUFFY, *A HISTORY OF PUBLIC HEALTH IN NEW YORK CITY 1625-1866* 7-10 (1968) (stating New York implemented an ordinance directed at immoderate drinking, and another action intended to keep the area clean).

161. *See* Parmet, *supra* note 157, at 286.

162. *See* BLAKE, *supra* note 160, at 3-7 (stating settlers “frequently held fast days . . . because of sickness,” and the President of Harvard requested funding for medical books to help provide an educational basis for medical training).

163. *See generally id.* at 8 (noting that many early medical practitioners learned via an “apprenticeship system” modeled after the teaching method used in England).

164. *See generally* Katherine Park, *Medicine and the Renaissance, in* WESTERN MEDICINE: AN ILLUSTRATED HISTORY 66-79 (Irvine Loudon, ed., 1997); BERNHARD J. STERN, *SOCIETY AND MEDICAL PROGRESS* 21-24 (1941).

165. DUFFY, *supra* note 160, at 8-9.

166. *Id.* at 7.

167. *Id.* at 9 (Dr. Johannes La Montagne, New York’s first physician, arrived in

responsible for making exceptions to a City Council edict granting barber-surgeons the exclusive rights to practice their trade, making it possibly the first medical licensing rule in the colonies.<sup>168</sup> Boston attempted to institute “licensing” in 1649, but had no method of enforcement.<sup>169</sup>

Licensing was, at least in part, an attempt to assure the public of quality care when very few people were well trained.<sup>170</sup> As the early New York experience shows, the partnership between medical practitioners and public officials was an early and essential development in state health administration.<sup>171</sup> Officials would rely on the advice of privately trained doctors and back their educated opinions with the force of law.<sup>172</sup>

Licensing constituted only one of several key health care policies developed in early America. Most colonists understood the need to be proactive in preventing illness. By the turn of the eighteenth century, much of the hold religious institutions had over Boston’s government affairs had diminished.<sup>173</sup> This allowed health conscious citizens to advocate their causes to city leaders.<sup>174</sup> The shift significantly altered the role of the medical community.<sup>175</sup> Instead of religious doctrines guiding the course of health care practices, the direct connection with city leaders permitted a more secular and scientific approach.<sup>176</sup>

Responding to this advice, Boston’s selectmen and General Court imposed sanitary restrictions on butchers, distillers, and others to prevent decay and nuisances from invading the city streets.<sup>177</sup> It also experimented with street cleaning and waste regulations, mostly to keep city streets free of filth.<sup>178</sup> Boston also successfully adopted a standard port quarantine process requiring

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1637).

168. *Id.*

169. *See* BLAKE, *supra* note 160, at 9 (stating that “the General Court in 1649 required surgeons, physicians, and midwives to do nothing contrary to the known approved rules of their art . . . but provided no means of execution”).

170. *See id.*; *see also* DUFFY, *supra* note 160, at 9, 33-34.

171. *See* BLAKE, *supra* note 160, at 9.

172. *Id.*

173. *Id.* at 23-26; *see* JAMES F. COOPER, JR., TENACIOUS OF THEIR LIBERTIES: THE CONGREGATIONALISTS IN COLONIAL MASSACHUSETTS 11-14 (1999) (discussing the early role churches played in controlling Massachusetts politics).

174. *See* BLAKE, *supra* note 160, at 23-24.

175. *Id.*

176. *See id.*

177. *Id.* at 29.

178. *Id.* at 30-31.

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interrogations of all incoming ships; if any crew member was sick or if its departure point was experiencing an epidemic, no crew would be let ashore.<sup>179</sup>

In the late seventeenth century New Amsterdam fell under English rule and became New York.<sup>180</sup> The city's Council passed a law in 1693 that permitted a tax on residents for cleansing and paving the streets, although it was not truly effective.<sup>181</sup> The city also passed laws to prevent the roaming of hogs and cattle which "cause[d] great stench and filth within this City,' help[ed] to infect the streets, and thus engender[ed] serious sickness."<sup>182</sup> These first sanitation laws reflected a commitment on the part of local officials proactively to involve themselves in public health.<sup>183</sup> The state of medicine was such that one of the few agreed upon principles was that filth and putrescence brought disease.<sup>184</sup> If filth was a disease-causing agent, it was the city's responsibility to fix the problem.<sup>185</sup>

New York also followed Massachusetts' lead and established a basic licensure law.<sup>186</sup> It ordered that no person shall practice medicine without the consent of an established member of the profession "to restrain the presumptuous arrogance of such as, through confidence of their own skill or any other sinister respects, dare boldly attempt to exercise violence upon or towards the body . . . ."<sup>187</sup> The law was severely underenforced, but it established a framework for direct public involvement in the practice of private medicine.<sup>188</sup>

Probably the most notable actor in the licensure movement was Dr. Caldwell Colden of New York. He practiced as a surgeon and quickly rose to become a leading public official.<sup>189</sup> He was

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179. *Id.* at 32.

180. See HENRY WILLIAM ELSON, HISTORY OF THE UNITED STATES OF AMERICA 138 (1904), available at <http://www.usahistory.info/colonies/New-York.html>.

181. DUFFY, *supra* note 160, at 25-26.

182. *Id.* at 29.

183. *Id.* at 23-24.

184. *Id.*

185. *Id.*

186. *Id.* at 33.

187. *Id.* (quoting JAMES J. WALSH, HISTORY OF THE MEDICAL SOCIETY OF THE STATE OF NEW YORK 11 (1907)).

188. *Id.* at 33-34.

189. *Id.* at 42-43. "[H]e was without question the first significant medical figure in New York." *Id.* at 43.



influential in establishing the first statewide licensing law in 1760.<sup>190</sup> It required that all persons wishing to practice medicine must appear before an appointed government council and imposed fines on any person caught practicing without a license.<sup>191</sup> The laws increased the value of medical education to both the community and to doctors who were financially dependant upon those willing to see them.<sup>192</sup>

The more visible regulation of medical professionals also encouraged the creation of hospitals, or sick houses. By 1773, New York had appropriated money and land to several esteemed members of a recently founded medical college and construction began.<sup>193</sup> The rise of the medical college, the hospital and licensing were all interrelated.<sup>194</sup> As licensing increased a doctor's need for education, the greater student enrolments required clinics where the trade could be practiced.<sup>195</sup> Boston developed much faster in this area as the city's Selectmen approved a quarantine hospital in 1719.<sup>196</sup> Public officials made ad-hoc decisions regarding whom to quarantine, but relied on the opinion of respected doctors before making a final order.<sup>197</sup>

Mass epidemics were likely the impetus for most public action as exhibited by cities' significant investment in quarantine laws. Smallpox brought disaster to Boston in 1721, 1729, and again in 1752 killing hundreds and sickening thousands.<sup>198</sup> Philadelphia was plagued in 1736 and Charleston was hit in 1738.<sup>199</sup> The epidemics marked two important changes in public health care. First, inoculations were invented and local governments became contentiously involved in their regulation.<sup>200</sup> Many of the new

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190. *Id.* at 65.

191. *Id.* at 65-66. Medical licensing was still very much in its infancy and not very effective. Medical societies that were largely constituted with educated doctors wanted to ensure the sanctity of their professions, but had little ability to oversee daily operation of apprenticed or self trained surgeons. For a more thorough discussion of early licensing see PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 44-47 (1982).

192. DUFFY, *supra* note 160, at 65.

193. *Id.* at 66-67.

194. *Id.* at 65-66.

195. *Id.* at 66.

196. BLAKE, *supra* note 160, at 35-36.

197. *Id.* at 46.

198. *Id.* at 54-55, 75, 83-87 (noting the various outbreaks).

199. *Id.* at 78, 82. Philadelphia took little effort in developing any long term strategies and was hit with minor epidemics nearly every four years. *Id.* at 111-12.

200. *Id.* at 62-63, 96-97.

educated doctors inoculated the sick without city approval, sparking concern among public officials that the practice may endanger rather than benefit public health.<sup>201</sup> Eventually city governments caved, and although many had made vaccination illegal for a period, most eventually permitted or required vaccinations.<sup>202</sup> The debate marks an important chapter in state experimentation. Communities did not practice inoculation in the same manner. Boston experienced a fifty-year battle over whether inoculation was a desired or healthy activity and at points outlawed the practice.<sup>203</sup> New York on the other hand embraced it mid-century and continued to inoculate despite controversy.<sup>204</sup>

The increase of quarantine houses was also dramatic, but most importantly, epidemics encouraged the recording of vital statistics.<sup>205</sup> Cities began experimenting with inoculation and needed to assess effectiveness. Although birth and death certificates had been issued in Boston for nearly 100 years, the records were incomplete and not much significance to public health.<sup>206</sup> Taking toll of the causes of death was probably essential for students of medicine who could now look at patterns of disease and attempt to discern root causes.

The inability of doctors to determine the etiology of most diseases also pressed governing bodies to pursue preventive sanitation and curative quarantine strategies.<sup>207</sup> In early and revolutionary America, much of medical science was devoted to understanding and curing disease, and this was closely related to sanitation.<sup>208</sup> Practitioners did not understand germ theory and saw their job as not only treating the sick, but also providing conditions to keep them healthy.<sup>209</sup> For example, cities would often halt ships at port if infection was present.<sup>210</sup> Even more astonishing, often every ship departing from plagued cities was ordered inspected, often by medical professionals, until the epidemic was considered

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201. *Id.*

202. *Id.* at 114-15.

203. *Id.* at 52-73 (discussing the beginning of the inoculation debate), 82-98 (discussing the later years of the inoculation debate).

204. *Id.* at 97.

205. *Id.* at 106-07.

206. *Id.* at 106.

207. *See* Parmet, *supra* note 157, at 295.

208. *Id.*

209. *Id.*

210. *See* BLAKE, *supra* note 160, at 80-82.

over.<sup>211</sup> These positions would become even more pronounced in post revolutionary states.<sup>212</sup>

## 2. *Post-Revolution and Municipal Controls*

By 1800 it was clear that local and state government had a role to play in health care. Johann Peter Frank, an enlightenment writer and doctor, believed the core function of government was to act as “medical police” to “apply certain principles for the health care of people living in society.”<sup>213</sup> The city of Chicago was founded on these principles in 1833 after a cholera epidemic necessitated an organized response.<sup>214</sup>

The Massachusetts Supreme Court issued one the most resounding and clear indications of health care’s role in city governance. In *Baker v. City of Boston*,<sup>215</sup> a landowner had used a creek running by his property to transport goods, which the city had set to fill.<sup>216</sup> He challenged the right of the city to restrict his access to water, but the court found it was within the right and duty of the city to do what it must to protect public health.<sup>217</sup>

It has not been denied, nor can it be, that the mayor and aldermen are clothed with legislative powers and prerogatives to a certain extent, and that they are fully empowered to adopt measures of police, for the purpose of preserving the health, and promoting the comfort, convenience and general welfare of the inhabitants within the city. Among these powers no one is more important than that for the preservation of the public health. It is not only the right but the imperative duty of the city government, to watch over the health of the citizens, and to remove every nuisance, so far as they may be able, which may endanger it. And they have necessarily the

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211. *Id.* at 78.

212. Parmet, *supra* note 157, at 295-96.

213. WILLIAM J. NOVAK, *THE PEOPLE’S WELFARE: LAW AND REGULATION IN NINETEENTH CENTURY AMERICA* 192 (1996) (quoting JOHANN PETER FRANK, *A System of Complete Medical Police*, in *SELECTIONS FROM JOHANN PETER FRANK* (Erna Lesky ed., 1976)).

214. *Id.* at 193. By the following year, “a stringent health code (including provisions for the removal of nuisances, the disposal of waste, street cleaning, house inspection, mandatory public works, a cholera hospital, and Committees of Vigilance) greeted the onset of a new cholera season.” *Id.*

215. 12 Pick. 184 (Mass. 1831).

216. *Id.* at 188.

217. *Id.* at 198.

power of deciding in what manner this shall be done; and their decision is conclusive, unless they transcend the powers conferred by the city charter, or violate the constitution.<sup>218</sup>

The strength of this language is not surprising considering every member on the court lived through the small pox and “yellow fever” epidemics (mostly typhoid, typhus, and malaria) that swept the east coast in the early nineteenth century.<sup>219</sup> The diseases were disastrous and hit every city on a near yearly basis causing evacuations and mass quarantines.<sup>220</sup> Even before 1800, New York authorized a commission to study the conditions and causes of disease.<sup>221</sup> The resulting report covered everything from possible causes to recommended solutions and set the stage for a flurry of activities.<sup>222</sup> By 1810, New York had a full time city health inspector, a Board of Health, and had taken the recommendation of local doctors to require the issuance of death certificates.<sup>223</sup> The New York Board even commissioned medical studies to pave the direction for new policies.<sup>224</sup>

Philadelphia had established its Board of Health before the turn of the century and although Boston’s Board was founded in 1799, it did not get full state authorization until 1816.<sup>225</sup> In both cases, however, the Boards were given broad and welcomed powers. Boston’s Board was permitted “to make rules, regulations and orders for preventing, removing, or destroying nuisances, sources of filth, and causes of sickness . . . .”<sup>226</sup> These included regulations on everything from specifying burial site depth to recording the

218. *Id.* at 197-98.

219. *See generally* BLAKE, *supra* note 160, at 126-27, 151-76; DUFFY, *supra* note 160, at 97-123.

220. BLAKE, *supra* note 160, at 126-27, 151-76; DUFFY, *supra* note 160, at 97-123. The problem is that the illnesses being contracted probably were not significantly affected by most public health measures. Quarantine would have been only moderately effective, and possibly detrimental, because most of the illnesses were bacterial mosquito borne, not contagious like the plague. While draining cellars and filling bogs helped, it probably did not resolve the problem.

221. DUFFY, *supra* note 160, at 135-37.

222. *Id.*

223. *Id.* at 143-49.

224. *Id.* at 156.

225. NOVAK, *supra* note 213, at 201. It is also important to note that Boston was not actually chartered as a city until 1822. Prior to that, most governing had been at the county level, not by city governance. *See* BLAKE, *supra* note 160, at 234.

226. NOVAK, *supra* note 213, at 201 (quoting MASS. GEN. LAWS ch. 44 (1816), “An act to empower the town of Boston to choose a Board of Health, and to prescribe their power and duty.”).

name, age, and sex of the deceased.<sup>227</sup>

New York's board was comprised of predominantly medical officials.<sup>228</sup> Boston's early health officials were mostly politicians, often seeking appointment to the board as a political stepping-stone.<sup>229</sup> Despite these differences, heads of the boards took their roles seriously. Benjamin Whitman, who served as Chair of the Boston Board of Health for twelve years, upon his resignation stated:

It is . . . all important that the Board of Health, who are daily conversant with the state and condition of the city . . . and with those causes which aggravate disorders, and impair the health and comfort of the people, should have the power . . . promptly and effectually to make all such orders and regulations, as become indispensable . . . .<sup>230</sup>

Like other pronouncements of the era, the Board's power was not meant to address issues such as poverty or economic concerns. In 1819, Boston's Board expressed the limits of its authority after a physician called its attention to the poverty that often resulted from long bouts with disease:

[I]t is not within [our] official powers or duty, to afford relief to that unhappy family—as [our] authority and duty only extends to such sick and diseased persons, as are affected, or eminently exposed to contagious or malignant disorders, such as jeopardize the health and life of the citizens . . . and not to cases of poverty and distress or sickness of an ordinary nature . . . .<sup>231</sup>

These self imposed limitations did not prevent the boards from achieving moderate successes. Cities dramatically improved programs for sanitation, quarantine housing, and some basic treatment in substandard hospitals.<sup>232</sup> However, the lack of significant medical advancements during the period meant little changed in the methods used to combat health care problems. The medical revolution of the mid-nineteenth century would inevitably expand the state's role in medical regulation even

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227. BLAKE, *supra* note 160, at 212, 214.

228. See DUFFY, *supra* note 160, at 130-44.

229. BLAKE, *supra* note 160, at 230.

230. *Id.* at 236 (quoting Bd. of Health, Comm. of Week, Records (1821-24), May 10, 1823 (farewell address by Benjamin Whitman)).

231. *Id.* at 241 (quoting Bd. of Health, Comm. of Week, Records (1821-21), Aug. 17, 1819 (the Board members' response)).

232. See *id.* at 192, 207.

further.

### 3. *The Modern State Administrative System*

The medical advancements of the mid-nineteenth century such as anesthesia, sterilization of instruments, and the eventual understanding of germ theory transformed the medical profession and its regulations.<sup>233</sup> Medical college admissions and graduate rates soared accordingly.<sup>234</sup> This placed an economic hurdle before well-trained and well-educated clinicians who were competing with many self-taught or simply self-professed doctors.<sup>235</sup>

Educated doctors, who were probably motivated in part by their wallets and in part by legitimate concern for the practice of their profession, succeeded in finally pressuring state health boards to enact clear and strong licensing laws by the 1870s.<sup>236</sup> These licensing schemes, like their predecessors, never explicitly delineated control over specific practices. Rather, licensure laws simply required accreditation from reputable medical programs and left the practice of medicine to the medical community.<sup>237</sup> It was clear administrators would not and could not effectively control medical developments. As was the case in the Colonies, doctors would go to public officials, present their ideas, and regulations would be born.

The number of people graduating from medical schools had another important impact: hospital growth. What began as a proliferation of quarantine hospitals nearly a century earlier was by 1850 a new public necessity. For example, between 1800 and 1855, Bellevue's patient role increased nearly 1000 percent.<sup>238</sup> By 1860 it was treating nearly 6000 patients annually, and thousands more were being seen at one of New York's eight other newly developed hospitals and asylums.<sup>239</sup> Additionally, grim facilities were opened

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233. See Edward P. Richards, *The Police Power and Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA—Qualified Managed Care Organizations*, 8 ANNALS HEALTH L. 201, 209-10 (1999).

234. See DUFFY, *supra* note 160, at 473.

235. See *id.* at 474-75; STARR, *supra* note 191, at 81-85.

236. See STARR, *supra* note 191, at 81-85; Richards, *supra* note 233, at 211.

237. Richards, *supra* note 233, at 211.

238. DUFFY, *supra* note 160, at 250 (only 186 patients were seen over the peak summer months in 1803).

239. *Id.* at 498-99.

to “treat” the mentally ill.<sup>240</sup>

Prior to 1825, most communities did not consider insanity a health care issue.<sup>241</sup> Insanity was instead often viewed as a moral disease. Communities would send ill individuals to prisons, care for them privately, or in some cases literally sneak the impaired into neighboring towns with the hope of pushing off their burden.<sup>242</sup> While several asylums existed, care for the mentally ill was not considered a public function until Massachusetts took the lead in 1838.<sup>243</sup> Many local communities would pay for the housing of the dangerously ill, but as the number of terminally mentally ill patients increased, cities could no longer afford to deal with them effectively.<sup>244</sup> This resulted in battles between state and local authorities.<sup>245</sup>

Local governments did not want to give up power over their institutional housing, but needed the financial backing of the state.<sup>246</sup> Expectedly, local governments were soon largely cut out. Since state funding was at issue, the state needed to regulate admissions, length of stays, and treatments provided.<sup>247</sup> It is not necessary to delve into the type of care provided or the extent to which health professionals were involved in the legislation. The nature of the service can be gleaned from the debate between state and local officials.<sup>248</sup> Both governing bodies envisioned care for ill citizens as part of their primary responsibility.<sup>249</sup> When the state eventually assumed the position, it was seen as a partnership between the local and state level; federal involvement was not even considered.

Significant state involvement naturally led to the creation of permanent oversight agencies. Lemuel Shattuck’s 1850 *Report of the Sanitary Commission of Massachusetts* was influential in reorganizing state public health planning and succeeded in instituting the first

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240. *Id.* at 499-500.

241. *See* RUTH B. CAPLAN, *PSYCHIATRY AND THE COMMUNITY IN NINETEENTH CENTURY AMERICA: THE RECURRING CONCERN WITH THE ENVIRONMENT IN THE PREVENTION AND TREATMENT OF MENTAL ILLNESS* 65-66 (1969).

242. *Id.*

243. *Id.* at 66.

244. *Id.* at 66-67.

245. *Id.* at 67.

246. *Id.* at 67-70.

247. *Id.*

248. *Id.* at 63.

249. *Id.* at 66.

state Board of Health in 1869.<sup>250</sup> As one author describes:

State boards were usually charged with the following responsibilities: (1) the organization of local boards; (2) the collection of medical and vital statistics; (3) the investigation of the causes of disease and mortality; (4) the removal of causes of disease (especially nuisances) with the cooperation of local sanitary officers; (5) the supervision of state hygiene institutions like prisons and asylums; and (6) the supervision of quarantine.<sup>251</sup>

The idea of statewide agencies and uniform public health governance attracted many around the country. In 1872, the American Public Health Association was founded and quickly issued recommendations on state health care practices.<sup>252</sup> The Association urged state boards to conduct oversight, assistance, and collection of statistics, but sanitation and individual care should remain at the local level.<sup>253</sup> Shortly after, public health laboratories were founded to research the causes of, and cures for, diseases.<sup>254</sup> Both state and local laboratories were to detect diseases and design controls, develop new diagnostic procedures, and manufacture and distribute vaccines.<sup>255</sup> By 1913 every state had some form of health department.<sup>256</sup>

The short history detailed above does not provide an exhaustive examination of the multitude of activities in which states have traditionally engaged, but it does indicate the ways in which health care was a chief regulatory area of state and local governments. Although the size and reach of public health bodies drastically expanded over the last 100 years, the basic functions performed by local communities and state offices have not significantly changed.

#### *D. Federal Regulation: A Modern Tradition*

The real emergence of national action in the health care arena arose with Roosevelt's New Deal.<sup>257</sup> Prior to 1900, the federal

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250. WILSON G. SMILLIE, PUBLIC HEALTH ADMINISTRATION IN THE UNITED STATES 13 (1935).

251. NOVAK, *supra* note 213, at 203.

252. See SMILLIE, *supra* note 250, at 213, 216-17.

253. *Id.* at 17-18.

254. *Id.* at 18.

255. *Id.* at 175-80.

256. *Id.* at 16, fig. II.

257. See James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12



government only marginally involved itself in health care activities.<sup>258</sup> Within the first quarter of the century, however, Congress made a few significant regulations that paved the way for the explosion in federal health care involvement. In 1906, Congress passed the Food and Drug Act, which sought to prevent adulteration, mislabeling, and fraud in the food and drug industry.<sup>259</sup> Its requirements aimed at “protecting the pocketbook of the consumer as much as the health.”<sup>260</sup> Today, the revised Act regulates nearly all the “testing, marketing, and promotion” of medicines in the United States.<sup>261</sup> However, both the original and revised Act of 1938 applied, on its face, to only those items introduced to or received in interstate commerce.<sup>262</sup> The Maternity and Infancy Act of 1921, another important pre-New Deal step, was the first major federal spending program devoted to public health.<sup>263</sup> Funding was given to states that agreed to develop obstetrics and child care programs.<sup>264</sup>

These laws signify the two main sources of federal health care authority—the spending power under Article 1, Section 8<sup>265</sup> and the commerce power under Article 1, Section 8.<sup>266</sup> The manner of regulation associated with each is significantly different. The spending power does not enable Congress to require or to *forcefully* prevent direct action by a state.<sup>267</sup> Rather, if Congress would like a state to adopt a particular program, it must offer the state a choice.<sup>268</sup> The state can receive federal dollars only if it adopts the measures suggested by Congress.<sup>269</sup> However, the state has the

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J.L. & HEALTH 309, 331 (1998).

258. *Id.* at 331-33; JENNIE JACOBS KRONEFELD, THE CHANGING FEDERAL ROLE IN U.S. HEALTH CARE POLICY 67-69 (1997).

259. KRONEFELD, *supra* note 258, at 70.

260. *Id.*

261. *Id.*

262. *See* 21 U.S.C. § 331 (2002) (providing a clear jurisdictional hook).

263. *Id.*; Hodge, *supra* note 257, at 332.

264. Hodge, *supra* note 257, at 332.

265. U.S. CONST. art. I, § 8.

266. U.S. CONST. art. I, § 4.

267. *See, e.g.,* South Dakota v. Dole, 438 U.S. 203, 211 (1987) (implying that the federal government cannot compel state action pursuant to the spending power).

268. *See* Pennhurst State Sch. & Hosp. v. Halderman, 451 U.S. 1, 17 (1981) (stating that a state must be given the free choice to voluntarily accept or reject federal funds).

269. *Id.*

authority to reject the funding and not implement the program.<sup>270</sup> The passage of the Sixteenth Amendment, which established the federal income tax, provided the government with an enormous new purse<sup>271</sup> with which the government could finance, among other things, health care initiatives. The Social Security Act of 1935 was the first major national push to make use of these new funds. It established direct aid for maternal and child services and invested in local boards of health, health laboratories, and research into disease and sanitation control.<sup>272</sup> The Supreme Court has not addressed the constitutionality of the spending portion of the Act.<sup>273</sup> Presumably, this is because the power to spend for the general welfare was presumed by most to be a valid exercise of federal authority.

Under the spending power, Congress possesses nearly unlimited discretion as to how and on what programs tax dollars will be spent.<sup>274</sup> It is constrained only by the rule that while Congress may encourage states to act, it cannot compel a state to carry out those acts.<sup>275</sup> This has allowed for a large federal effort to help improve health care in the United States, pursuant to the government's ability to spend for the general welfare. For instance, the National Institute of Health, which was founded in 1930 for the basic purpose of researching hygiene and disease, has blossomed to include a National Cancer Institute, National Eye Institute, National Institute on Child Health and Human Development, and even a National Center for Complimentary and Alternative Medicine, to name just a few.<sup>276</sup> These centers and institutes are primarily research, development, and financial assistance bodies, developing programs and strategies which are then offered to states for implementation.<sup>277</sup> Other Acts, like the Mental Health Act of

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270. See, e.g., *Kansas v. United States*, 214 F.3d 1196, 1202-03 (making distinctions between impermissible coercion and a situation where states are "free to reject" the funding).

271. Hodge, *supra* note 257, at 333.

272. KRONEFELD, *supra* note 258, at 70-71.

273. See generally *Steward Mach. Co. v. Davis*, 301 U.S. 548 (1938) (upholding the statutes' taxing authority).

274. See *South Dakota v. Dole*, 438 U.S. 203, 206-07 (1987) (establishing the few limitations on the spending power).

275. *New York v. United States*, 505 U.S. 144, 166 (1992).

276. See National Institute of Health, Institutes Centers, and Offices, at <http://www.nih.gov/icd/> (listing twenty institutes currently within the National Institute of Health).

277. *Id.* (providing brief descriptions of each institute).

1946, the Mental Retardation Facilities & Community Mental Health Service Act of 1963 which financed the growth and development of local mental health facilities, and the passage of Medicare and Medicaid in 1966 further expanded federal reach.<sup>278</sup>

In contrast to the spending power, the commerce power enables Congress to prevent certain state (or even private) activities that differ from the manner in which it desires to regulate commerce.<sup>279</sup> For example, the Controlled Substance Act (CSA),<sup>280</sup> enacted in 1970, sets a baseline for all marketing, distribution, and sale of drugs in the United States. The CSA goes beyond many other federal health care measures by attempting to regulate very local activities within the medical profession. The CSA includes provisions governing the quantity of drugs that may be prescribed or distributed.<sup>281</sup> The Attorney General is authorized to revoke the registration of any person who does not comply with these provisions<sup>282</sup> and the CSA even allows suspension if the Attorney General deems an action to be “an imminent danger to the public health or safety.”<sup>283</sup>

Although the CSA is not an express statement of control over health care decisions, the modern practice of medicine necessitates the use of some type of drug. The apparent discretion given to the Attorney General to decide whether an action is an imminent threat to public health gives the office enormous control over medical decisions.<sup>284</sup> The CSA, by its own terms, also directly governs the mere possession of a controlled substance.<sup>285</sup> It curiously fails to require that the substance be manufactured, distributed, or even that the possessor have the intent to distribute or manufacture the substance. Governing the mere possession of drugs pushed federal regulation into uncharted territory.

Federal reach under the Commerce Clause has also affected

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278. See FUTURE OF PUBLIC HEALTH, *supra* note 135, at 68.

279. See, e.g., *New York*, 505 U.S. at 167 (discussing recognition of regulatory power over private activities specifically and regulatory powers more generally).

280. Controlled Substance Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801-904 (2004)).

281. 21 U.S.C. § 823(g)(1)(c) (2004).

282. *Id.* § 824(a)(4).

283. *Id.* § 824(d).

284. *Id.* § 824(d). The Attorney General will be able to make medical decisions regarding when a drug is an imminent danger, which could restrict doctors in their ability to prescribe medications they believe will assist their patients.

285. *Id.* § 844(a).

medical decision-making in less direct ways. In 1974, Congress passed the Employee Retirement and Income Security Act (ERISA).<sup>286</sup> A main provision of the Act preempts state laws that relate to employee benefit plans.<sup>287</sup> These plans include employer provided health care plans.<sup>288</sup> States that desire to ensure insurance companies provide the type and quality of care believed most beneficial to its citizens have often found ERISA imposed preemption bars.<sup>289</sup> This includes such things as state tort and contract actions when state law requires coverage for certain medical practices, but the employer's selected plan does not.<sup>290</sup>

A detailed history and overview of federal public health regulation is beyond the scope of this article, but the examples given above provide an adequate look into the nature of federal health care regulation. Today, federal health care programs are mostly governed by six agencies: "1) The Centers for Disease Control; (2) the National Institutes of Health; (3) the Food and Drug Administration; (4) The Health Resources and Services Administration; (5) the Alcohol, Drug Abuse and Mental Health Administration; and (6) the Agency for Toxic Substances and Disease Registry."<sup>291</sup> These combined agencies are involved in many aspects of health care. They assess and gather health related statistics, research and develop cures for diseases, implement funding for health care and medical provisions, develop and implement health care policies, seek to educate the public and health care professionals, and a host of other activities from policy setting to direct care.<sup>292</sup>

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286. See Employee Retirement Income Securities Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (codified as amended at 29 U.S.C. §§ 1001-1461 (1988 & Supp. V 1993)).

287. 29 U.S.C. § 1144(a) (2004) (including benefit plans as defined in 29 U.S.C. § 1003 (2004)).

288. 29 U.S.C. § 1103.

289. See James E. Holloway, *ERISA, Preemption and Comprehensive Federal Health Care: A Call for "Cooperative Federalism" to Preserve the States' Role in Formulating Health Care Policy*, 16 CAMPBELL L. REV. 405, 439-42 (1994).

290. *Id.* at 420-21.

291. FUTURE OF PUBLIC HEALTH, *supra* note 135, at 166.

292. *Id.* at 168-70.

IV. *RAICH* AND THE REACH OF NEW FEDERALISMA. *The Role of Traditional State Interests*

Because *Lopez* and *Morrison* do not address where the traditional state interest issue falls into the Commerce Clause analysis, it is possible that the Court will follow the Ninth Circuit and resolve *Raich*<sup>293</sup> without discussing the extent to which health care is traditionally a state concern. If the Court does exclude the issue from its analysis in *Raich* entirely, it could affect future health care-related Commerce Clause cases by signaling that the traditional state interest consideration will not factor into *Morrison* analysis. A result along those lines, however, would speak more to the future of Commerce Clause jurisprudence generally than to health care. Likewise, the Court may dispose of *Raich*, without reaching the Commerce Clause issue at all, by holding that the plaintiffs do not have standing.<sup>294</sup> Because the first scenario would impact health care at most tangentially, and the second not at all, the implications of both are beyond the scope of this article. The more likely scenario is that the Court will follow *Lopez* and *Morrison* and include the traditional state concern issue in its Commerce Clause analysis. The potential for *Raich* to have a broader impact on health care rests in this possibility—in how the Supreme Court will define, interpret, and weigh the traditional state interest at issue.<sup>295</sup>

Part III reveals that, while health care has traditionally been the province of the states, the federal government has become increasingly involved in regulating health. In addition, it is clear that a great deal of federal health care regulation is constitutional and, without discussing the merits of particular policies, we

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293. 352 F.3d 1222 (9th Cir. 2003).

294. Although neither party has addressed standing in its briefs to the Supreme Court, Judge Beam's Ninth Circuit dissent argued that the plaintiffs did not have standing. *Id.* at 1235-37 (Beam J., dissenting).

295. See *supra* Part II.B. Although the parties briefed the question of medical necessity to the Supreme Court, the Ninth Circuit did not address this question and the Supreme Court did not grant *certiorari* on the issue. See *Raich*, 352 F.3d 1222 (9th Cir. 2003), *cert. granted*, 124 S.Ct. 2909 (June 28, 2004) (No. 03-1454). So, though a holding on medical necessity grounds would also have an effect on health care generally, these facts make it unlikely that the Court will address medical necessity for individual use in *Raich*.

generally believe that significant federal involvement in health care is desirable. In the area of Medicaid, for example, ceding federal power to states may weaken patient protections and decrease the access to health care for poor, disabled, or elderly citizens.<sup>296</sup> Federal power over some areas of public health may even preclude state regulation,<sup>297</sup> either through preemption<sup>298</sup> or the dormant Commerce Clause, which prevents states from engaging in divisive or protectionist regulatory policies.<sup>299</sup> Few of the major federal health regulations, such as Medicaid, conflict with the notion that health care is traditionally a state concern. But, the federal government's increased involvement in health policy contributes to the difficulty for the Supreme Court in *Raich* of addressing and defining which areas of health care constitute a traditional state concern and which do not.

The plaintiffs and the Government in *Raich* both argue that the traditional state concern factor weighs in their favor. The Government argues that the plaintiffs wish to “function essentially as unregulated and unsupervised drug manufacturers and pharmacies”<sup>300</sup> and that the determination of what medical products can be made available for medical use is not an area of regulation traditionally reserved to the states.<sup>301</sup> The plaintiffs’ argue that the federal government has primary authority over protecting consumers from misbranded drugs but that the relationship between patients and doctors is an area traditionally

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296. See generally Dayna Bowen Matthew, *The “New Federalism” Approach to Medicaid: Empirical Evidence that Ceding Inherently Federal Authority to the States Harms Public Health*, 90 KY. L.J. 973 (2001) (arguing that empirical evidence indicates increasing state control over Medicaid leads to undesirable results).

297. See, e.g., Wendy E. Parmet, *Regulation and Federalism: Legal Impediments to State Health Care Reform*, 19 AM. J.L. & MED. 121 (1993) (discussing the various ways in which federal authority may preclude states from experimenting with health care reforms).

298. See *supra* Part III (discussing how ERISA preempts state regulation in employee benefits).

299. Maine’s effort to lower prescription drug prices for people without a prescription drug insurance plan is an example of a state healthcare policy that faced a dormant Commerce Clause challenge. The Supreme Court, however, ruled in favor of Maine. *Pharm. Research & Mfrs. v. Walsh*, 538 U.S. 644 (2003); see also Whitney Magee Phelps, Comment, *Maine’s Prescription Drug Plan: A Look Into the Controversy*, 65 ALB. L. REV. 243 (2001) (discussing the dormant Commerce Clause issues related to Maine’s prescription drug law).

300. Petitioners’ Brief at 33-34, *Raich* (No. 03-1454).

301. Brief of Amici Curiae Dupont at 15-17, *Raich* (No. 03-1454) [hereinafter Dupont Brief].

reserved to the states.<sup>302</sup> This question is, in some ways, tied to the Commerce Clause question of what level of generality should be used to define the regulated class of activities.<sup>303</sup> However, the Supreme Court's analysis of the traditional state concern issue would impact health care's relationship with the Commerce Clause independent of the purely Commerce Clause questions.

If the Court accepts the Government's argument that the activity at issue is not a traditional state concern, it is difficult to imagine a health care related activity that would be. This is because the Government argues that the federal power to regulate interstate medical products also extends over the state's traditional role in regulating the doctor patient relationship despite the purely intrastate character of the activity.<sup>304</sup> "In short, neither the purported medical use of marijuana nor the role of a physician in approving it provides the slightest basis for excluding it from the comprehensive coverage of the CSA . . . ."<sup>305</sup> If the Court finds this reasoning persuasive in the context of its traditional state interest analysis, it would hold that the unchallenged federal power over commercial interstate distribution of medicines<sup>306</sup> includes the corollary intrastate regulation of related activities. This theory would not necessarily preclude all Commerce Clause challenges related to health care. A government regulation might still fail the *Morrison* test even if the activity regulated is not a traditional state interest. But such a reading would make it difficult to conceive of a health care activity that could be classified as a traditional state concern.

Similarly, the Court could find that the activity in *Raich* is traditionally left to the states and still hold for the Government based on the four *Morrison* factors. This outcome, though, is probable only if the Court accepts the Government's assertion that the activity at issue is the regulation of medical products. But,

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302. See generally Nurses Brief at 17, *Raich* (No. 03-15481).

303. Compare Brief of Amici Curiae Constitutional Law Scholars, *Raich* (No. 03-1454) with Petitioners' Brief, *Raich* (No. 03-1454). For example, the government's traditional state concern argument dovetails with its assertion that the activity engaged in by the plaintiffs should be defined broadly as "affect[ing] the marijuana market as a whole" for purposes of Commerce Clause analysis. Petitioners' Brief at 20.

304. Petitioners' Brief at 40-41.

305. *Id.* at 41.

306. See Nurses Brief at 5-6 (agreeing that Congress has used its commerce power to protect consumers from interstate sales of medicines but arguing that this power has not historically included intrastate activity).

whatever the ultimate outcome of *Raich*, the plaintiff's position on the state interest issue seems to align closely and persuasively with the history of health care regulation in the United States. The plaintiffs distinguish local health care activity, like the physician's practice of medicine, as an area traditionally regulated and left to the states from the sort of health care the federal government has historically regulated.<sup>307</sup> This accurately reflects the vast majority of federal health care laws, which have not generally intruded into state functions but rather attacked problems that states had not—and possibly could not have—dealt with themselves. For example, the 1906 Food and Drug Act, “Congress’ first significant enactment in the field of public health,”<sup>308</sup> did not regulate an area already addressed by the states. Indeed, one of the Government’s *amici* acknowledges that “[i]n 1900, medical products were essentially unregulated,”<sup>309</sup> even as it argues that the 1906 Act demonstrates the federal government has traditionally regulated the activity at issue in *Raich*.<sup>310</sup> But the 1906 Act had nothing to do with regulating the relationship between physicians and patients that had traditionally been left to the states; rather, it was enacted to combat the widespread problem of interstate trade in adulterated and misbranded drugs.<sup>311</sup>

Like a great deal of federal health care legislation, the 1906 Act did not encroach into areas regulated by the states. It regulated health care in a way states had not.

The expansion of national powers into the field of public health prompted a change in public health objectives . . . . Merely controlling the effects of public health problems was inadequate. National powers allowed for the broad regulation of the very conditions which led to such problems. Thus, public health strategy has changed from the localized treatment and prevention of public health dilemmas to the advance control of the conditions in which such effects arose.<sup>312</sup>

Supreme Court cases from the early 1900s confirm the distinction between the scope of federal regulation and the areas of health care traditionally left to the states. In *Linder v. United*

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307. See Appellants’ Opening Brief, *Raich* (No. 03-15481).

308. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996).

309. Brief of Amici Curiae Dupont at 15, *Raich* (No. 03-1454).

310. *Id.* at 16.

311. *Medtronic*, 518 U.S. at 475.

312. *Hodge*, *supra* note 257, at 337-38.



*States*,<sup>313</sup> the Court addressed the application of the Harrison Act—a 1914 law regulating products containing opium and cocaine through Congress’ taxing power—to a tax-paying physician who had given one tablet of morphine and three tablets of cocaine to an addicted patient, without filing out the appropriate tax form.<sup>314</sup> The statute imposed a tax on a physician’s distribution of opiates and coca-derived substances in the course of his professional services,<sup>315</sup> but the Government argued that distribution to an addict, without supervision and control of a physician, was outside the professional practice of medicine.<sup>316</sup> The Court disagreed with this argument, stating that “direct control of medical practice in the States is beyond the power of the Federal Government.”<sup>317</sup>

*Linder*, which was decided well after the government began to regulate interstate traffic in medicine, supports the distinction advanced by the plaintiffs.<sup>318</sup> If the Court holds that the activity in *Raich* has traditionally been a state concern, it will clarify some of the possible tensions between the notion of health care as a state concern and the increase in federal public health regulation consistent with the traditional understanding articulated in *Linder*. The holding could have a strong impact on other areas of health care by influencing healthcare-related Commerce Clause cases. But the ruling would not jeopardize the vast majority of federal health care law that is either unrelated to Congress’ commerce power or unquestionably regulates commercial activity. Such a holding would not automatically place local health care activity outside the scope of federal regulatory power, as overlapping regulatory authority between state and federal law is possible.<sup>319</sup> The potential impact of adopting this distinction in *Raich* on future Commerce Clause cases is best demonstrated by analyzing how it

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313. 268 U.S. 5 (1925). This case is also discussed by *amici* to the plaintiffs in *Raich*. Nurses Brief at 17, *Raich* (No. 03-15481).

314. *Linder*, 268 U.S. at 11.

315. *Id.* at 12.

316. *Id.* at 16. “[The tablets] were not administered by him or by any nurse or other person acting under his direction, nor were they consumed or intended for consumption in his presence.” *Id.*

317. *Id.* at 18.

318. *Id.* at 17. “Congress cannot, under the pretext of executing delegated power, pass laws for the accomplishment of objects not entrusted to the Federal Government.” *Id.*

319. As noted above, the Court in *Raich* could find that the plaintiff’s activity has traditionally been regulated by the states, but hold against them because of other Commerce Clause factors.

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might affect examples of particular federal health care regulations grounded in the commerce power.

B. *Health Care Law After Raich*

1. *Medical Marijuana*

California's Compassionate Use Act (CUA) is a model of current state/federal health care conflicts. The CUA was designed not as a market regulatory tool, but solely as a public health measure.<sup>320</sup> Its purpose was "[t]o ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana . . . ."<sup>321</sup> The Act serves two traditional state interests. First, it directly governs health care practice as it exempts doctors from certain state criminal laws relating to the illegal sale or cultivation of marijuana.<sup>322</sup> It has also traditionally been within a state's prerogative to experiment with new methods of treating disease and illness, similar to previous state practices with inoculation.<sup>323</sup>

Other state medical marijuana laws also show an express medical decision at work. For example, Maine's medical marijuana provision provides that "a person . . . may lawfully possess a usable amount of marijuana for medical use if, at the time of that possession, the person has available an authenticated copy of a medical record or other written documentation from a physician" demonstrating one of several enumerated medical conditions.<sup>324</sup> Maine medical marijuana patients would be engaging in the possession of a "useable amount"<sup>325</sup> of marijuana, for personal medical use pursuant to "written documentation from a physician" in conformity with state law, similar to the facts implicated in

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320. See CAL. HEALTH & SAFETY CODE § 11362.5 (West 1996) (illustrating the purpose of the legislation).

321. *Id.* § 11362.5(b)(1)(A).

322. *Id.* § 11362.5(d).

323. See *supra* notes 201-204.

324. ME. REV. STAT. ANN. tit. 22 § 2382-B(5) (1975).

325. *Id.* § 2382-B(3)(E) ("Usable amount of marijuana for medical use' means 2 1/2 ounces or less of harvested marijuana and a total of 6 plants, of which no more than 3 may be mature, flowering plants.").

*Raich*.<sup>326</sup>

A finding that these types of programs are traditionally matters of state concern would undercut the government's assertion that the broader regulatory scheme envisioned by the CSA covers the "use of controlled substances for medical purposes and the role of physicians in approving their use."<sup>327</sup> The Court's history of rejecting such claims bodes well for state health care advocates. As noted above, in *Linder*, for example, the Court refused to accept that distribution of drugs to an addict fell outside the practice of medicine.<sup>328</sup>

A finding that many medical marijuana laws belong to a class of traditional state functions does not necessarily remove all federal regulatory power, and not just in Commerce Clause cases. The spending clause could be used to encourage the states to oppose medical marijuana programs. Additionally, entering into treaties, such as the 1961 Single Convention on Narcotic Drugs,<sup>329</sup> may require federal intervention into areas traditionally governed by the states.<sup>330</sup> However, a finding that the Single Convention mandates that the CSA apply to state medical marijuana is independent of whether a matter traditionally left to the states is beyond the reach of the Commerce Clause.

## 2. *Physician-Assisted Suicide*

Like medical marijuana, activity performed in conformity with statutes that permit physician-assisted suicide may be beyond the reach of federal commerce power if the activity is found to be a traditional state interest. Oregon's Death With Dignity Act<sup>331</sup> was upheld by the Ninth Circuit after two citizen initiatives and a lengthy battle in federal court.<sup>332</sup> The law permits licensed Oregon

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326. See *Raich v. Ashcroft*, 352 F.3d 1222, 1225-26 (9th Cir. 2003). By contrast, however, the California statute at issue in *Raich* exempted from prosecution patients who possessed marijuana "for the personal medical purposes of the patient upon the *written or oral* recommendation or approval of a physician." *Id.* at 1225 (emphasis added) (citing CAL. HEALTH & SAFETY CODE § 11362.5(d) (West 1996)).

327. Petitioners' Brief at 40, *Raich* (No. 03-1454).

328. 268 U.S. 5 (1925).

329. Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407 (1967), 520 U.N.T.S. 151 (1964).

330. See Dupont Brief, *supra* note 301, at 10.

331. OR. REV. STAT. § 127.800 (2003).

332. See Scott Gast, *Who Defines "Legitimate Medical Practice?" Lessons Learned from the Controlled Substances Act, Physician-Assisted Suicide, and Oregon v. Ashcroft*, 10 VA.

doctors to prescribe drugs to patients for use in ending their own lives.<sup>333</sup> Of course, however, the Controlled Substance Act regulates the actual medications being prescribed. The CSA classifies drugs based upon a determination by the Attorney General regarding multiple factors relating to a substance's medicinal and addictive properties.<sup>334</sup> It also allows the Attorney General to deny or revoke a registration if he concludes the registration would be "inconsistent with the public interest."<sup>335</sup>

In 2001, John Ashcroft issued an interpretive ruling that the dispensing of controlled substances for the purposes of suicide was inconsistent with the public interest and threatened to revoke the registration of any practitioner that prescribed medications for such purposes.<sup>336</sup> The ruling was immediately contested. The District Court, and the Ninth Circuit on appeal, found that as worded, the CSA did not authorize the Attorney General to decide whether physician-assisted suicide is a permissible medical practice.<sup>337</sup> Because the federal policy at issue was based on an interpretive ruling, the underlying legal standard is much different than *Raich*, and neither court considered whether Congress had the authority under the commerce clause to prevent physician-assisted suicide over a validly enacted state law.<sup>338</sup> Despite these differences, the question of health care as a traditional state concern is quite similar in each case.

The Supreme Court has also implied that physician-assisted suicide implicates the traditional state health concern. Justice O'Connor noted in *Washington v. Glucksberg*, "States are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues," and will act as "laboratories" for constructing safe and humane policies.<sup>339</sup> O'Connor's statement rings of a strong constitutional preference for deferring to state legislatures. While the Death with Dignity Act is an assertion of a traditional state power, it may not be controlled directly by the

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J. SOC. POL'Y & L. 261, 261-63 (2002).

333. OR. REV. STAT. ANN. § 127.800 (2003).

334. 21 U.S.C. § 811 (2004).

335. *Id.* § 823(f).

336. Gast, *supra* note 332, at 262.

337. *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077, 1088-89 (D. Or. 2002), *rev'd*, 368 F.3d 1118, 1125-26 (9th Cir. 2004).

338. *See Ashcroft*, 368 F.3d at 1125.

339. *Washington v. Glucksberg*, 521 U.S. 702, 737 (1997) (O'Connor J., concurring).

outcome in *Raich*, in that it does not equally involve the distribution of marketing of medicines—an accepted federal function.

For instance, the Act does not set out a single particular purpose or define its function other than through piecing together multiple sections.<sup>340</sup> Nor does it alter the federal requirements for obtaining prescription drugs. It specifies only the procedures that must be followed, in addition to those required by the CSA, by any medical practitioner prescribing lawfully available medications for the purpose of ending a life.<sup>341</sup>

Although the Act does not define its purpose, Oregon has asserted that the law “establish[es] and enforce[s] standards of conduct within its borders relative to everyone there.”<sup>342</sup> While the explicit interference with the Act by Congress would present unique Commerce Clause concerns, in the current legal dispute the traditional state interest analysis and arguments are largely similar to those in *Raich*.<sup>343</sup> As in the medical marijuana context, the federal government’s argument in *Oregon v. Ashcroft* would largely permit the federal government to declare what is an appropriate medical purpose even if a state disagrees with the determination.<sup>344</sup> A finding that regulation of the activity in *Raich* is traditionally left to the states would give greater force to Oregon’s argument that the proper federal role is regulating the traffic and safety of particular substances, not interpreting whether those substances should be lawfully prescribed to particular patients.

### 3. *Stem Cell Research and Human Cloning*

“Human life is a creation of God - not a commodity to be exploited by man,” said President George W. Bush, discussing stem cells in Dallas before the Texas Knights of Columbus convention.<sup>345</sup> Rarely has the stem cell debate been publicly phrased in terms of

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340. See OR. REV. STAT. § 127.800-.897 (2003).

341. *Id.*

342. Appellee’s Brief of the State of Oregon at 20, *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2000) (No. 3:0101647) (quoting *Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954)).

343. See Brief for Appellants at II.C., *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2000) (No. 02-35587).

344. *Id.*

345. Ken Fireman, *Election 2004: On the Conservative Side Vying for Catholic Vote, Bush Reiterates Views and Promises More Funding for Religious Charities*, NEWSDAY, Aug. 4, 2004, at A18.

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commerce, rather than medicine or public health. But the federal commerce power, however, could play a significant role in the future legislation related to stem cells and human cloning.

In 2001, the House of Representatives passed the Human Cloning Prohibition Act of 2001 (HCPA).<sup>346</sup> The Act specified that:

It shall be unlawful for any person or entity, public or private, in or affecting interstate commerce, knowingly—  
 (1) to perform or attempt to perform human cloning; (2) to participate in an attempt to perform human cloning; or  
 (3) to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo.<sup>347</sup>

The prohibition does not immediately come across as a significant limitation on state health care practices. However, the term “human cloning” was defined as “human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism (at any stage of development) . . . .”<sup>348</sup> This is an incredibly broad definition.<sup>349</sup> The inclusion of the qualifier “(at any stage of development)” would necessarily include the point immediately after a human cell is duplicated. Such a broad definition implicates another line of medicinal policy that is not instantly apparent from the title of the Act—stem cell research.

Cloning and stem cell research actually share a common scientific base. Both practices often implement a practice called somatic cell nuclear transplantation or transfer (SCNT).<sup>350</sup> The cloning procedure for much stem cell research and direct human cloning “is identical up to the point where a blastocyte created through SCNT is either implanted into a woman’s uterus (reproductive cloning) or used as a source of stem cells (research cloning).”<sup>351</sup> If passed, the HCPA would prevent both reproductive

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346. H.R. 2505, 107th Cong. (2001); see Jonathan S. Schwartz, *The Human Cloning Prohibition Act of 2001: Vagueness and Federalism*, 43 JURIMETRICS J. 79, 81-82 (2002).

347. H.R. 2505, 107th Cong. § 2(a) (proposed 18 U.S.C. § 302) (2001).

348. H.R. 2505, 107th Cong. § 2(a) (proposed 18 U.S.C. § 301(1)).

349. See Schwartz, *supra* note 346, at 82-83.

350. Charity Schiller, Comment, *Stem Cell Research and Conditional Federal Funding: Do State Laws Allowing More Extensive Research Pose a Problem for Federalism?*, 31 PEPP. L. REV. 1017, 1027 (2004).

351. Alexander Morgan Carpron, *Placing a Moratorium on Research Cloning to Ensure Effective Control over Reproductive Cloning*, 53 HASTINGS L.J. 1057, 1061 (2002).

and research cloning.

In November of 2004, California voters approved Proposition 71, the California Stem Cell Research and Cures Act (Stem Cell Act).<sup>352</sup> The Act in part, amends the California Constitution to create an Institute for Regenerative Medicine that has the authority to fund SCNT stem cell production for research purposes.<sup>353</sup> The motivation behind the Act cannot be any clearer. It is designed to: “Maximize the use of research funds by giving priority to stem cell research that has the greatest potential for therapies and cures, specifically focused on . . . vital research opportunities that cannot, or are unlikely to receive timely or sufficient federal funding . . . .”<sup>354</sup> New Jersey also permits the use of SCNT research, but expressly prohibits the sale, transfer, or exchange of stem cell products for any “valuable consideration.”<sup>355</sup> New Jersey has removed the commercial nature of the research and resigned the issue to purely medical bases.<sup>356</sup>

However, members of Congress continue to introduce the HCPA with the intent to prevent the type of research expressly provided for by New Jersey and California Law.<sup>357</sup> The supporters of HCPA find authority under the “Public Health Services Act, [PHSA] which gives the FDA the power to regulate ‘biological products’ that are used to treat medical conditions.”<sup>358</sup> The FDA has also stated that human cloning falls within the definition of the Food, Drug, and Cosmetic Act because the cloned cells can be defined as a drug.<sup>359</sup> Further, “drugs” are defined as “articles (other than food) intended to affect the structure or any function of the body.”<sup>360</sup>

We are not going to assess whether this interpretation of the Food, Drug and Cosmetic Act is correct, but the opposing positions put forth by New Jersey and California will assuredly spark legal challenge if the federal ban becomes law. More important for our

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352. Stem Cell Research and Cures Act, at <http://www.curesforcalifornia.com/initiative.php> [hereinafter Stem Cell Act] (last visited Feb. 13, 2005).

353. *Id.* § 4 sec. 3.

354. *Id.* § 3 ¶ 2.

355. N.J. STAT. ANN. §§ 26:2Z-1 to -2(c)(1) (West 2004).

356. *See id.*

357. *See* Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. (2003); S. 245, 108th Cong. (2003).

358. H.R. REP. NO. 108-18, at 3 (2004), (Report from the House Committee on the Judiciary on the Human Cloning Prohibition Act of 2003).

359. *Id.*

360. *Id.*

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analysis is whether the act of using SCNT technology to clone a cell is a health care function. California and New Jersey's laws could not be more attuned to an area of traditional state concern. In both cases the law's purpose is to research and develop treatments and cures for disease, the most traditional area of state health care regulation.<sup>361</sup> The HCPA would intrude into a pure research arena, an area we have shown to be within a state's traditional function.

The actual language of the PHSA requires that drugs must be "used to treat medical conditions."<sup>362</sup> The Supreme Court noted in *Jones v. United States*<sup>363</sup> that because the words "used . . . in an activity affecting interstate . . . commerce" appeared in a federal arson statute, the word "used" must mean something directly commercial in nature.<sup>364</sup> Otherwise, the distinction between federal and state concerns would be lost.<sup>365</sup>

Although *Jones* involved an issue of statutory interpretation, the Court might have followed this route to avoid having to find the statute unconstitutional for intruding too broadly into traditional state activities.<sup>366</sup> Likewise, in the context of human cloning, the act of cloning itself is akin to a surgical procedure, a medical practice that appears to be a purely traditional state activity. To permit a broad reach into all aspects of cloning, regardless of the program's design, purpose, or methods of implementation, would be to curtail a state's ability to research solutions to state wide medical problems or dictate the tenets of its own medical practice. This reading accepts the need for the national uniform distribution and control of medicines, but it reserves states the traditional right to engage in medical experimentation. Extending the theory underlying the *Jones* decision to human cloning provides courts with a clear dividing line between traditionally local and traditionally federal concerns.

However, even if such a result occurred, a determined Congress or Executive might still be able to prevent states from

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361. See *supra* Part III.

362. H.R. REP. NO. 108-18, at 2 (2004).

363. 529 U.S. 848, 856-58 (2000); see also *Solid Waste Agency v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 171-75 (2001) (limiting the definition of § 404(a) of the Clean Water Act because an expansive definition would intrude too broadly into intrastate activities).

364. *Id.* at 857-58.

365. *Id.* at 854 (finding that "used" meant the arson statute only applied to commercial buildings).

366. See Craig M. Bradley, *Federalism and the Federal Criminal Law*, 55 HASTINGS L.J. 573, 585 (2004).



engaging in stem cell research. In 2004, President Bush began a push in the United Nations to enter into a treaty banning stem cell research and human cloning.<sup>367</sup> Although most nations seem to oppose such a position, (even close allies of the United States) a treaty could effectively prevent state experimentation, regardless of how traditional the activity may be.<sup>368</sup>

If the election of 2004 is prescient in any way, then the stem cell and cloning debate will only increase in the coming years. Religious conservatives will almost surely continue to push for passage of the HCPA or similar laws. Other states may also join California and New Jersey in directly funding, or at a minimum, permitting research cloning.

#### 4. *Abortion*

The abortion debate's relationship to Commerce Clause jurisprudence is twofold. First, whether the practice is a matter of traditional state concern, and second, if it is, whether the right to an abortion pursuant to *Roe v. Wade*<sup>369</sup> will be affected by the greater state protection such a determination may afford. In addressing the first point, it is hard to deny that performing an abortion is a medical act. While it may also be part of a doctor's employment, the act itself involves medical decisions. The examination of current federal attempts to restrict abortion rights<sup>370</sup> exhibits how a finding that the act of performing an abortion is within the sphere of traditional state power affects the availability and right to the procedure.

Congress has generally not opted to involve itself in the abortion debate through direct regulation. Rather, it has used its spending power to influence state and private actions, mostly geared towards restricting abortion access.<sup>371</sup> However, in 2003,

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367. See Maggie Farley, *U.S. Campaigns for Treaty to Ban Use of Embryo Stem Cells; Bush administration's proposal would prohibit human and therapeutic cloning for medical research. World body is divided on the issue*, L.A. TIMES, Oct. 23, 2004, at A3.

368. *Id.* ("Nearly 130 nations, including close U.S. allies such as Britain, Japan and India, say that each nation should be allowed to decide for itself whether to regulate therapeutic cloning."). See also U.S. CONST. art. II § 2; Dupont Brief, *supra* note 301, at 15-18 (showing how a U.N. treaty may require Congress to pass legislation curtailing areas traditionally within the ambit of state sovereignty).

369. 410 U.S. 113 (1973).

370. See, e.g., Partial Birth Abortion Ban Act of 2003, Pub L. No. 108-105 (117 Stat.) (codified as 18 U.S.C. § 1531 (2004)).

371. See *Harris v. McRea*, 448 U.S. 297 (1980) (upholding the denial of Medicaid funds for abortions); *Rust v. Sullivan*, 500 U.S. 173 (1991) (upholding a

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President Bush signed into law the Partial-Birth Abortion Ban Act (PBABA).<sup>372</sup> Worded similarly to the HCPA, the ban prohibits “[a]ny physician who, in or affecting interstate or foreign commerce, knowingly performs a partial-birth abortion and thereby kills a human fetus shall be fined under this title or imprisoned not more than 2 years, or both.”<sup>373</sup> Three United States District Courts in the summer of 2004 found the Act unconstitutional as written.<sup>374</sup> None of these courts addressed Congress’ power to enact the law, despite one court even authoring a 173-page memorandum.<sup>375</sup> Instead, the law has been found invalid under *Stenberg v. Carhart*<sup>376</sup> because it fails to provide an adequate exception for the health of the mother.<sup>377</sup>

If the PBABA was challenged on Commerce Clause grounds, Professor Allan Ides has argued that the Court would be hard pressed to find the Act does not invade a traditional state function.<sup>378</sup> Not only does the PBABA parallel the wording of the HCPA,<sup>379</sup> both laws seek to criminalize the performance of an act: there, “human cloning,” and here, performing an abortion. As Professor Ides points out, it is also nearly identical to the VAWA, ruled unconstitutional in *Morrison*.<sup>380</sup> The VAWA involved solely “an act of gender-based violence [and] is in no way dependent on the presence of a commercial transaction.”<sup>381</sup>

The PBABA stands on equal footing with Congress’ attempts to prevent human cloning and violence against women. None of the acts necessarily require the exchange of goods or services or some other economic transaction that generally invokes the need for national action.<sup>382</sup> The mere act of performing an abortion is

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prohibition on the distribution of abortion related information by federally funded clinics).

372. Pub L. 108-105 (117 Stat.) (codified as 18 U.S.C. § 1531 (2004)).

373. *Id.* (codified at 18 U.S.C. § 1531(a)).

374. *See Carhart v. Ashcroft*, 331 F. Supp. 2d 805, 808 (D. Neb. 2004); *Nat’l Abortion Fed’n v. Ashcroft*, 330 F. Supp. 2d 436, 493 (S.D.N.Y. 2004); *Planned Parenthood Fed’n of Am. v. Ashcroft*, 320 F. Supp. 2d 957, 960 (N.D. Cal. 2004).

375. *Carhart*, 331 F. Supp. 2d at 805.

376. 530 U.S. 914 (2000).

377. *See Nat’l Abortion Fed’n*, 330 F. Supp. 2d at 487.

378. Allan Ides, *The Partial-Birth Abortion Ban Act of 2003 and the Commerce Clause*, 20 CONST. COMMENT 441, 451 (2003).

379. *See generally* H.R. REP. NO. 108-18, at 2.

380. *See* Ides, *supra* note 378.

381. *Id.* at 446.

382. *See supra* notes 306-311 and accompanying text (explaining the distinction between needs giving rise to federal action and matters of traditional state

independent of any broader federal regulatory authority. It is a medical function and is unrelated to any function beyond the regulation of medical care. The decision to perform an abortion is a complex medical decision regarding the safety of the mother, the stage of fetal development, as well as other mental and physical health concerns.<sup>383</sup> These decisions have been and may remain with state authorities if the Court is serious about applying the traditional state interest doctrine.

With respect to state laws restricting abortion, a number of scholars have expressed concern that a strong states right's position could allow states to prohibit abortion and eviscerate nationally protected rights. Professor Marc Spindelman argues that although abortion is a constitutionally protected right, the *Raich* and *Oregon v. Ashcroft* "line of judicial thinking about states' rights . . . is eminently capable of uprooting and overturning constitutional rights [that] the Court has recognized."<sup>384</sup> Specifically, Spindelman is concerned that courts will accept abortion as being within a traditional area of state health care concern and thus, be hesitant to restrict states from expanding or contracting the practice as they see fit.<sup>385</sup> Without analyzing the issues in depth, it seems unlikely that the traditional state interest determination will allow states to pass laws that violate the Constitution. The individual liberties expounded in the Constitution's amendments are designed to prevent state interference with individual rights, even in areas traditionally left to the states.<sup>386</sup>

The central debate in *Raich* that federal authorities cannot interfere with non-economic exclusively state functions does not give a state free reign to then interfere with rights granted under the Constitution. In fact, respecting federalism may actually enhance federal authority to enforce the individual protections the Constitution provides. Comity entails a respect for the separate spheres of power. When those boundaries are more carefully

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concern).

383. See Hutton Brown et al., *Special Project: Legal Rights and Issues Surrounding Conception, Pregnancy, and Birth*, 39 VAND. L. REV. 597 (1986).

384. Marc Spindelman, *A Dissent from the Many Dissents from Attorney General John Ashcroft's Interpretation of the Controlled Substances Act*, 19 ISSUES L. & MED. 3, 36-37 (2003) (quoting Marc Spindelman, *Protecting Suicide and Hurting Women*, LEGAL TIMES, May 27, 2002, at 51).

385. *Id.*

386. See generally 16A AM. JUR. 2D *Constitutional Law* § 388 (discussing the basic function of a bill of rights).

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patrolled, the intrusion of one sovereign into the realm of the other commences only when necessary, not simply when desired. Limiting federal authority in commerce cases will reduce the overlap between state and federal regulations. Thus, when Congress acts pursuant to Section 5 of the Fourteenth Amendment to protect the rights of United States citizens, Congress will more clearly be viewed as acting as a protectorate instead of just a policy maker.

## V. CONCLUSION

Just what qualifies as a traditional state interest is unclear. The determination will depend, at least in part, on the manner in which the activity at issue is classified. However, independent of these aspects of Commerce Clause analysis, *Raich* has the potential to significantly impact health care by clarifying the extent to which the field is a traditional state concern in the midst of increasing federal involvement. Although it is possible that the Court may resolve *Raich* without a significant discussion of the relationship between state and federal authority over health care, the Ninth Circuit's decision in *Oregon v. Ashcroft* indicates that the issue will continue to be important, whatever the outcome of *Raich*. As our discussion and analysis of the history of federal and state health care regulation reveals, a framework which distinguishes regulation of the doctor and patient relationship from regulation of the safety of prescription drugs or federal benefits spending may prove the most consistent with the historical understanding of the state's traditional role in health care.