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Kevin Outterson

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# HEALTH CARE, TECHNOLOGY AND FEDERALISM

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*Kevin Outterson\**

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## I. INTRODUCTION

The regulation of health care has traditionally been the province of the states, most often grounded in the police power. In Colonial times, this division of responsibility was a rational response to the technological level of the eighteenth century, although even in the youth of the Republic some health and safety regulation required national and international action. With the growth of distance-compression technology, the increase in mobility of goods and services, and a significant federal financial role in health care, the grip of the police power on the regulation of health care has been weakened. Discussion of the police power is enjoying something of a renaissance,<sup>1</sup> which motivates this attempt to track the interaction of health care, technology and federalism.

This article first examines the historical regulation of health care as a police power, and thus, primary state regulatory jurisdiction. Part III is a survey of the modern landscape of federal regulation of health care under the Spending Power and the Commerce Clause of the U.S. Constitution. The nature of technology to compress distance and to permit increased mobility and the resulting effects on health care and federalism are described in Part IV. Part V examines several arenas of conflict between technology and regulation of health care, including e-health, privacy, portability of nurse licensure, medical error reporting, Internet pharmacies, ERISA preemption, and genomics. Finally, the conclusion makes some observations regarding the future of health care regulation in our federal system.

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<sup>1</sup> See, e.g., John S. Baker, Jr., *State Police Powers and the Federalization of Local Crime*, 72 TEMPLE L. REV. 673 (1999); Richard A. Epstein, *Law, Economics, and Social Conservatism: Externalities Everywhere?: Morals and the Police Power*, 21 HARV. J.L. & PUB. POL'Y. 61 (1997); Alan N. Greenspan, *The Constitutional Exercise of the Federal Police Power: A Functional Approach to Federalism*, 41 VAND. L. REV. 1019 (1988); Glenn H. Reynolds & David B. Kopel, *The Evolving Police Power: Some Observations for a New Century*, 27 HASTINGS CONST. L.Q. 511 (2000); Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANN. HEALTH L. 201 (1999).

## II. THE COLONIAL ETHOS OF STATE HEALTH REGULATION

A. *Health Care and the Police Power*

## 1. The Police Power

The phrase "police power" is not found in the Constitution, but is frequently employed in constitutional jurisprudence.<sup>2</sup> Chief Justice Marshall thought the police power generally included governmental duties and powers that were best exercised locally; such powers were reserved to the states under the Tenth Amendment,<sup>3</sup> although other definitions have been proffered.<sup>4</sup> Archetypal examples of the police power include public safety and public health.<sup>5</sup> Justice

<sup>2</sup> See, e.g., *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662 (1981) (holding that an Iowa restriction on truck length burdened interstate commerce, despite claim that statute was valid exercise of police power); *Berman v. Parker*, 348 U.S. 26 (1954) (upholding District of Columbia redevelopment plan as a valid exercise of the police power); *Minnesota v. Barber*, 136 U.S. 313, 322-25 (1890) (ruling that a Minnesota statute was unconstitutional when it required local inspection of fresh beef no more than twenty-four hours prior to slaughter, effectively excluding all out of state fresh beef); *Patterson v. Kentucky*, 97 U.S. 501, 505-06 (1878) (finding that state police power includes safety regulation of illuminating oils, notwithstanding grant of federal patent to excluded oil); *Railroad Co. v. Husen*, 95 U.S. (5 Otto) 465, 469-70 (1877) (holding that state cannot "under cover of its police powers, substantially prohibit or burden either foreign or interstate commerce") (Strong, J.); *Mayor of New York v. Miln*, 36 U.S. (11 Pet.) 102, 132-33 (1837) (upholding a rule requiring registration and bonding of all immigrants landing in New York as a local regulation of paupers under the police power); *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824) (holding that grant of exclusive steam powered navigation by New York violated Commerce Clause); see also ERNST FREUND, *THE POLICE POWER: PUBLIC POLICY AND CONSTITUTIONAL RIGHTS* (1904); Wendy E. Parmet, *Regulation and Federalism: Legal Impediments to State Health Care Reform*, 19 AM. J.L. MED. & ETHICS 121 (1993).

<sup>3</sup> See *Gibbons*, 22 U.S. at 203 (Chief Justice Marshall interpreted a broad role for the Commerce Clause, but allowed that the states retained certain powers under the Tenth Amendment, including the police powers, to wit: that "immense mass of legislation, which embraces every thing within the territory of a State, not surrendered to the general government: all which can be most advantageously exercised by the States themselves. Inspection laws, quarantine laws, health laws of every description, as well as laws for regulating the internal commerce of a State, and those which respect turnpike roads, ferries, &c., are component parts of this mass."). See also *Miln*, 36 U.S. at 132; FREUND, *THE POLICE POWER*, *supra* note 2, at 3-4. In *Gibbons v. Ogden*, Chief Justice Marshall conceded that state powers reserved under the Tenth Amendment and the Commerce Clause could both reach the same activity. 22 U.S. at 204-09.

<sup>4</sup> Compare, e.g., FREUND, *THE POLICE POWER*, *supra* note 2, at iii ("the power of promoting the public welfare by restraining and regulating the use of liberty and property," a formulation so broad that it is difficult to distinguish the police power from any power permitted under the Constitution), with CHRISTOPHER GUSTAVUS TIEDEMAN, *A TREATISE ON THE LIMITATIONS OF POLICE POWER IN THE UNITED STATES: CONSIDERED FROM BOTH A CIVIL AND CRIMINAL STANDPOINT* (1886) (discussing the protection of individuals in society from direct harm). See also Reynolds & Kopel, *supra* note 1, at 511 (drawing comparisons of the view of Freund, Tiedeman and Bork on the police power).

<sup>5</sup> See *Dean Milk Co. v. Madison*, 340 U.S. 349, 354-56 (1951) (Madison local pasteurization ordinance ruled unconstitutional, as it was "not essential for the protection of local health interests" and burdened interstate commerce, even though Madison's power to protect the health and safety of its people was "unquestioned"); *Miln*, 36 U.S. at 133 (New York law requiring registration and bonding of immigrants landing in New York found to be a proper use of the police power to reduce crime and the state burden for the care of paupers; no conflict found with federal laws regulating immigration or commerce; police powers

Douglas, writing for the majority in *Berman v. Parker*, described it more broadly:

Public safety, public health, morality, peace and quiet, law and order - these are some of the more conspicuous examples of the traditional application of the police power to municipal affairs. Yet they merely illustrate the scope of the power and do not delimit it . . . . The concept of the public welfare is broad and inclusive . . . . The values it represents are spiritual as well as physical, aesthetic as well as monetary. It is within the power of the legislature to determine that the community should be beautiful as well as healthy, spacious as well as clean, well-balanced as well as carefully patrolled.<sup>6</sup>

## 2. Health Regulation in the Early Republic

Historically, health care regulation could be fairly described as local. Prior to the 1880's, most examples of health regulation in the United States were responses to the outbreak of infectious disease.<sup>7</sup> Transmission of the relevant diseases was by face-to-face or local contact,<sup>8</sup> which facilitated a predominantly local response. These efforts were almost exclusively municipal initiatives, with little state or federal assistance.<sup>9</sup> The first real American hospital was established

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described as "powers which relate to merely municipal legislation, or what may, perhaps, more properly be called internal police." *Id.* at 139.; *Gibbons*, 22 U.S. 1 (health quarantine laws are generally regarded as police powers).

<sup>6</sup> 348 U.S. at 32-33 (citations omitted).

<sup>7</sup> See generally Helen Brock, *North America, A Western Outpost of European Medicine*, in *THE MEDICAL ENLIGHTENMENT OF THE EIGHTEENTH CENTURY* (Andrew Cunningham & Roger French, eds., 1990) (describing the state of the American medical profession after the War of Independence); GEOFFREY MARKS & WILLIAM K. BEATTY, *THE STORY OF MEDICINE IN AMERICA* (1973); PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* (1982); Ross D. Silverman, *Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards*, 26 AM. J.L. & MED. 255, 256 nn. 4-7 (2000).

<sup>8</sup> Hence the mass exodus from municipalities during epidemics of Yellow Fever, as described in WILLIAM G. ROTHSTEIN, *AMERICAN PHYSICIANS IN THE NINETEENTH CENTURY: FROM SECTS TO SCIENCE*, at 58-59 (1972).

<sup>9</sup> See MARKS, *supra* note 7, at 55-64, 263-266 (1973) (discussing the history of municipal response to epidemics in the Eighteenth Century). The first convention of local health boards was not held until May, 1857. As late as 1872, the effort was still overwhelmingly municipal: only Massachusetts, California and Virginia had state boards of health, compared to 124 municipal counterparts. See *id.* at 265-66. Federal work was largely limited to the armed services, such as the Marine Hospital Service for disabled seamen, established in 1798. Although it appears to be a predecessor to the Veterans Administration, in fact the Marine Hospital Service eventually became the U.S. Public Health Service at a much later date. See *id.* at 263; STARR, *supra* note 7, at 184-85 (discussing the reorganization of the Marine Hospital Service under the newly appointed Surgeon General in 1870 and the brief tenure of the National Board of Health from 1879 to 1883). One short-lived federal effort was the work of the Freedmen's Bureau, which in 1865 began to provide relief, education and health care to former slaves and Southerners dislocated by the Civil War. See JOHN HOPE FRANKLIN & ALFRED A. MOSS, JR., *FROM SLAVERY TO FREEDOM, A HISTORY OF AFRICAN AMERICANS* 228-32 (7th ed. 1994). For a discussion of the public health history of this period, see James G. Hodge, Jr., *The Role of Federalism and Public Health Law*, 12 J.L. & HEALTH 309, 325 (1997-98).

by the City of Philadelphia in 1752.<sup>10</sup> The first boards of health were municipal: Petersburg, Virginia in 1780,<sup>11</sup> Baltimore in 1793, Philadelphia in 1794 and Boston in 1797.<sup>12</sup> States did not begin to seriously address health care themselves until after the Civil War.<sup>13</sup>

### 3. *Jacobson and Lochner*

One example of the health care police power in the eighteenth and nineteenth centuries was the power to compel vaccinations. Vaccination litigation focused on the rights and responsibilities of the individual vis-à-vis the governmental unit and the obligation to protect the public health against epidemic. For example, in *Jacobson v. Massachusetts*,<sup>14</sup> the Supreme Court upheld a mandatory vaccination statute, allowing that Massachusetts had the power to enact "all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other States."<sup>15</sup> In this time and place, the medical model for addressing smallpox was mass vaccination, which necessitated that a high percentage of the local population be vaccinated.<sup>16</sup> Under the Massachusetts law, local boards of health could evaluate the local health situation and issue a regulation requiring mandatory smallpox vaccinations of the local population. Cambridge adopted a local regulation,<sup>17</sup> but Jacobson refused to

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<sup>10</sup> See Brock, *supra* note 7, at 201; MARKS, *supra* note 7, at 55-64 (noting that the Philadelphia Hospital was chartered in 1751 by Dr. Thomas Bond and Benjamin Franklin to care for paupers and to serve as a teaching hospital).

<sup>11</sup> The first board of health appears to have been founded in Petersburg, Virginia in 1780. See MARKS, *supra* note 7, at 263 (1973).

<sup>12</sup> See Hodge, *supra* note 9, at 325-26. Many of these municipal boards oversaw the cleaning of public areas and the disposal of waste. See Brock, *supra* note 7, at 210.

<sup>13</sup> Louisiana was apparently the sole ante-bellum example, in 1855. See Hodge, *supra* note 9, at 327; STARR, *supra* note 7, at 184 (noting the ineffectiveness of the Louisiana board). Louisiana was followed by Massachusetts (1869) (a successful board which was a model in many states), California (1871) and Virginia (1871). See MARKS, *supra* note 7, at 266. The magnitude of public health issues raised by the Civil War may well have spurred the states to act.

<sup>14</sup> 197 U.S. 11 (1905).

<sup>15</sup> *Id.* at 25 (Harlan, J.). Justice Harlan had the support of only four members of the Court for this proposition, as shown by the decision two months later in *Lochner v. New York*, 198 U.S. 45 (1905) (striking down a New York law regulating the working hours of bakers within the state).

<sup>16</sup> Immunization presents a classic free rider problem. Each immunization carries some incremental cost and risk of iatrogenesis. Effectiveness of immunization as a public health measure requires that a large percentage of the population be treated. Once this threshold is reached (which varies by disease), then the population is effectively protected, even though a small minority may not have been immunized. For this small group (the free riders), the incremental costs of immunization are likely to outweigh the incremental benefits to them. Absent a mandatory program, each individual might rationally avoid immunization altogether, hoping to be one of the few who did not undertake the procedure.

<sup>17</sup> The Boston area boasts a celebrated history regarding public health and smallpox. In 1721, the great preacher Cotton Mather and Dr. Zabdiel Boylston defied the authority of the Boston selectmen and justices as well as the medical establishment and embarked on the first American program of smallpox inoculation. See Brock, *supra* note 7, at 208-09; MARKS, *supra* note 7, at 217-31.

comply, citing health risks and unproven efficacy.<sup>18</sup> While *Jacobson* states that public health is a police power reserved to the states,<sup>19</sup> the reasoning is grounded in the social compact: the rights of the individual to liberty must be balanced against the common good of society; Jacobson's right, weighed in the balance, was found wanting.<sup>20</sup> State power to compel vaccination might be exercised in some localities and toward particular persons in such an unconstitutionally arbitrary, unreasonable or unnecessary manner, but such was not the case in Cambridge, Massachusetts.<sup>21</sup> The police power of the state will ordinarily be upheld unless the regulation bears no real or substantial relationship to public health, public morals or public safety, or is arbitrary or oppressive and invades fundamental rights.<sup>22</sup>

The Supreme Court historically reviewed the state exercise of health related police powers under a very deferential standard. Writing in 1904, Professor Freund stated:

[S]o far no case has arisen in which the judgment of the state that a restraint was required in the interest of health and safety, operating exclusively upon internal interests, and respecting the principle of equality, has been overruled by the United States Supreme Court.<sup>23</sup>

One year later, in the much-maligned *Lochner* case, the Supreme Court gave Freund the first contrary example, striking down a New York law restricting the work hours for bakers, enacted on health grounds, as exceeding the police powers of the state.<sup>24</sup> The majority searched for an individual right under the

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<sup>18</sup> Jacobson could point to older cases such as *Landon v. Humphrey*, 9 Day 209 (Conn. 1832) (malpractice award of \$500 for paralysis of the lower arm following mandatory smallpox vaccination), cited in KENNETH ALLEN DE VILLE, *MEDICAL MALPRACTICE IN NINETEENTH CENTURY AMERICA: ORIGINS AND LEGACY* 1 (1990). Evidence questioning the safety of inoculation was abundant in the eighteenth century. A smallpox epidemic in Boston in 1752 caused 500 deaths, possibly initiated by inoculation. See ROTHSTEIN, *supra* note 8, at 30. Inoculation was an early form of vaccination, both less effective and more dangerous. See MARKS, *supra* note 7, at 230-31 (discussing the work of Edward Jenner).

<sup>19</sup> See *Jacobson*, 197 U.S. at 24-25 ("The authority of the State to enact this statute is to be referred to what is commonly called the police power -- a power which the State did not surrender when becoming a member of the Union under the Constitution.").

<sup>20</sup> See *id.* at 26-28. The Court considered the "local option" nature of the Massachusetts law, which required vaccination only if the local board determined it was necessary for the public health, as well as the danger of a smallpox epidemic. Little credence was given to defendant's attempts to disprove the efficacy of smallpox vaccination or to establish the possibility of iatrogenic harm thereby. See *id.* at 26-28, 30-31.

<sup>21</sup> See *id.* at 27-28.

<sup>22</sup> See *id.* at 28, 31. A narrow majority of the Court recently cited *Jacobson* favorably in *Kansas v. Hendricks*, 521 U.S. 346 (1997), a case upholding the involuntary civil commitment of a predatory child sexual offender. But see *Care and Treatment of Crane*, 7 P.3d 285 (Kan. 2000) *cert. granted*, 69 U.S.L.W. 3641 (U.S. Apr. 2, 2001) (Kansas Supreme Court distinguished *Kansas v. Hendricks*, and held that civil commitment of a sexual offender requires proof that the defendant cannot control his dangerous behavior).

<sup>23</sup> FREUND, *supra* note 2, at 124.

<sup>24</sup> *Lochner v. New York*, 198 U.S. 45 (1905). For a review of three revisionist books discussing

Constitution to invalidate the rule, settling upon the “liberty” interest in the Fourteenth Amendment.<sup>25</sup> In the Fourteenth Amendment, the word “liberty” is part of the Due Process Clause.<sup>26</sup> The *Lochner* majority opinion is thus a leading milestone<sup>27</sup> on the Court’s journey through substantive due process.

#### 4. Public Health and Interstate Commerce

As the population and interstate travel expanded, health regulation cases reached the Supreme Court which were not purely local in character. Two illustrative cases from the early twentieth century are *Brimmer v. Rebman*<sup>28</sup> and *Louisiana v. Texas*.<sup>29</sup> Both cases address the balance between state public health regulation and interstate commerce. In *Brimmer v. Rebman*, a Virginia statute required inspection of fresh meat sold more than one hundred miles from the place of slaughter.<sup>30</sup> A tax was imposed to cover the cost of inspection.<sup>31</sup> Prior to railroad transport and mechanical refrigeration, one hundred miles might have been a reasonable health restriction.<sup>32</sup> Nevertheless, the Court invalidated the statute as an impermissible burden on interstate commerce:

Undoubtedly, a state may establish regulations for the protection of its people against the sale of unwholesome meats, provided such regulations do not conflict with the powers conferred by the [C]onstitution upon Congress, or infringe rights granted or secured by that instrument. But it may not, under the guise of exerting its police powers, or of enacting inspection laws, make discriminations against the products and industries of some of the states in favor of the products and industries of its own or of other

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*Lochner*, see Gary D. Rowe, *The Legacy of Lochner: Lochner Revisionism Revisited*, 24 LAW & SOC. INQUIRY 221 (1999) (reviewing OWEN M. FISS, *HISTORY OF THE SUPREME COURT OF THE UNITED STATES: TROUBLED BEGINNINGS OF THE MODERN STATE, 1888-1910* (1993); HOWARD GILLMAN, *THE CONSTITUTION BESIEGED: THE RISE AND DEMISE OF LOCHNER ERA POLICE POWERS JURISPRUDENCE* (1993); and MORTON J. HORWITZ, *THE TRANSFORMATION OF AMERICAN LAW, 1870-1960: THE CRISIS OF LEGAL ORTHODOXY* (1992)).

<sup>25</sup> See *Lochner*, 198 U.S. at 54.

<sup>26</sup> U.S. CONST. amend XIV, § 1.

<sup>27</sup> Some would insist it was a millstone. The search for substance in the Fourteenth Amendment may find stronger textual support in the Privileges or Immunities Clause. See *infra* note 56 and part VI.

<sup>28</sup> 138 U.S. 78 (1891).

<sup>29</sup> 176 U.S. 1 (1900).

<sup>30</sup> 138 U.S. 78 (1891).

<sup>31</sup> See *id.*

<sup>32</sup> See *id.*



states.<sup>33</sup>

In *Louisiana v. Texas*, reported cases of yellow fever in New Orleans led Texas to impose a quarantine that Louisiana found objectionable.<sup>34</sup> Louisiana alleged that the Texas quarantine was imposed for discriminatory commercial reasons having little to do with fear of a yellow fever epidemic.<sup>35</sup> The case was dismissed on Eleventh Amendment jurisdictional grounds,<sup>36</sup> but the Court evidenced some skepticism concerning the motives of Texas in enacting this quarantine.

With these cases and others,<sup>37</sup> the Court began to grapple with health regulation in the interstate context, concomitant with the growth of the nation's commerce.

## B. *The Development of Professional Licensing*

### 1. The Free Market in Health Care Services: Circa 1850

In the seventeenth and eighteenth centuries, the practice of medicine was carried on in the United States without authoritative professional regulation.<sup>38</sup> A national consensus was slow to develop on the need for regulation of the healing professions. Americans were largely self sufficient in medical matters.<sup>39</sup> Many turned to autodidactic healers<sup>40</sup> who provided succor in a laissez-faire

<sup>33</sup> *Brimmer*, 138 U.S. at 82.

<sup>34</sup> 176 U.S. 1 (1900).

<sup>35</sup> *See id.*

<sup>36</sup> *See id.* at 22-23. Eleventh Amendment jurisprudence was recently discussed in *Bd. of Trustees of the Univ. of Alabama v. Garrett*, 531 U.S. 356 (2001) (Rehnquist, C.J.) and *Kimel v. Florida Bd. of Regents*, 528 U.S. 62, 72-73 (2000) (O'Connor, J.). Oral arguments will be heard in Fall 2001 in another Eleventh Amendment case, *Mathias v. WorldCom Tech., Inc.*, cert granted 1215 S.Ct. 1224 (2001). The resurgence of the Eleventh Amendment can be viewed as another echelon of new federalism.

<sup>37</sup> *See, e.g., Dean Milk Co. v. Madison*, 340 U.S. 349 (1951) (Madison pasteurization law operated as a violation of the Commerce Clause by effectively prohibiting the sale of milk from Illinois); *Compagnie Francaise de Navigation a Vapeur v. Louisiana*, 186 U.S. 380 (1902) (anti-immigration restriction upheld as a valid quarantine restriction); *Schollenberger v. Pennsylvania*, 171 U.S. 1 (1898) (Pennsylvania ban on oleomargarine was an unconstitutional burden on interstate commerce).

<sup>38</sup> Virtually every state passed nonexclusive licensing laws by the end of the eighteenth century. *See Brock, supra* note 7, at 204 (English experience with professional monopolies created broad colonial opposition to exclusive professional licensure); *see also DE VILLE, supra* note 18, at 65-86. Beginning in 1838, states repealed even the weak nonexclusive laws. By 1850, only New Jersey and the District of Columbia had any authoritative regulation of physicians. *See id.* at 86. This may have been the height of laissez-faire in health care in America.

<sup>39</sup> *See Brock, supra* note 7, at 215 (discussing the domestic and folk medicine practiced in America).

<sup>40</sup> Freedom from exclusive licensing permitted many alternative forms of therapy to flourish, some of which were quite dangerous. *See DE VILLE, supra* note 18, at 79-81. Rival medical sects hindered the move to exclusive licensure, jealous for their position and income. *See ROTHSTEIN, supra* note 8, at 305.

environment.<sup>41</sup> Given what we know about the poor quality of elite American medicine in the 1800's, this was not an entirely irrational response.<sup>42</sup> This free market environment also suited the political philosophy of the Revolution and the Jacksonian era: In lieu of the English experience with Crown monopolies in the sixteenth and seventeenth centuries, Americans were determined to oppose exclusive privileges such as mandatory licensure of professionals.<sup>43</sup>

The result was an absence of authoritative state regulation. The enacted rules were mostly limited to nonexclusive licenses that did not grant a monopoly over the practice of medicine:

The limited nature of medical knowledge and the lack of skill of American physicians were reflected in colonial medical licensure laws. Throughout the colonial period, physicians attempted to obtain licensure legislation limiting the practice of medicine to qualified practitioners. Most legislatures, however, would enact only honorific licensing measures . . . .<sup>44</sup>

Typically, the nonexclusive license boards operated on a county level, evaluating the applicant's education and other qualifications, and receiving a fee if the application was approved.<sup>45</sup> This pecuniary interest did not motivate a careful screening process.<sup>46</sup> Worse, a license was valid statewide and an applicant could turn to various county boards, *seriatim*, until one found the applicant (or the fee) acceptable.<sup>47</sup> The resulting low standards were predictable,<sup>48</sup> but not necessarily

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Some of these traditional healers were Native Americans. See Brock, *supra* note 7, at 213-16. For a proposal regarding current use of Native American healers under the Indian Health Care Improvement Act, see Holly T. Kuschell-Haworth, *Jumping Through Hoops: Traditional Healers and the Indian Health Care Improvement Act*, 2 DEPAUL J. HEALTH CARE L. 843 (1999).

<sup>41</sup> It is reasonable to describe the health care market as "market driven" during this period, a phrase which has recently gained currency in health policy and management circles. See, e.g. REGINA HERZLINGER, MARKET DRIVEN HEALTH CARE: WHO WINS, WHO LOSES IN THE TRANSFORMATION OF AMERICA'S LARGEST SERVICE INDUSTRY (1997) (without a discussion of the previous existence of a free market in health care services in America).

<sup>42</sup> See STARR, *supra* note 7, at 56. The poor state of elite medicine was more of a scientific failure than a market failure. See *id.*

<sup>43</sup> See *The Slaughter House Cases*, 83 U.S. (16 Wall.) 36, 104 (1872) (Field, J., dissenting); Brock, *supra* note 7, at 204; STARR, *supra* note 7, at 56-59. The history of the licensure and regulation of the health professions in the United Kingdom is quite different during this period. See generally THE MEDICAL ENLIGHTENMENT OF THE EIGHTEENTH CENTURY (Andrew Cunningham & Roger French, eds., 1990) (collected essays on 18th century British and colonial medical practice); NOEL PARRY & JOSE PARRY, THE RISE OF THE MEDICAL PROFESSION (1976) (history of British apothecaries and physicians).

<sup>44</sup> ROTHSTEIN, *supra* note 8, at 37.

<sup>45</sup> See *id.*

<sup>46</sup> See *id.*

<sup>47</sup> See *id.*

<sup>48</sup> See *id.* at 79.

detrimental to the public good. Low threshold standards permit competition and allow consumers to choose lower quality services or services well suited to their particular needs or interests.<sup>49</sup>

## 2. The Shift Towards Professional Regulation: 1850 - 1920

The environment began to change in the decades following the 1850's. The American Medical Association was formed, and devised its Code of Ethics at its second convention in 1847.<sup>50</sup> Advances in scientific medicine finally provided treatments that were effective and a basis for dispassionate evaluation of the various medical sects and treatment alternatives.<sup>51</sup> The authority of elite physicians soared during this period, particularly during the Spanish American War,<sup>52</sup> giving physicians greater power to set regulatory standards.<sup>53</sup> With enforceable standards came a dramatic increase in medical malpractice cases tried against physicians.<sup>54</sup> The rival sects of medicine began to form joint medical boards in an effort to present a united front to the state in their appeal for tougher licensing laws.<sup>55</sup> Each state addressed these questions individually, only gradually converging towards compatible regulatory positions through fortuity, reciprocity agreements or model laws. The state power to regulate professions was given great latitude in *The Slaughter House Cases*,<sup>56</sup> and found similar freedom in *Dent v. West Virginia* to

<sup>49</sup> See RICHARD A. EPSTEIN, *BARGAINING WITH THE STATE* 196-97 (1993) (citing Keith B. Leffler, *Physician Licensure: Competition and Monopoly in American Medicine*, 21 J. LAW & ECON. 165 (1978)).

<sup>50</sup> See DEVILLE, *supra* note 18, at 79.

<sup>51</sup> See ROTHSTEIN, *supra* note 8, at 323-24; HERMAN MILES SOMERS & ANNE RAMSAY SOMERS, *DOCTORS, PATIENTS, AND HEALTH INSURANCE: THE ORGANIZATION AND FINANCING OF MEDICAL CARE* 22 (1961) (describing the impact of germ theory and antibiotics on medicine in the 1860s and 1870s).

<sup>52</sup> See STARR, *supra* note 7, at 141 (describing the positive change in attitudes of military line officers towards physicians, particularly with regard to infectious diseases).

<sup>53</sup> See *id.* at 79-144 (Book One, Chapter Three: The Consolidation of Professional Authority 1850-1930)).

<sup>54</sup> See DEVILLE, *supra* note 18, at 65.

<sup>55</sup> See ROTHSTEIN, *supra* note 8, at 305-10.

<sup>56</sup> 83 U.S. (16 Wall.) 36 (1872) (In a 5-4 decision, the Court allowed a Louisiana law to stand which granted an exclusive slaughter house franchise for New Orleans to a single corporation, arguably dispossessing hundreds of butchers and others of their professions; in reaching this result, the Court offered a narrow reading of the Fourteenth Amendment Privileges or Immunities Clause). If the Privileges or Immunities Clause had applied in this situation, the Court could have found a substantive right in the Fourteenth Amendment independent of the Due Process Clause. This particular issue is generating considerable scholarly attention. See, e.g., Michael Kent Curtis, *Historical Linguistics, Inkblots, and Life After Death: The Privileges or Immunities of Citizens of the United States*, 78 N.C. L. REV. 1071 (2000); Michael Kent Curtis, *Resurrecting the Privileges or Immunities Clause and Revising the Slaughter-House Cases Without Exhuming Lochner: Individual Rights and the Fourteenth Amendment*, 38 B.C. L. REV. 1 (1996); Philip B. Kurland, *The Privileges or Immunities Clause: 'Its Hour Come Round at Last'?*, 1972 WASH. U. L.Q. 405 (1972); John Harrison, *Reconstructing the Privileges or Immunities Clause*, 101 YALE L.J. 1385 (1992); Tim A. Lempert, *Recent Case: The Promise and Perils of "Privileges or Immunities": Saenz v. Roe*, 119 S. Ct. 1518 (1999), 23 HARV. J.L. & PUB. POL'Y 295 (1999); Daniel J. Levin, Note, *Reading the Privileges or Immunities Clause: Textual Irony, Analytical Revisionism, and an Interpretive*

regulate the health professions under the police power.<sup>57</sup>

This power knew few limits. In *Hawker v. New York*, the plaintiff in error had practiced medicine in New York for many years prior to the adoption of the physician licensing law in 1893.<sup>58</sup> The state established standards for physician licensure, including educational and competency requirements.<sup>59</sup> One of these standards barred a convicted felon from the practice of medicine.<sup>60</sup> Hawker had been convicted of a felony in New York some twenty years prior to the adoption of the physician licensing law.<sup>61</sup> Writing for the majority, Justice Brewer sided with the police power of the state to protect “the ignorant and credulous” from “the imposition of quacks, adventurers, and charlatans,” despite the argument that an ex post facto punishment was levied thereby.<sup>62</sup> Upon reading Justice Harlan’s dissent, we learn that the prior felony was for performing an abortion.<sup>63</sup> Beyond the specific facts of the case, *Hawker* and its siblings hold that the state police power to regulate the professions is limited only by the rational connection test.<sup>64</sup>

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Truce, 35 HARV. C.R.-C.L. L. REV. 569 (2000); Kevin Christopher Newsom, *Setting Incorporationism Straight: A Reinterpretation of the Slaughter-House Cases*, 109 YALE L.J. 643 (2000); Trisha Olson, *The Natural Law Foundation of the Privileges or Immunities Clause of the Fourteenth Amendment*, 48 ARK. L. REV. 347 (1995); Derek Shaffer, Note, *Answering Justice Thomas in Saenz: Granting the Privileges or Immunities Clause Full Citizenship Within the Fourteenth Amendment*, 54 STAN. L. REV. 709 (2000); Kimberly C. Shankman & Roger Pilon, *Reviving the Privileges or Immunities Clause to Redress the Balance Among States, Individuals, and the Federal Government*, 3 TEX. REV. L. & POL. 1 (1998); Laurence H. Tribe, Comment, *Saenz Sans Prophecy: Does the Privileges or Immunities Revival Portend the Future - or Reveal the Structure of the Present?*, 113 HARV. L. REV. 110 (1999); Stacey L. Winick, Comment, *A New Chapter in Constitutional Law: Saenz v. Roe and the Revival of the Fourteenth Amendment's Privileges or Immunities Clause*, 28 HOFSTRA L. REV. 573 (1999).

<sup>57</sup> 129 U.S. 114, 121-22 (1889) (in a case involving a physician who was already practicing in West Virginia when the state passed its physician licensing law, the Court held that while persons have a right to pursue any lawful calling or business, the state, under its police power, can impose regulation for the general welfare, even if the effect is to prevent a person from practicing the profession); see also *Semler v. Oregon State Bd. of Dental Examiners*, 294 U.S. 608 (1935) (state board may regulate the practice of dentistry in its discretion); *McNaughton v. Johnson*, 242 U.S. 344 (1917) (ophthalmologist did not prevail on a Fourteenth Amendment claim; state regulation upheld); *Collins v. Texas*, 223 U.S. 288 (1912) (osteopath found to violate state medical practice statute; no violation of the Fourteenth Amendment); *Watson v. Maryland*, 218 U.S. 173, 175-76 (1910) (state statute prohibiting the practice of medicine without state registration does not violate the Fourteenth Amendment); *Hawker v. New York*, 170 U.S. 189, 194 (1898) (state had broad discretion in describing the qualifications necessary to practice medicine in the state); see also Silverman, *supra* note 7, at 257.

<sup>58</sup> 170 U.S. 189 (1898).

<sup>59</sup> See *id.*

<sup>60</sup> See *id.*

<sup>61</sup> See *id.*

<sup>62</sup> *Id.* at 194-95 (quoting *State v. Hathaway*, 21 S.W. 1081, 1083 (Mo. 1893)).

<sup>63</sup> See *id.* at 201 (Harlan, J., dissenting) (arguing that at the time of Hawker’s crime, the abortion statute did not impose the additional penalty of prohibition from the practice of medicine; to reach the same result through the subsequently enacted physician licensing statute was an unconstitutional ex post facto law)

<sup>64</sup> See *Schwartz v. Bd. of Bar Examiners of New Mexico*, 353 U.S. 232, 239 (1957) (upholding conditions to granting a license to practice law so long as the condition bears a rational connection with the applicant’s “fitness or capacity to practice law”).

The revolution from laissez-faire to monopoly regulation was substantially completed before 1920.<sup>65</sup> Indeed, by 1910, the Court thought that the ability of a state to utilize its police power to regulate trades and professions was "too well settled" to warrant detailed discussion, particularly when the issue related closely to public health,<sup>66</sup> limited only by constitutional provisions such as the Fourteenth Amendment,<sup>67</sup> the First Amendment,<sup>68</sup> the Article IV Privileges and Immunities Clause<sup>69</sup> and the Commerce Clause.<sup>70</sup> As Professor Epstein has bemoaned, government has been unable to resist the temptation to attach economic conditions to licensure.<sup>71</sup>

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<sup>65</sup> See Richards, *supra* note 1, at 210 (1999); see also *supra* note 7 and sources cited therein.

<sup>66</sup> Watson v. Maryland, 218 U.S. at 176.

<sup>67</sup> U.S. CONST. amend. XIV; see Polhemus v. AMA, 145 F.2d 357 (1944). Several early cases challenging state regulation were brought (unsuccessfully) under the Privileges and Immunities Clause or the Equal Protection Clause of the Fourteenth Amendment. See *supra* note 57 and sources cited therein.

<sup>68</sup> U.S. CONST. amend. I; see Health Systems Agency of Northern Virginia v. Virginia State Bd. of Medicine, 424 F. Supp. 267 (1976).

<sup>69</sup> U.S. CONST. art. IV, § 2. Modern cases interpreting the Article IV Privileges and Immunities Clause generally involve discriminatory treatment of non-residents, such as *Lunding v. New York Tax Appeals Tribunal*, 522 U.S. 287 (1998) (denial of alimony expense deductions for non-residents was a "unwarranted denial to citizens of other States of the privileges and immunities enjoyed by citizens of New York"), and *United Bldg. & Const. Trades Council v. Mayor and Council of Camden*, 465 U.S. 208 (1984) (a basic right is at stake when nonresidents are denied employment in public works due to a 40% residency hiring requirement). The state professional licensure of attorneys has also been limited under the Privileges and Immunities Clause. See, e.g., *Supreme Court of Virginia v. Friedman*, 487 U.S. 59 (1988) (Privileges and Immunities Clause forbids Virginia Supreme Court rule that required non-resident attorneys to obtain permanent residence in Virginia in order to gain Virginia bar admission by reciprocity without examination); *Supreme Court of New Hampshire v. Piper*, 470 U.S. 274 (1985) (bar admission cannot be limited to state residents; under Privileges and Immunities Clause analysis, the practice of law is protected as a national fundamental right).

<sup>70</sup> U.S. CONST. art. I, § 8, cl. 3. After *Darby v. United States*, 312 U.S. 100 (1941), the state police power is susceptible to complete preemption by federal legislation under the Commerce Clause and the Spending Power, although the holding of *National League of Cities v. Usery*, 426 U.S. 833 (1976) raised some questions concerning the Tenth Amendment. In *National League of Cities*, five members of the Court decided that the Commerce Clause did not "directly displace the States' freedom to structure integral operations in areas of traditional governmental functions," a holding which was overruled nine years later when Justice Blackmun switched sides in *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528 (1985). A proper discussion of these cases must be saved for another day, as well as discussion of new federalism cases such as *New York v. United States*, 505 U.S. 144 (1992) (Congress cannot "commandeer" state governments to regulate, grounded in the federal structure of the Constitution as well as the Tenth Amendment) and *United States v. Lopez*, 514 U.S. 549 (1995) (lack of a substantial, commercial jurisdictional nexus between interstate commerce and the Gun-Free School Zones Act caused the Act to fall outside of the Commerce Clause).

<sup>71</sup> See EPSTEIN, *supra* note 49, at 198-202; see also Michael H. LeRoy, et al., *The Law and Economics of Collective Bargaining for Hospitals: An Empirical Public Policy Analysis of Bargaining Unit Determinations*, 9 YALE J. REG. 1 (1992) (discussing whether courts have been too willing to enforce restrictions on licensure).

C. *Summary: Health Care Regulation from the Era of Gas Lamps to Genomics*

The regulation of health care was, of practical necessity, a municipal function during the Colonial period, remaining so during the first century of the Republic. State regulation prior to the 1850's was sporadic, ineffective and often merely carried water for local efforts. The federal role prior to the New Deal was primarily confined to the armed forces, Native Americans, and the short-lived Freedmen's Bureau.<sup>72</sup> Only gradually did the state and federal roles expand, as technology and mobility progressed.<sup>73</sup> Driven by the technological and social level of the ambient society, municipal regulation of health care was a reflection of the era, rather than an immutable Constitutional principle of federalism, much as the municipal nature of gas lamps in the 1800's does not necessarily control modern jurisprudence concerning utilities.<sup>74</sup> As health care has developed from the era of gas lamps to modern genomics, so has the regulatory milieu. These developments are chronicled in the following sections.

### III. THE GROWTH OF FEDERAL HEALTH CARE REGULATION UNDER THE SPENDING POWER AND THE COMMERCE CLAUSE

#### A. *The Growth of Federal Health Care Expenditures*

Following the New Deal and the Great Society, the federal role in health care expanded with vigor. In the New Deal, Congress exercised the Commerce Clause authority to regulate, while the Great Society funded that authority with social programs. Beginning in 1948, the federal government financed the construction of thousands of hospital projects under the Hill-Burton program.<sup>75</sup> Medicare and Medicaid were adopted in 1965, and today, the federal government

<sup>72</sup> In his well-regarded study of American medicine in the eighteenth and nineteenth centuries, Paul Starr has little to say about federal health care activity prior to 1930. See STARR, *supra* note 7, at 30-32; see also Hodge, *supra* note 9, at 330 n.129 (describing the increased federal role after the New Deal); Kuschell-Haworth, *supra* note 40, at 845-46 (discussing the Snyder Act of 1921); FRANKLIN, *supra* note 9, at 228-32 (Freedmen's Bureau).

<sup>73</sup> See Michael S. Morgenstern, *The Role of the Federal Government in Protecting Citizens from Communicable Diseases*, 47 U. CIN. L.R. 537, 541-44 (1978).

<sup>74</sup> See, e.g. AT&T Corp. v. Iowa Utilities Bd., 525 U.S. 366 (1999) (FCC had authority under Telecommunications Act of 1996 to implement local-competition rules for telephone services); but see *id.* at 402 ("Since Alexander Graham Bell invented the telephone in 1876, the States have been, for all practical purposes, exclusively responsible for regulating intrastate telephone service. Although the Telecommunications Act of 1996 altered that more than century-old tradition, the majority takes the Act too far in transferring the States' regulatory authority wholesale to the Federal Communications Commission.") (Thomas, J., dissenting).

<sup>75</sup> See Hospital Survey and Construction Act of 1946, 42 U.S.C. §§ 291-291o-1 (2000). By June 30, 1971, 10,748 Hill-Burton hospital construction projects had been approved, at a total cost of \$12.8 billion, including the federal share totalling \$3.7 billion. See JUDITH R. LAVE & LESTER B. LAVE, *THE HOSPITAL CONSTRUCTION ACT: AN EVALUATION OF THE HILL-BURTON PROGRAM, 1948-1973* 13 (1974).

spends \$267.8 billion per year<sup>76</sup> to finance the health care of approximately 39 million Americans<sup>77</sup> through Medicare.<sup>78</sup> Medicaid<sup>79</sup> reaches 36 million indigent residents<sup>80</sup> at an annual combined state and federal cost of \$203.3 billion.<sup>81</sup> An additional 3.3 million low-income children<sup>82</sup> are covered by SCHIP.<sup>83</sup>

This growth in the federal role in health care can be attributed to at least three causes. First, social change encouraged a federal role, as a result of “varying patterns of economic growth, shifts in population to urban areas, societal changes, and, of course, the Civil War and the Fourteenth Amendment.”<sup>84</sup> Second, the federal role was a recognition that medical technology and understanding had progressed: it was no longer deemed sufficient to treat infectious diseases at a local level since coordinated national and international efforts could be more effective.<sup>85</sup> Finally, health was increasingly recognized as a public good, and the cost of an effective response necessitated access to national sources of revenue to fund the programs.<sup>86</sup>

### B. *Gibbons v. Ogden*

The seeds of this federal sequoia may be found in *Gibbons v. Ogden*, a familiar case wherein Chief Justice Marshall established a broad role for federal power under the Commerce Clause.<sup>87</sup> In *Gibbons*, all state powers that affect commerce with foreign nations or among the states are subject to concurrent federal jurisdiction, including preemption under the Supremacy Clause. Chief Justice

<sup>76</sup> See Sheila Smith et al., *The Next Ten Years of Health Spending: What Does the Future Hold?*, HEALTH AFFAIRS Sep./Oct. 1998, at 129 (projected 2001 costs).

<sup>77</sup> See Health Care Financing Administration, *Medicare Basics* (2001) (visited Apr. 26, 2001) <<http://www.medicare.gov/basics/overview.asp>>.

<sup>78</sup> See Social Security Amendments of 1965 (Medicare), 42 U.S.C. §§ 1395-1395ggg (2000).

<sup>79</sup> See Social Security Amendments of 1965 (Medicaid), 42 U.S.C. §§ 1396-1396v (2000).

<sup>80</sup> See Health Care Financing Administration, *Medicaid Information* (2001) (visited Apr. 26, 2001) <<http://www.hcfa.gov/medicaid/medicaid.htm>>.

<sup>81</sup> See Smith, *supra* note 76, at 129.

<sup>82</sup> See Health Care Financing Administration, *State Children's Health Insurance Program* (2001) (visited Apr. 26, 2001) <<http://www.hcfa.gov/init/fy2000.pdf>>.

<sup>83</sup> See Balanced Budget Act of 1997 (SCHIP), 42 U.S.C. §§ 1397aa-1397jj (2001).

<sup>84</sup> Hodge, *supra* note 9, at n. 128 and accompanying text.

<sup>85</sup> The global eradication of smallpox would not have been possible without international cooperation. See FRANK FENNER, ED., *SMALLPOX AND ITS ERADICATION* (History of International Public Health, No. 6) (1989).

<sup>86</sup> See SOMERS, *supra* note 51, at 397 et seq. (in a Brookings Institute study published four years before the adoption of Medicare, the authors discuss the need for comprehensive health coverage); see also Larry Kramer, *Understanding Federalism*, 47 VAND. L.R. 1485, 1497-98 (1994) (the New Deal required federal intervention because the crisis was beyond the resources of the states).

<sup>87</sup> 22 U.S. (9 Wheat.) 1 (1824).

Marshall refused to restrict the Commerce Clause to a geographical interpretation,<sup>88</sup> reasoning that commerce among the states may begin and end at any point within a state and does not acquire and relinquish its constitutional character merely for the brief moment of passage across a state boundary.<sup>89</sup> The Commerce Clause thus grants "plenary" power to the federal government,<sup>90</sup> leaving to exclusive state jurisdiction only "completely internal" matters.<sup>91</sup> Even this limited sphere may not be constitutionally mandated, but is left to the states when federal regulation is "inconvenient" and "unnecessary."<sup>92</sup>

The scope of the Commerce Clause has suffered many refinements since 1824,<sup>93</sup> but the modern view is remarkably consistent with Chief Justice Marshall's vision.<sup>94</sup>

### C. *The Growth of Federal Health Care Regulation*

Federal regulation of health care is grounded in two Article I, Section 8 enumerated powers: the Spending Power and the Commerce Clause.

#### 1. The Spending Power

Under the Spending Power, Congress attaches conditions upon the receipt of federal funds, such as state adoption of regulations or accession to federal

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<sup>88</sup> See *id.* at 203.

<sup>89</sup> See *id.* at 195.

<sup>90</sup> *Id.* at 196.

<sup>91</sup> *Id.* at 194.

<sup>92</sup> *Gibbons*, 22 U.S. at 194.

<sup>93</sup> Only thirteen years later, but after the death of Chief Justice Marshall, the Court in *Mayor of New York v. Miln*, 36 U.S. (11 Pet.) 102, 139 (1837), stated that under the Constitution, police powers were "not thus surrendered or restrained; and that, consequently, in relation to these, the authority of a State is complete, unqualified and exclusive." *Id.* at 139. One reading of *Mayor of New York v. Miln* is that it stands for local law enforcement and the regulation of paupers as police powers under exclusive and unqualified state control. See *id.* at 139 and 148 ("Can anything fall more directly within the police power and internal regulation of a State, than that which concerns the care and management of paupers or convicts . . . ?") (Thompson, J., concurring). While language in the case is arguably to blame for this conclusion, it seems clear that if the regulation at issue had clearly conflicted with a valid federal commerce statute, then the Supremacy Clause would have intervened. See *id.* at 158 (Story, J., dissenting). In addition, if the apparent holding of *Mayor of New York v. Miln* is to be believed, then what are we to make of the federalization of crimes committed within the states, or of the current federal programs to alleviate poverty, if the authority of the state in these areas is "complete, unqualified and exclusive"? *Id.* at 139. For a discussion of the federal police power, or the lack thereof, see *supra* note 1 and sources cited therein.

<sup>94</sup> See, e.g., *Wickard v. Filburn*, 317 U.S. 111 (1942) ("At the beginning Chief Justice Marshall described the federal commerce power with a breadth never yet exceeded."); *United States v. Darby*, 312 U.S. 100 (1941) (upholding the Fair Labor Standards Act of 1938 when applied to a lumber manufacturer; held to be a proper use of the Commerce Clause); but see *United States v. Lopez*, 514 U.S. 549 (1995); *New York v. United States*, 505 U.S. 144 (1992).



standards.<sup>95</sup> As the Greek army was admitted into Troy within the famous horse, so federal regulation has followed the appropriation of federal health care funds.<sup>96</sup> Some examples will illustrate the scope of this power.

a. *The Hill-Burton Act*

The regulatory price of federal Hill-Burton<sup>97</sup> funds included standards relating to construction,<sup>98</sup> the prevailing wage rule of the Davis-Bacon Act,<sup>99</sup> responsibility to provide charity care,<sup>100</sup> and possible exposure to civil rights actions for discrimination.<sup>101</sup>

b. *The National Health Planning and Resources*

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<sup>95</sup> Cooperative federalism ties receipt of federal money to voluntary accession by the recipient states to federal regulatory requirements. Prominent examples include Medicaid, Aid to Families With Dependent Children, and the Federal Highway Program. See Jerry L. Mashaw & Theodore R. Marmor, *The Case for Federalism and Health Care Reform*, 28 CONN L.R. 115 (1995). In many cases, the federal programs in question are so important to the states that the likelihood of rejection of the federal offer is slight. This relationship might be better termed "co-opted federalism". *Id.* While many of us may be forgiven for deeming the Spending Power as plenary and well settled, a recent symposium revealed potential challenges to the Spending Power, together with its traditional defenses. Compare Lynn A. Baker, *The Spending Power and the Federalist Revival*, 4 CHAPMAN L. REV. 195 (2001) (calling for greater judicial scrutiny under the Spending Clause); John C. Eastman, *Restoring the "General" to the General Welfare Clause*, 4 CHAPMAN L. REV. 63 (2001) (historical analysis of the meaning of "general" as a limitation on the Spending Clause); Celestine Richards McConville, *Federal Funding Conditions: Bursting Through the Dole Loopholes*, 4 CHAPMAN L. REV. 163 (2001) (vindicate federalism interests through enhanced scrutiny of conditions placed on receipt of federal funds); and Bradley A. Smith, *Hamilton at Wits End: The Lost Discipline of the Spending Clause vs. the False Discipline of Campaign Finance Reform*, 4 CHAPMAN L. REV. 117 (2001) (a broad interpretation of the Spending Clause places unrealistic pressure on the campaign finance system); with Erwin Chemerinsky, *Protecting the Spending Power*, 4 CHAPMAN L. REV. 89 (2001) (traditional defense of Spending Power); Earl M. Maltz, *Sovereignty, Autonomy and Conditional Spending*, 4 CHAPMAN L. REV. 107 (2001) (state autonomy is best left to the political process).

<sup>96</sup> Beware of bureaucracies bearing gifts. Unlike Troy, the federal strings should not have come as a surprise, but see *McCall v. Pacificare of California, Inc.*, \_\_ Cal. 4th \_\_ (opinion filed May 3, 2001), available at 2001 WL 460692 (Cal.) ("Ironically, '[t]he first section of the Medicare Act explicitly states [Congress's] intent to minimize federal intrusion in the area.'") (quoting *Massachusetts Medical Society v. Dukakis*, 815 F.2d 790, 791 (1st Cir. 1987) (citations omitted)).

<sup>97</sup> See *supra* note 75.

<sup>98</sup> See 42 U.S.C. § 291c(b) (2000).

<sup>99</sup> See 42 U.S.C. § 291e(a)(5) (2000). The Davis-Bacon Act is codified at 40 U.S.C. §§ 276a-276a-5 (2000).

<sup>100</sup> See *Euresti v. Stenner*, 458 F.2d 1115 (10th Cir. 1972) (receipt of Hill-Burton funds creates clear duty to provide reasonable amounts of charity care); see also *Gordon v. Forsyth County Hosp. Auth.*, 409 F. Supp. 708, *aff'd in part and vacated in part on other grounds* 544 F.2d 748 (4th Cir. 1976) (hospital that did not receive Hill-Burton funds is not obligated to provide charity care); but cf. *Lile v. Univ. of Iowa Hosp. & Clinics*, 674 F. Supp. 288 (1987) (no duty to provide charity care when Hill-Burton repayment obligation was met through alternative means).

<sup>101</sup> Compare *Hodge v. Paoli Mem'l Hosp.* 576 F.2d 563 (3d Cir. 1978) (mere acceptance of Hill-Burton funds does not bring all hospital actions under color of state law); with *Simkins v. Moses H. Cone Mem'l Hosp.*, 323 F.2d 959 (4th Cir. 1963) (receipt of Hill-Burton funds is sufficient state action to implicate the protections of the Fourteenth Amendment).

*Development Act*

Beginning in 1974, acceptance of federal funds also obligated states to adopt certificate of need laws relating to health facility planning.<sup>102</sup> Most states have retained these laws,<sup>103</sup> even after the federal requirement was abolished in 1986.<sup>104</sup> Like the fossilized footprints of an extinct dinosaur, the tracks of the federal National Health Planning law can still be found in the laws of 35 states.

*c. Medicare and Medicaid Conditions of Participation*

Acceptance of Medicare and Medicaid funding requires that health care providers such as hospitals meet HCFA's Conditions of Participation covering many aspects of facility operation and regulation.<sup>105</sup> Since Medicare, Medicaid, and related government programs account for estimated annual revenues of \$637.4 billion in 2001,<sup>106</sup> this is an offer that cannot be refused. These rules are often enforced through private accreditation organizations. For hospitals, the Joint Commission on Accreditation of Healthcare Organizations is the private accreditation organization that meets Medicare's standards.<sup>107</sup> The uniform national standards of the Joint Commission represent a federalization of hospital licensing standards, enforced upon state licensed hospitals through the vector of Medicare.<sup>108</sup>

*d. Prohibition of Private Practice with Medicare-Eligible Individuals*

Medicare prohibits a physician from providing private medical services to Medicare-eligible individuals unless the physician certifies to Medicare that the

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<sup>102</sup> See National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300k-1 *et seq.* (1986) repealed by Pub. L. 99-660, § 701(a) (Nov. 14, 1986, effective Jan. 1, 1987).

<sup>103</sup> According to a November 1999 survey, 35 states retain CON laws. Community Catalyst, *Certificate of Need Laws: A Comparison of State Laws Chart (1999)* (visited Apr. 26, 2001) <<http://www.communitycat.org/index.php3?fldID=89>>. For a complete survey of the history of the adoption and repeal of the National Health Planning and Resources Development Act, see Patrick John McGinley, *Beyond Health Reform: Reconsidering Certificate of Need Laws In A Managed Competition System*, 23 FLA. ST. U. L. REV. 141 (1995).

<sup>104</sup> See McGinley, *supra* note 103.

<sup>105</sup> Conditions of participation have been established for hospitals, 42 U.S.C. § 1395x(e) (2001); 42 C.F.R. §§ 482.1-482.66 (2001) and home health services, 42 U.S.C. § 1395x(m); 42 C.F.R. §§ 484.1-484.55 (2001), as well as several other types of providers.

<sup>106</sup> See Smith, *supra* note 76, at 129.

<sup>107</sup> See 42 U.S.C. § 1395bb(a) (2001).

<sup>108</sup> The Joint Commission has embarked on a cooperative federalism project since it began recognizing the work of other accreditation organizations in some circumstances. See Joint Commission on Accreditation of Healthcare Organizations, *Government Relations, Cooperative Accreditation Initiative (2001)* (visited May 2, 2001) <<http://www.jcaho.org/govt/reduction.html>>.

physician will not participate in Medicare for at least two full years.<sup>109</sup> This extraordinary interference with freedom of contract cannot be waived by the patient.<sup>110</sup> Given the significant role that Medicare reimbursement plays in most physician's practices, few are likely to agree to a two year program termination. This provision might be testing the outer boundaries of the Spending Power.<sup>111</sup>

## 2. The Commerce Clause

The federal government has also adopted substantive health regulation under the Commerce Clause, unrelated to the receipt of federal funds, which in some cases explicitly pre-empts state law.<sup>112</sup> Some of these laws have interesting technological components. In this vein, consider the HIPAA administrative simplification rules,<sup>113</sup> which require national<sup>114</sup> adoption of certain data formats for all health care transactional information. Prior to adoption, approximately 400 different formats for health care data transfer<sup>115</sup> crippled efforts to adopt a more efficient consensual standard. HIPAA was enacted, in part, to bring order to the health information chaos, saving tens of billions of dollars.<sup>116</sup>

A second major HIPAA provision imposed federal standards on health insurance portability and other market reforms. In the market reform rules, Congress gave each state three choices: (1) pass state health insurance laws in compliance with the federal standard and retain local enforcement; (2) create an acceptable alternative approved by HCFA and enforce it with local agencies; or (3) default to the federal rules with enforcement by HCFA.<sup>117</sup>

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<sup>109</sup> See 42 C.F.R. §§ 405.400-405.455 (1999).

<sup>110</sup> See *id.*

<sup>111</sup> In *Fullilove v. Klutznick*, 448 U.S. 448 (1980), the Court upheld a ten percent set-aside program under the Spending Power, but the scope of the Spending Power cannot be unlimited, *South Dakota v. Dole*, 483 U.S. 203 (1987) (O'Connor, J., dissenting). See *supra* note 95.

<sup>112</sup> The HIPAA administrative simplification provision pre-empts contrary state law, 42 U.S.C. § 1320d-7(a)(1) (2000), whereas the HIPAA privacy law leaves more restrictive state law in place, 42 U.S.C. § 1320d-7(a)(2)(B) (2000).

<sup>113</sup> Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§ 1320d to 1320d-8 (2001). Two sets of final regulations have been issued to date under this law: the Transactions and Code Set Rules, 42 C.F.R. §§ 160.101-162.1802 (2001) and the Privacy Rule, 42 C.F.R. §§ 160.101-160.312 (2001).

<sup>114</sup> The successful adoption of *national* standards leads to the question of whether *international* standards are also appropriate. Some current standards enjoy international adoption, such as time and calendar; others remain rooted in national or regional practice such as consumer electrical distribution.

<sup>115</sup> See Health Insurance Reform: Standards for Electronic Transactions, 65 Fed. Reg. 50,312 (Aug. 17, 2000) (preamble).

<sup>116</sup> The U.S. Department of Health and Human Services estimates that the administrative simplification regulations will provide a net savings to the health care industry of \$29.9 billion over 10 years. See U.S. Dep't of Health & Human Services, *HHS News, HHS Announces Electronic Standards To Simplify Health Care Transactions* (Aug. 11, 2000), (visited Apr. 26, 2001) <<http://aspe.hhs.gov/admsimp/final/press1.htm>>.

<sup>117</sup> See 42 U.S.C. §§ 300gg to 300gg-92 (2001); Len M. Nichols and Linda J. Blumberg, *A Different*

A final example, completely unrelated to HIPAA, is Title 21 of the United States Code, Food and Drug, by which the federal government preempted much of the regulation of food and drug safety, which had previously been handled by the states. State regulation of food had given rise to several Supreme Court cases, often concerning unfair burdens on interstate commerce cast by state health and safety laws.<sup>118</sup>

#### IV. TECHNOLOGY AND CHANGE

Technology has altered the balance in both healthcare and federalism. As we have seen, the emergence of scientific medicine gave birth to the modern medical profession, as well as authoritative state regulation.<sup>119</sup> Technology supports the bureaucratic apparatus through which the federal government collects taxes to fund the exercise of the Spending Power. The Industrial Revolution and urbanization placed people and machines in dangerous juxtaposition, eventually leading to public health and safety regulation.<sup>120</sup> The introduction of the steamship, the railroad, the automobile, and air transport each provided additional mobility. Mobility of both people<sup>121</sup> and commerce arguably spelled the doom of judicially enforced states' rights under the Commerce Clause, as Professor Kramer recounts:

To begin with, between the Civil War and World War I the economies of the separate states became functionally integrated. By 1930, practically everyone consumed or produced goods bought and sold in other states. Improvements in transportation and communication accelerated this process, as wire services and radio (not to mention telegraph and telephone) made events around the country immediately accessible. Other states became less distant, and what happened there was of considerable importance. These developments, in turn, made national solutions necessary for problems that had previously been handled at the state level. As product, labor, and capital markets became nationally integrated, state regulation ceased to work; in many instances it became part of the problem. Distinctions like

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*Kind of 'New Federalism'? The Health Insurance Portability and Accountability Act of 1996*, HEALTH AFFAIRS, May/June 1998, at 34. Most states chose the first path. *See id.*

<sup>118</sup> *See, e.g., supra* notes 2, 5 and 37 and sources cited therein.

<sup>119</sup> *See supra* parts II and III.

<sup>120</sup> *See, e.g., Lochner v. New York*, 198 U.S. 45, 66 (1905) ("While this [police] power is inherent in all governments, it has doubtless been greatly expanded in its application during the past century, owing to an enormous increase in the number of occupations which are dangerous, or so far detrimental, to the health of employees as to demand special precautions for their well-being and protection, or the safety of adjacent property.") (Harlan, J., dissenting) (citations omitted).

<sup>121</sup> Americans continue to be mobile individuals. *See* Robert Suro, *Movement at Warp Speed*, AM. DEMOGRAPHICS, Aug. 1, 2000.

“commerce versus manufacture,” “direct versus indirect,” or “local versus interstate” no longer made sense in a nation where effects necessarily rippled across state lines.

Matters came to a head with the economic crisis of the 1930s, which proved beyond the competence of states to deal with individually. FDR’s New Deal called for federal regulation on an unprecedented scale. After a brief but spirited effort to hold the line, the Supreme Court capitulated in a series of well known decisions rendered between 1937 and 1942. The federal government acquired vastly expanded power to regulate private activity, and for all practical purposes the era of judicially enforced federalism came to an end.<sup>122</sup>

Justice O’Connor, while recognizing the historical record, “would prefer to hold the field and, at the very least, render a little aid to the wounded.”<sup>123</sup>

Due to the emergence of an integrated and industrialized national economy, this Court has been required to examine and review a breathtaking expansion of the powers of Congress. In doing so the Court correctly perceived that the Framers of our Constitution intended Congress to have sufficient power to address national problems. But the Framers were not single-minded. The Constitution is animated by an array of intentions. Just as surely as the Framers envisioned a National Government capable of solving national problems, they also envisioned a republic whose vitality was assured by the diffusion of power not only among the branches of the Federal Government, but also between the Federal Government and the States. In the 18th century these intentions did not conflict because technology had not yet converted every local problem into a national one. A conflict has now emerged, and the Court today retreats rather than reconcile the Constitution’s dual concerns for federalism and an effective commerce power.<sup>124</sup>

Technological change is not always a sufficient warrant for legal change. In the assisted suicide case, the Court noted that “[b]ecause of advances in medicine and technology, Americans today are increasingly likely to die in

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<sup>122</sup> Kramer, *supra* note 86, at 1497-98 (footnotes omitted). Economists might say that increased mobility highlighted locational disparities and interstate externalities, both of which argued for a federal standard. See Daniel Shaviro, *An Economic and Political Look at Federalism in Taxation*, 90 MICH. L.R. 895 (1992).

<sup>123</sup> Garcia v. San Antonio Metro. Transit Auth., 469 U.S. 528, 580 (1985).

<sup>124</sup> *Id.* at 581 (citations omitted in text and footnotes).

institutions, from chronic illness.”<sup>125</sup> Despite the nod to technological change, the Court stepped back from embracing a constitutional right to die:

Attitudes toward suicide itself have changed since Bracton, but our laws have consistently condemned, and continue to prohibit, assisting suicide. Despite changes in medical technology and notwithstanding an increased emphasis on the importance of end of life decision-making, we have not retreated from this prohibition.<sup>126</sup>

In addition, technology itself has changed. The icon of the Industrialized Revolution was the factory: a centralized, automated process center. In the Digital Revolution, the Internet has replaced the factory as the favored model, with the potential for a decentralizing technological paradigm. Digital technology “may make local regulation desirable at one time, national at another, local at still a third (as may be happening now in the swiftly developing communications industry).”<sup>127</sup> Two notable features of digital technology are its ability to reduce information costs and compress distance: “In general, in terms of information, much of what was scarce is becoming abundant, much of what was distant is coming closer, much of what was secret is opening up.”<sup>128</sup>

#### A. *Technology and Information Costs*

In his remarkably prescient essay at the end of the Second World War, Dr. Vannevar Bush sketched the blueprint for the Internet, which he called the “memex,” as a tool for greatly reducing the cost of information storage and retrieval, and thus advancing civilization:

Presumably man’s spirit should be elevated if he can better review his shady past and analyze more completely and objectively his present problems. He has built a civilization so complex that he needs to mechanize his records more fully if he is to push his experiment to its logical conclusion and not merely become bogged down part way there by overtaxing his limited memory. His excursions may be more enjoyable if he can reacquire the privilege of forgetting the manifold things he does not need to have immediately at hand, with some assurance that he can find

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<sup>125</sup> Washington v. Glucksberg, 521 U.S. 702, 716 (1997) (citation omitted).

<sup>126</sup> *Id.* at 719.

<sup>127</sup> Kramer, *supra* note 86, at 1500 (concurrent state and federal jurisdiction allows power to be allocated and reallocated, but courts are poorly suited to make these judgments; hence, he concludes, judicially enforced federalism is dead).

<sup>128</sup> M. Ethan Katsh, *Symposium: Emerging Media Technology and the First Amendment: Rights, Camera, Action: Cyberspatial Settings and the First Amendment*, 104 YALE L.J. 1681, 1687 (1995).

them again if they prove important.

The applications of science have built man a well-supplied house, and are teaching him to live healthily therein. They have enabled him to throw masses of people against one another with cruel weapons. They may yet allow him truly to encompass the great record and to grow in the wisdom of race experience. He may perish in conflict before he learns to wield that record for his true good. Yet, in the application of science to the needs and desires of man, it would seem to be a singularly unfortunate state at which to terminate the process, or to lose hope as to the outcome.<sup>129</sup>

Knowledge that is no longer centrally controlled, but is readily available in distributed form such as the Internet can theoretically support distributed forms of government as well:

The hope for self-government today lies not in relocating sovereignty but in dispersing it. The most promising alternative to the sovereign state is not a cosmopolitan community based on the solidarity of humankind but a multiplicity of communities and political bodies - some more extensive than nations and some less - among which sovereignty is diffused.<sup>130</sup>

Of course, George Orwell was possessed of a decidedly more pessimistic view of the authoritarian possibilities inherent in the modern age.

#### B. *Technology and Distance Compression*

Distance compression is not unique to digital technology. The introduction of the automobile expanded the geographic scope of the physician's practice, increasing market penetration in the early twentieth century.<sup>131</sup> All forms of modern communication and transportation can be seen as distance (or time) compression devices. The unique feature of the Internet is its complete indifference to geography and distance:<sup>132</sup> "these lines on the ground mean little in cyberspace."<sup>133</sup>

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<sup>129</sup> Vannever Bush, *As We May Think*, ATLANTIC MONTHLY, Jul. 1945, at 108.

<sup>130</sup> Michael J. Sandel, *America's Search for a New Public Philosophy*, ATLANTIC MONTHLY, Mar. 1996, at 57, 73-74, *quoted in* David R. Johnson & David Post, *Symposium: Surveying Law and Borders: Law and Borders - The Rise of Law in Cyberspace*, 48 STAN. L.R. 1367, 1397 (1996).

<sup>131</sup> See STARR, *supra* note 7, at 65.

<sup>132</sup> See Dan L. Burk, *Jurisdiction in a World Without Borders*, 1 VA. J.L. & TECH. 3 (1997); Johnson, *supra* note 130, at 1368, 1370 ("Territorial borders, generally speaking, delineate areas within which different sets of legal rules apply. There has until now been a general correspondence between borders drawn in physical space (between nation states or other political entities) and borders in 'law space'. . . . The Net thus radically subverts the system of rule-making based on borders between physical spaces, at least with respect to the claim that Cyberspace should naturally be governed by territorially defined rules."); Katsh, *supra* note

Freedom from distance related constraints may have interesting implications for government. It may lead to the development of international standards, much as the Industrial Revolution facilitated (and benefited from) the rise of strong nation states. The efficiency arguments successfully applied to the Commerce Clause for the past two centuries also lend support for not stopping the legal convergence at the United States border. Clearly, this is the path of the European Union.

Increased federal dominance is also certainly possible, in areas such as education, taxation, and professional services such as law and medicine.<sup>134</sup> Each of these activities can be partially performed online,<sup>135</sup> and the federal government may choose to exercise supremacy. Reducing the importance of distance may also permit power to be further distributed to the states, as the location best suited for the particular endeavor. With modern technology, the efficiency goal of national uniformity could be met through an interconnected network of local actors.

### C. *Technical Standards*

Before moving on to examine the case studies, a brief discussion of technical standards is appropriate. Technical standards, such as the HIPAA administrative simplification rules, are an interesting form of health care regulation.

Technological advance produces certain items or services that, by their essential nature, can best be provided through adoption of a standard,<sup>136</sup> even if the

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128, at 1694 ("Electronic networks change how much time is needed to move and access information but it is their impact on the dimension of distance, even more than on the time dimension, that may bring about the most profound change. Computer networks allow much information that was previously inaccessible and valueless because it was in a distant place, to become useful and valuable when it is accessible via a network. Similarly, people with whom one could only maintain a "distant" relationship can now become co-workers who can efficiently interact with each other. As information that was previously isolated and separate is shared and used as if it were in one place, and as people who were once separated communicate more often, new relationships and new institutions are formed"); Nicholas Terry, *Structural and Legal Implications of E-Health*, 33 J. HEALTH L. 605 (2000).

<sup>133</sup> WILLIAM J. MITCHELL, *CITY OF BITS: SPACE, PLACE AND THE INFOBAHN* (1995), *quoted in* Katsh, *supra* note 128, at 1717.

<sup>134</sup> The Telecommunications Act of 1996 ended a century-old tradition of state regulation with federal rules for local access. *AT&T Corp. v. Iowa Utilities Board*, 525 U.S. 366, 371 (1999) ("Until the 1990s, local phone service was thought to be a natural monopoly. States typically granted an exclusive franchise in each local service area to a local exchange carrier (LEC), which owned, among other things, the local loops (wires connecting telephones to switches), the switches (equipment directing calls to their destinations), and the transport trunks (wires carrying calls between switches) that constitute a local exchange network. Technological advances, however, have made competition among multiple providers of local service seem possible, and Congress recently ended the longstanding regime of state-sanctioned monopolies.")

<sup>135</sup> See Johnson, *supra* note 130, at 1377-78, 1382 (discussing an Internet-based jurisdiction to replace traditional local regulation patterns).

<sup>136</sup> The Internet is a network of networks that operate on common technical standards, allowing free transfer of information. Cell phones are able to roam on different networks due to the use of a common technical standard. Television transmission and reception is possible due to the common standards for frequency and signal strength.



standard is itself arbitrary.<sup>137</sup> Adoption of a standard does not necessarily freeze innovation; technology may retain dynamic opportunities for improvement.<sup>138</sup>

Standards may be public or proprietary, but proprietary standards are likely to be less efficient. By their nature, competing standards require additional consumer costs.<sup>139</sup> Furthermore, if a single proprietary standard becomes dominant and is protected by intellectual property laws, the resulting market power may allow monopolistic behavior.<sup>140</sup> By establishing reasonable public standards, national efficiencies can be reaped.<sup>141</sup> As commerce continues to expand, the argument for efficiency will call for the adoption of such standards, ultimately on an international basis.

#### D. *Technology and Federalism: A Modest Conclusion*

One should not draw a hasty conclusion from this analysis, other than to say that hasty conclusions are often wrong; nevertheless, while technology may have played a key role in the expansion of federal power in the first two centuries of the Republic, we should not assume that the banner of technology, once unfurled, will necessarily rally the troops to the federal side. Instead, the changing nature of technology calls for a careful analysis of whether it has a positive, negative or neutral impact on the federalism question at hand.

<sup>137</sup>

An example of an arbitrary - but necessary - standard is driving on the right (or left) side of the road. Selection of one or the other standard produces no apparent benefit, so long as everyone on the road adheres to the selected arbitrary standard. Another example of arbitrary standards are weights and measures, which were discussed by counsel in *Gibbons v. Ogden*, 22 U.S. 1, 40-41 (1824), as the type of legislation requiring uniform national adoption, and which are federal powers granted under Article I. U.S. CONST., art. I, § 8, cl. 5. An example of a non-arbitrary standard could be the twenty-four hour day.

<sup>138</sup>

Fifty years ago, certain services were regarded as natural monopolies that could only be delivered through a single-owner system. Prominent examples would have been electrical and telephone utilities. See *AT&T Corp. v. Iowa Utilities Bd.*, 525 U.S. 366 (1999); *id.* at 402 (Thomas, J., dissenting). Technological change has now permitted competition in the local delivery of electricity and telephone service. Just as the description of natural monopolies has not remained static, one should not expect adopted standards to lead inexorably to atrophy.

<sup>139</sup>

One example would be the VHS and Beta videotape systems, which for a time required manufacturers to produce videotapes in both formats. After a period of competition, the VHS system dominated the market and Beta tapes (and tape players) were relegated to history. Premature adoption of a mandated standard has its own disadvantages; if a governmental mandate had required 8-Track as the sole format for music then much of the consumer electronics innovations of the last thirty years might have been lost.

<sup>140</sup>

This is one of the basic theories proffered by the government in *United States v. Microsoft*, 97 F. Supp. 2d 59 (D.D.C. 2000) *on appeal* 213 F.3d 764 (D.C. Cir. 2000).

<sup>141</sup>

The most effective standards are not noticed in everyday life. Take for example the United States standard for most consumer electrical devices. Devices for the U.S. market that are to operate on alternating current invariably are designed for 110 to 120 volts, carried through a two or three prong plug which fits into all consumer electrical outlets across the United States. The advantages of a single national standard are obvious, particularly when one visits another country that operates on a different standard. Imagine the difficulty if Indiana adopted the British style of prong, or 220 volts as standard; worse yet, if each state created its own standards. Many other examples could be cited, including railroad gauges, time and calendars, music and video formats, the Internet, and cell phones. Competition can remain robust once the open public standard is adopted.

## V. TECHNOLOGY, REGULATION AND HEALTHCARE: CASE STUDIES

A. *E-Health and State Based Licensure of Physicians*

Technology is blurring the boundaries of the geographic fiefdoms that have traditionally governed health care. The physician is no longer the exclusive gatekeeper for clinical information.<sup>142</sup> Moving beyond telemedicine, e-health promises (or threatens) to bring clinical interactions to the Internet, without regard to distance or jurisdiction.<sup>143</sup> Surgical robots may permit world-renowned surgeons to operate on a patient at any distance.<sup>144</sup> Patients can maintain relationships with physicians during travel or after relocations, or initiate relationships *ex nihilo* across the country or across the world.<sup>145</sup> E-health businesses are potentially subject to the regulatory authority of many different jurisdictions.<sup>146</sup> As e-health frees the physician from a purely local practice, a major regulatory collision is imminent, as Professor Nicholas Terry has observed:

This lack of physicality, the decoupling of physician from jurisdiction-delimited practice, severely challenges state licensing systems that apply to healthcare professionals. Telemedicine statutes that have been passed in a few states may map to a narrow range of business-to-business e-Health businesses. However, in the case of most business-to-consumer e-Health models ... many practitioners will be risking a charge of unlicensed practice of medicine, while their patients may face an additional risk of dealing with a physician without (typically geographically limited) malpractice insurance coverage. Inevitably, as e-Health

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<sup>142</sup> See Bruce Merlin Fried, et al., *E-Health: Technologic Revolution Meets Regulatory Constraint*, HEALTH AFFAIRS, Nov./Dec. 2000, at 124, 125 (health content provided online); Barry R. Furrow, *Broadcasting Clinical Guidelines on the Internet: Will Physicians Tune In?*, 25 AM. J.L. & MED. 403-21 (1999); Terry, *supra* note 132, at 608. See also the website of EBM Solutions, Inc. regarding providing peer-reviewed clinical information to physicians and patients in parallel formats. See EBM Solutions, Inc., *Evidence-Based Medicine* (visited on May 5, 2001) <<http://www.webebm.com>>.

<sup>143</sup> See Jeff Goldsmith, *The Internet and Managed Care: A New Wave of Innovation*, HEALTH AFFAIRS, Nov./Dec. 2000, at 42, 48-50 (discussing clinical uses of the Internet such as medical management and decision support); Jerome P. Kassirer, *Patients, Physicians, and the Internet*, HEALTH AFFAIRS, Nov./Dec. 2000, at 115; Silverman, *supra* note 7.

<sup>144</sup> See Cinda Becker, *Look, No Hands: With Surgical Robotics, Industry Embraces Cutting-Edge Technology*, MODERN HEALTHCARE, Apr. 30, 2001, at 36-40, 46.

<sup>145</sup> See *id.*

<sup>146</sup> See Fried et al., *supra* note 142, at 128-30; J.D. Kleinke, *Vaporware.com: The Failed Promise of the Health Care Internet*, HEALTH AFFAIRS, Nov./Dec. 2000, at 57, 63 (anti-referral and fraud and abuse laws will hinder the development of internet health care ventures); M. Kevin Outterson, *Physicians, E Health and Liability*, Address Before the American Health Lawyers Association Physicians and Physician Organizations Law Institute (April 19 & 20, 2001) (available at <<http://www.healthlawyers.org>>); Stephen T. Parente, *Beyond the Hype: A Taxonomy of E-Health Business Models*, HEALTH AFFAIRS, Nov./Dec. 2000, at 89, 97.

expands, these issues will provide impetus for adoption of more portable licensing requirements, increased reciprocity, and even transnational qualifications.<sup>147</sup>

The present system is a welter of jurisdictions: federal, state, private associations and local institutions. Federal regulation of health care is plenary under the Commerce Clause and follows ubiquitous federal funds under the Spending Power.<sup>148</sup> The states have settled the disputes amongst the medical sects and have reached consensus on what constitutes licensed medical practice.<sup>149</sup> The Liaison Committee on Medical Education's national accreditation process dominates medical education.<sup>150</sup> Training and licensure of both domestic and international medical graduates is coordinated through the private National Resident Matching Program.<sup>151</sup> Peer review is still primarily conducted at the local institutional level, or in Medicare-designated regional Peer Review Organizations, each operating under various state<sup>152</sup> and federal statutes.<sup>153</sup> A recently announced quality initiative by the Health Care Financing Administration may centralize many elements of this process through national data analysis.<sup>154</sup> While the peer review committees meet locally, much of the key information is either sent to, or received from the National Practitioner Data Bank, established under federal law to track errant physicians nationwide.<sup>155</sup> Parallel trade associational and private efforts also

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<sup>147</sup> Terry, *supra* note 132, at 607-08 (citations omitted). In addition to Professor Terry's comment on malpractice insurance coverage, e-health raises questions about the applicable malpractice standard. If the physician is in one state and the patient in another, which local standard of care should apply? Or more fundamentally, should not the applicable standard be national - or international - rather than local?

<sup>148</sup> See *supra* note 95.

<sup>149</sup> See *supra* part II.

<sup>150</sup> The Liaison Committee on Medical Education is a private organization selected by the American Medical Association and the Association of American Medical Colleges. See Liaison Committee on Medical Education (visited May 29, 2001) <<http://lcme.org/overview.htm>>.

<sup>151</sup> See National Resident Matching Program (visited May 6, 2001) <<http://nrmp.aamc.org/nrmp/>>. For a review of the international medical graduate process for licensure in the U.S., see Saeid B. Amini, *Discrimination of International Medical Graduate Physicians By Managed Care Organizations: Impact, Law and Remedy*, 2 DEPAUL J. HEALTH CARE L. 461 (1999).

<sup>152</sup> For a list of state peer review statutes, see Susan O. Scheutzow, *State Medical Peer Review: High Cost But No Benefit -- Is It Time For a Change?*, 25 AM. J.L. & MED. 7, 58-60 (1999).

<sup>153</sup> See Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11101-11152 (2001).

<sup>154</sup> The Department of Health and Human Services recently formed a Patient Safety Task Force to address medical errors. See DEPT. OF HEALTH AND HUMAN SERVICES, PATIENT SAFETY TASK FORCE SHEET (undated, cir. 2001) (copy on file); DEPT. OF HEALTH AND HUMAN SERVICES, RESEARCH IN HHS: PATIENT SAFETY REPORTING SYSTEMS AND NATIONAL SUMMIT ON PATIENT SAFETY DATA COLLECTION AND USE (Apr. 23, 2001) (copy on file).

<sup>155</sup> See 42 U.S.C. §§ 11131-11137 (2000). This information includes malpractice judgments, settlement payments, disciplinary actions, and license suspensions. A second federal effort is the Healthcare Integrity and Protection Data Bank. See DEPT. OF HEALTH & HUMAN SERVICES, PROGRAM MEMORANDUM AB-01-57 (Apr. 24, 2001).

exist.<sup>156</sup>

In the nineteenth century, local control of credentialing made eminent sense: the local physicians were in the best position to judge the quality of the physician and the harm to patients occurred locally. Today, with technology such as the National Practitioner Data Bank, the utility of state peer review and licensure systems is open to challenge as duplicative and unnecessary. However, instead of requiring a federal assumption of the system, the national databases may improve the effectiveness of the various state medical boards by lowering their information costs and blocking itinerant rouge physicians. In this fashion, technology may improve the effectiveness of the current "system", blunting calls for federal reform, particularly if state medical boards make liberal provision for interstate practice of e-health.<sup>157</sup> With the reduced cost of information, and the potential gains from e-health, states should rely more on the national databases, as well as comity, in permitting cross border practice.

#### B. Health Care Privacy

The rise of electronic databases and communications technology has raised fears of invasions of health care privacy.<sup>158</sup> When medical records were only physical, and stored at the physician's office, any invasion of privacy was local and sporadic.<sup>159</sup> As technology permitted the electronic transmission of health claims and clinical information, it became possible to exploit privacy on a national and systematic basis, often with pecuniary motives. Much ink (and some blood) has been spilled in the health care policy journals during the past decade on the issue of privacy.<sup>160</sup> With the adoption of the administrative simplification and privacy rules

<sup>156</sup>

Various trade associations offer data bases, such as the Federation of State Medical Boards Physician Data Center, which offers a public database (*available at* <<http://www.docinfo.org>>) on 115,000 state medical board actions taken against 35,000 physicians. See Federation of State Medical Boards, *Welcome to FSMB Online* (visited May 6, 2001) <<http://www.fsmb.org/new.htm>>. For an example of a private service, see Healthgrades.com (visited May 6, 2001) <<http://www.healthgrades.com>>.

<sup>157</sup>

For an attempt to begin the coordinated regulation of e-health, see JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, REVISIONS TO SELECTED MEDICAL STAFF STANDARDS: COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS, MS.5.16 (eff. Jan. 1, 2001) (copy on file).

<sup>158</sup>

See generally Sharon J. Hussong, *Medical Records and Your Privacy: Developing Federal Legislation to Protect Patient Privacy Rights*, 26 AM. J.L. & MED. 453 (2000).

<sup>159</sup>

Such as the break in and theft of Daniel Ellsberg's psychiatric records by the White House "plumbers" unit on September 3, 1971.

<sup>160</sup>

Even a brief survey will strain the patience of devoted policy wonks. See, e.g., HEALTH DATA IN THE INFORMATION AGE: USE, DISCLOSURE, AND PRIVACY (M.S. Donaldson & K.N. Lohr, eds., 1994); OFFICE OF TECHNOLOGY ASSESSMENT, PROTECTING PRIVACY IN COMPUTERIZED MEDICAL INFORMATION (OTA-TCT-576, 1993); L.O. Gostin, et al., *Privacy and Security of Personal Information in a New Health Care System*, 270 JAMA 2487 (1993); Jon F. Merz, et al., *Hospital Consent for Disclosure of Medical Records*, 26 J.L. MED. & ETHICS 241 (1998); Michael C. Roach, *HIPAA Privacy: "Individual Rights" and the "Minimum Necessary" Requirements*, 33 J. HEALTH L. 549 (2000); Mark A. Rothstein, et al., *Protecting Genetic Privacy By Permitting Employer Access Only To Job-Related Employee Medical Information: Analysis of a Unique Minnesota Law*, 24 AM. J.L. & MED. 399 (1998); Symposium, *Medical Record Confidentiality and Data Collection*, 25 J.L. MED. & ETHICS 85-138 (1997) (five symposium articles on

of HIPAA,<sup>161</sup> and subsequent congressional inaction, the Department of Health and Human Services was authorized to promulgate regulations protecting the privacy of individually identifiable health information.<sup>162</sup> The Final Privacy Rule has now been issued,<sup>163</sup> although any hopes for “finality” are likely to be dashed as vast armies of lobbyists maneuver to modify the rules before implementation.<sup>164</sup>

The Final Privacy Rule reaches all “individually identifiable health information” in the United States, whether in an electronic format or not.<sup>165</sup> It is not limited to records created under federally reimbursed programs, and therefore Congress’ power to enact the privacy rule does not proceed from the Spending Power. The source must be the Commerce Clause, or perhaps, a constitutional right to privacy.

As a power under the Commerce Clause, the scope of the Final Privacy Rule in terms of federalism is remarkable. The rule clearly applies federal privacy regulation to items such as the handwritten notes of a psychiatrist seeing a private pay patient on a cash basis, both being life long residents of a single state. If challenged under the Constitution, the Final Privacy Rule must be defended on the basis that such notes are articles of interstate commerce, or affect interstate commerce in a substantial way.<sup>166</sup>

On the other hand, the Final Privacy Rule does not preempt state laws that impose more stringent privacy rules.<sup>167</sup> Congress mandated this approach in HIPAA.<sup>168</sup> Perhaps this is an example of Wechsler’s political federalism in action.<sup>169</sup> However, this HIPAA anti-preemption rule has recently been challenged

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medical record confidentiality).

<sup>161</sup> See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 2021 (1996) (codified as amended at 42 U.S.C. §§ 1320d-1320d-8 (2001)).

<sup>162</sup> Congress gave itself a deadline of August 20, 1999 to craft its own privacy rules; failing that deadline, the Health Care Financing Administration was instructed to promulgate its own rules by February 20, 2000. See Health Insurance Portability and Accountability Act of 1996 § 264 (codified at 42 U.S.C. §§ 1320d-3).

<sup>163</sup> See HIPAA Final Privacy Rule, 45 C.F.R. §§ 160.101-160.312 (2001).

<sup>164</sup> See Jeff Tieman, *Privacy Surprise: Bush Backs Tough Medical-Data Standards*, MODERN HEALTHCARE, Apr. 16, 2001, at 4, 16.

<sup>165</sup> Compare HIPAA Proposed Privacy Rule, 64 Fed. Reg. 59,918, 60,053 (Nov. 3, 1999) previously codified at 45 C.F.R. § 164.504 (definition of “protected health information”) with HIPAA Final Privacy Rule, 45 C.F.R. § 164.501 (2001) (definition of “protected health information”) to trace the expansion of the HIPAA privacy rule from merely electronic health records to virtually all health records.

<sup>166</sup> This standard may not be hard to meet. See *Wickard v. Filburn*, 317 U.S. 111 (1942) (upholding the federal power to regulate production of wheat for on farm use and personal consumption due to the effect on interstate commerce).

<sup>167</sup> See HIPAA Final Privacy Rule, 45 C.F.R. §§ 160.201 – 160.205 (2001).

<sup>168</sup> See 42 U.S.C. § 1320d-7 (2001).

<sup>169</sup> See Herbert Wechsler, *The Political Safeguards of Federalism: The Role of the States in the Composition and Selection of the National Government*, 54 COLUM. L. REV. 543 (1954), cited in *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 551 n. 11 (1985) (Blackmun, J.).

as a violation of the negative Commerce Clause.<sup>170</sup>

### C. Portability of Nurse Licensure

News reports warn that the United States is entering a period of shortage of registered nurses,<sup>171</sup> particularly due to the aging of the nursing workforce.<sup>172</sup> The distribution of registered nurses is not uniform across the country, varying greatly from state to state.<sup>173</sup> To the extent that quality of care is dependent upon the availability of nursing care,<sup>174</sup> a more efficient distribution of nurses between the states may improve health status.

The primary regulatory barrier to the free mobility of registered nurses is state licensure. If one can assume that the average nurse in a high ratio state, such as Massachusetts, is generally as well trained as the average nurse in a low ratio state, such as Texas, then it follows that free mobility of nurses from an area of relative surplus to an area of relative shortage would improve the overall delivery

<sup>170</sup> See *Quintiles Transnational Corp. v. WebMD Corp.*, No. 5:01-CV-180-B0(3) (E.D.N.C. Mar. 2, 2001) (in the context of a motion for preliminary injunction, the District Court said that health information may be an article of commerce, citing *Reno v. Condon*, 528 U.S. 141 (2000), and state laws cannot attach to such health information once the data leaves the state); Reece Hirsch, *The Not-So-Dormant Commerce Clause: Implications of the Quintiles-WebMD Case for HIPAA Preemption*, 10 Health L. Rep. (BNA) 765 (May 10, 2001). For a First Circuit opinion rejecting a dormant Commerce Clause attack on Maine's prescription drug plan, see *Pharmaceutical Research and Manufacturers of America v. Concannon*, No. 00-2446, 2001 U.S. App. LEXIS 9324 (1st Cir. May 16, 2001).

<sup>171</sup> See, e.g., Roni Rabin & Carol Eisenberg, *Experts Post Alert on Nurse Shortage; Serious Situation Predicted Within Decade*, CHI. TRIB., Mar. 12, 2001, available at <<http://www.chicagotribune.com>>; Luke Shockman, *Area Hospitals May Look Overseas to Fight Nursing Shortage*, TOLEDO BLADE, Apr. 11, 2001, available at <<http://toledoblade.com>>; Phoebe Zerwick, *Nursing A Shortage: Trained Nurses From Phillippines Help Fill a Void at Baptist*, WINSTON-SALEM J., Mar. 28, 2001, available at <<http://www.journalnow.com>>. Local perceptions of shortage may be flawed, since each of these states (Illinois, Ohio and North Carolina) already employ registered nurses at rates that exceed the national average. See BUREAU OF HEALTH PROFESSIONS, *THE REGISTERED NURSE POPULATION: THE NATIONAL SAMPLE SURVEY OF REGISTERED NURSES MARCH 2000: PRELIMINARY FINDINGS 10-11* (2001).

<sup>172</sup> See Peter I. Buerhaus et al., *Implications of an Aging Registered Nurse Workforce*, 283 JAMA 2948 (2000); Peter I. Buerhaus & Douglas O. Staiger, *Trouble in the Nurse Labor Market? Recent Trends and Future Outlook*, HEALTH AFFAIRS, Jan./Feb. 1999, at 214.

<sup>173</sup> For example, the national average, the top four and bottom four states:

Employed nurses per 100,000 population	
National Average	782
District of Columbia	1,675
Massachusetts	1,194
South Dakota	1,128
Rhode Island	1,101
Nevada	520
California	544
Utah	592
Texas	606

BUREAU OF HEALTH PROFESSIONS, *supra* note 171, at 10-11.

<sup>174</sup> See JACK NEEDLEMAN, ET AL., *HEALTH RESOURCES SERVICES ADMINISTRATION, NURSE STAFFING AND PATIENT OUTCOMES IN HOSPITALS* 130-34 (2001) (visited Apr. 30, 2001) <<http://bhpr.hrsa.gov/dn/staffstudy.htm>> (finding a positive correlation between patient outcomes potentially sensitive to nursing (OPSNs) and nurse staffing in acute care hospital inpatient units).

of care.<sup>175</sup>

Various states have responded to the impact of telecommunications technology and physical mobility<sup>176</sup> by reducing the regulatory barrier of state licensure through the adoption of the Interstate Nurse Licensure Compact, whereby states adopting the compact recognize the licensure of nurses from other compact states.<sup>177</sup> The first state to ratify the Compact was Maryland, effective July 1, 1999, followed to date by thirteen other states.<sup>178</sup> States signing the Compact facilitate the freer importation and exportation of nursing labor, since the nursing license becomes more portable. This effect becomes particularly powerful as the number of Compact states increases, geometrically increasing the number of possible relocations.<sup>179</sup>

<sup>175</sup>

This hypothesis may be valid so long as one establishes a positive correlation between staffing levels of registered nurses and improved health status. However, the most populous of the states with low nurse employment ratios, California, boasts above average health status indicators in categories such as percentage of mothers receiving prenatal care, infant mortality, percentage of infants of low birth weight, and incidence of death from cancer and heart disease. BUREAU OF HEALTH PROFESSIONS NATIONAL CENTER FOR HEALTH WORKFORCE INFORMATION AND ANALYSIS, HRSA STATE HEALTH WORKFORCE PROFILES-CALIFORNIA 3 (Dep't Health & Human Serv., Dec. 2000). Another large state with low nurse employment ratios, Texas, posted results near the national average. BUREAU OF HEALTH PROFESSIONS NATIONAL CENTER FOR HEALTH WORKFORCE INFORMATION AND ANALYSIS, HRSA STATE HEALTH WORKFORCE PROFILES-TEXAS 3 (Dep't Health & Human Serv., Dec. 2000). The region with the highest reported nurse employment ratio, the District of Columbia, reported health outcomes that fall far below national norms. BUREAU OF HEALTH PROFESSIONS NATIONAL CENTER FOR HEALTH WORKFORCE INFORMATION AND ANALYSIS, HRSA STATE HEALTH WORKFORCE PROFILES-DISTRICT OF COLUMBIA 3 (Dep't Health & Human Serv., Dec. 2000). One could argue that this result invalidates the correlation between high nursing staffing levels and improved health status. A more likely explanation is that other environmental factors, such as poverty, violence, and pre-existing health status, drives the health status indicators for the District of Columbia and that the high levels of nursing employment there reflect the heightened demand for health care services in a distressed region. See NEEDLEMAN, *supra* note 174. This position will also lead one to question whether the current distribution patterns of registered nurses actually reflects inefficiency caused by internal barriers to the free flow of labor. An alternative hypothesis is that nursing labor is thereby deployed to the regions of greatest need.

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Article I(a) of the Nurse Licensure Compact explicitly recognizes the impact of mobility and technology in rendering traditional state-based regulation inefficient: "The party states find that: . . . 3. the expanded mobility of nurses and the use of advanced communication technologies as part of our nation's healthcare delivery system require greater coordination and cooperation among states in the areas of nurse licensure and regulation; 4. new practice modalities and technology make compliance with individual state nurse licensure laws difficult and complex; 5. the current system of duplicative licensure for nurses practicing in multiple states is cumbersome and redundant to both nurses and states." National Council of State Board of Nursing, *Nurse Licensure Compact* (Nov. 6, 1998) <<http://www.ncsbn.org/files/mutual/compact.asp>>.

<sup>177</sup>

As of April 2001, fourteen states have adopted the Nurse Licensure Compact, including Arkansas, Delaware, Idaho, Iowa, Maine, Maryland, Mississippi, Nebraska, North Carolina, North Dakota, South Dakota, Texas, Utah and Wisconsin. See National Council of State Board of Nursing, *State Compact Bill Status* (last modified Apr. 17, 2001) <<http://www.ncsbn.org/files/mutual/billstatus.asp>>. Interstate compacts require Congressional approval under Article I, Section 10, Clause 3 of the U.S. Constitution.

<sup>178</sup>

See National Council of State Board of Nursing, *State Compact Bill Status* (visited April 25, 2001) <<http://www.ncsbn.org/files/mutual/billstatus.asp>>.

<sup>179</sup>

If only one state belongs to the Compact, the utility of the legislation is zero, since no one may benefit from the licensure portability. When the second state joins, residents of both states now have the option of mobility to the other. When the Compact is composed of five states, the number of possible relocations is twenty, and if one considers the possibility of e-health in five states, the number of possible

The Compact may also permit nurses not currently employed in nursing to more easily re-enter the nursing workforce even though they have moved from their state of licensure.<sup>180</sup> A review of the states that have joined the Compact yields no easy correlations: Compact states may be found in the Intermountain West,<sup>181</sup> the Midwest,<sup>182</sup> the South,<sup>183</sup> and the Atlantic Coast.<sup>184</sup> Some of these states have low nursing employment ratios,<sup>185</sup> suggestive of a need to import nursing labor, while others lead the nation in high nursing employment ratios.<sup>186</sup>

Compact federalism<sup>187</sup> enjoys some features that are more powerful than model law federalism.<sup>188</sup> The goal of uniformity<sup>189</sup> under model laws is thwarted in at least three ways. First, states exhibit an inevitable tendency to improvise local variations rather than enact truly uniform legislation.<sup>190</sup> Model legislation, at its best, yields parallel systems.<sup>191</sup> Second, divergent administrative practices between

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virtual relocations exceeds factorial five.

<sup>180</sup> In 2000, an estimated 466,235 licensed registered nurses were not currently employed in nursing, representing 17.3% of the total. See BUREAU OF HEALTH PROFESSIONS, *supra* note 171, at 1-2. While many factors probably account for the decision to leave nursing despite predictions of a national shortage, becoming licensed in a new state can be a significant impediment to remaining in nursing or rejoining the profession after a geographic move.

<sup>181</sup> Idaho and Utah.

<sup>182</sup> North Dakota, South Dakota, Nebraska, Iowa and Wisconsin.

<sup>183</sup> Texas, Arkansas and Mississippi.

<sup>184</sup> Maine, Delaware, Maryland and North Carolina.

<sup>185</sup> Such as Texas. See *supra* note 154.

<sup>186</sup> North Dakota, South Dakota, Maine and Iowa each exceed 1,000 employed nurses per 100,000 population, as compared to the national average of 782. See BUREAU OF HEALTH PROFESSIONS, *supra* note 171, at 10-11.

<sup>187</sup> By this term I mean the process of adopting legislation that is dependent upon similar action by other states in order to achieve the desired legislative result. Additional examples would include the Model Interstate Tax Compact and to some extent state insurance legislation on the National Association of Insurance Commissioners model such as retaliatory taxes and interstate administration of insolvent insurance companies. Multilateral treaties are a common example in the international sphere. Perhaps the Framers recognized the inherent power in interstate compacts when they drafted Article I, Section 10, Clause 3 of the U.S. Constitution, which requires Congressional approval for any state to "enter into any Agreement or Compact with another State."

<sup>188</sup> By this term I mean the work of various commissions on uniform state laws. The Uniform Commercial Code is a prominent example.

<sup>189</sup> Uniformity is a goal to the extent one values predictability and lowering the information costs to market participants concerning regulation.

<sup>190</sup> In model law federalism, the individual state cost of divergence from the model is low, absent an enforcement mechanism, which permits states to substitute local judgment for the model policy. The aggregation of these local variations threatens the efficiency goals of uniformity. By contrast, compact federalism requires near perfect adherence as the price of admission, preserving the goal of reducing regulatory barriers to free mobility.

<sup>191</sup> State variations in the Uniform Commercial Code are examples. Professors Mashaw and Marmor have suggested that federalism can play a constructive role in the development of health care policy, especially if a political impasse has blocked national reforms. See Mashaw & Marmor, *supra* note 95, at 115.



the states also threaten to upset the goals of uniformity.<sup>192</sup> Finally, many model laws suffer from tepid acceptance and may languish with only a few states in conformity.<sup>193</sup> To return to the current example of nurse licensure, model laws at their best would merely allow a nurse to apply to be licensed in a new state, confident that the education which was sufficient in the current state would be acceptable for licensure at the same level in the new state.<sup>194</sup> Compact federalism operates on a different level: anyone with a valid license in any member state is automatically permitted to practice in any other member state. Furthermore, states have a powerful incentive to join and conformity is self-policing. This power inherent in a reciprocity agreement may violate the negative Commerce Clause.<sup>195</sup>

#### D. Medical Error Reporting

Correction of medical errors is one key to improving the quality of health care.<sup>196</sup> In order to improve patient care systems, data on errors must be collected and analyzed to identify the root causes.<sup>197</sup> The National Practitioner Data Bank

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They celebrate the variation likely to emerge from this decentralized approach: "If change is to be workable and acceptable, it must take account of the real differences between New York and Idaho, Wisconsin and Louisiana," a sentiment certainly shared by the local bar. *Id.* at 116. They argue that states do well to make different policy choices concerning coverage and health policy. *See id.* While their position may have appeal in the context of health care reform, it enjoys less force in this discussion of licensure (which is admittedly beyond the scope of their article). What policy reasons can be marshaled today to support a nurse or physician licensure standard, or clinical standards of care, in New York that are significantly different from Idaho, Wisconsin or Louisiana?

<sup>192</sup> Divergent administrative rules and practices increase the information cost. The National Association of Insurance Commissioners provides a Model Regulation Service to attempt to standardize administrative procedures amongst the states. *See* NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS, MODEL LAWS, REGULATIONS AND GUIDANCE (2000).

<sup>193</sup> For example, the NAIC Model HMO Act is an important priority, and yet only 30 states have enacted it without substantial modifications. *See id.* at 430-36 (Vol. 2, 1997).

<sup>194</sup> One concern voiced about interstate competition is the "race to the bottom", wherein states will lower standards (or taxes) below optimum levels in an effort to compete with the other states for business. Lucian Arye Bebchuk, *Federalism and the Corporation: The Desirable Limits on State Competition in Corporate Law*, 105 HARV. L. REV. 1437 (1992) (interstate competition in corporation law); Michael K. Outerson, *Taxation Without Premeditation: An Economic Analysis of the Structure, Regulation and Strangulation of the Private Activity Bond Market*, 6 B.U.J. TAX L. 1 (1988) (interstate competition for industrial development through location incentives, namely the tax-favored private activity bond). Compact federalism, by contrast, creates a "race to the middle," by rewarding states which join the consensual standard of quality. As more states join the particular compact, the cost of exclusion from the compact to states at the top or the bottom of any given issues are increased.

<sup>195</sup> *See* *New Energy Co. of Indiana v. Limbach*, 486 U.S. 269, 274-75 (1988) (holding that a reciprocity provision in an otherwise discriminatory law favoring locally produced ethanol did not absolve a violation of the negative Commerce Clause. Reciprocity added additional power to the discriminatory effect of the ethanol tax abatement. Reciprocity is constitutionally permissible only when the underlying regulation is not discriminatory in its own right).

<sup>196</sup> *See* INSTITUTES OF MEDICINE, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn, et al., eds. 1999) (estimating that medical errors lead to 44,000 to 98,000 patient deaths per year in the United States).

<sup>197</sup> Harold Bressler, *The Sentinel Event Policy: A Response By the Joint Commission*, 33 J. HEALTH L. 519, 522-23 (2000) (defending the Joint Commission's Sentinel Event Reporting Policy and describing the

reporting systems have been described earlier in this article.<sup>198</sup> State standards for medical error reporting have also been effectively standardized through private accreditation agencies such as the Joint Commission.<sup>199</sup> The benefits of root cause analysis on a consistent national data platform are not suspended at state political boundaries, arguing for a single data reporting process and response structure for medical errors.

In nursing, the National Council of State Boards of Nursing (NCSBN) maintains its own error reporting service, the Disciplinary Data Bank, which contains information provided by the various state boards of nursing.<sup>200</sup> The NCSBN recommends that the state boards of nursing have access to the various national reporting data bases in order to effectively discipline wayward nurses:

Absent individual accountability standards, practitioners that leave organizations after serious errors occur and are employed elsewhere will never receive necessary remediation or education to address human factors, thus compromising the safety of the patient.<sup>201</sup>

This testimony actually supports the abolition of divergent state licensure standards, since a national standard relying upon a single credentialing data base would advance the stated goals more effectively and efficiently, even if administered through state boards or agencies.

#### E. Internet Pharmacies

Internet pharmacies (such as Drugstore.com or Walgreens.com) accept prescriptions over the Internet and generally deliver the products via package express such as UPS or Federal Express.<sup>202</sup> Although located in a single state, Internet pharmacies are potentially subject to the licensing jurisdiction of state boards of pharmacy in each of the 50 states, depending upon the location of the

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use of the data by the reporting institutions to perform root cause analyses to change systems and prevent errors). Disparate sources of data are also collected and analyzed by other organizations at the national level, such as the Agency for Health Research and Quality, the Centers for Disease Control, and the Food and Drug Administration. For a critique of the inadequacies of the National Practitioner Data Bank, see Robert Pear, *Incompetent Physicians are Rarely Reported as Law Requires*, N.Y. TIMES, May 29, 2001, available at <<http://nytimes.com>>.

<sup>198</sup> See *supra* notes 155-56.

<sup>199</sup> See Joint Commission on Accreditation of Healthcare Organizations, *Facts About Patient Safety* (visited May 2, 2001) <<http://www.jcaho.org/sentinel.safety.html>>.

<sup>200</sup> See NATIONAL SUMMIT ON MEDICAL ERRORS AND PATIENT SAFETY RESEARCH: HEARING BEFORE THE QUALITY INTERAGENCY COORDINATION TASK FORCE 13-14 (undated, cir. 2000) (statement of Joey Ridenour, Board President, The National Council of State Boards of Nursing, Inc.).

<sup>201</sup> *Id.* at 3.

<sup>202</sup> See Outterson, *supra* note 146, at 18.

customer.<sup>203</sup> Retailers like Walgreens had licenses in various states where they had physical stores, which simplified the regulatory process for expanding onto Internet.<sup>204</sup>

A proponent of federal control would argue that this 50 state pharmacy regulation system was inefficient, since Internet-only pharmacies were forced to duplicate its regulatory filings throughout the nation. Despite the hardship, several Internet-only pharmacies were able to achieve regulatory compliance, partially due to a streamlined process devised by the National Association of Boards of Pharmacy.<sup>205</sup>

In addition to legitimate vendors such as Drugstore.com, some Internet websites offer prescription drugs without a prescription, or with an online medical evaluation of doubtful usefulness.<sup>206</sup> These sites pose unique enforcement challenges, exploiting the distributed pattern of authority in federalism.<sup>207</sup> The ultimate government response was a coordinated private, state and federal certification for the legitimate sites, and parallel enforcement against the illegal ones.<sup>208</sup> While this response must be considered a work in progress, given the incredible technical challenge posed by the Internet, the regulators responded to the change in technology and performed admirably, without fundamentally altering the state-federal balance.

#### F. *ERISA Preemption*

One goal of the Employee Retirement Income Security Act of 1974<sup>209</sup> was to permit multi-state employers to offer a single retirement and health insurance benefit nationwide, without myriad permutations under state and local law. By preempting state law, ERISA allows a plan to offer a more administrable benefit design.<sup>210</sup> Administrative complexity (or impossibility) was viewed as an undue burden on interstate commerce.

The advance of technology now makes it possible to remove the portion of the ERISA preemption that was predicated on reducing administrative complexity. Unlike 1974, contemporary human resource software can track many different

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<sup>203</sup> See *id.* at 19, 21-22.

<sup>204</sup> See *id.*

<sup>205</sup> See *id.* at 23-24.

<sup>206</sup> See *id.* at 18.

<sup>207</sup> See *id.* at 19.

<sup>208</sup> See *id.* at 18-24.

<sup>209</sup> Codified at 29 U.S.C. § 1001 et seq. (2000).

<sup>210</sup> See Margaret G. Farrell, *ERISA Preemption and Regulation of Managed Health Care: The Case for Managed Federalism*, 23 AM. J.L. & MED. 251 (1997); see also *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 99-100 (1989); Nichols, *supra* note 117, at 28-29.

benefit plans across multiple jurisdictions.<sup>211</sup> While it may once have been true that complexity required a single federal solution, in the ERISA context, Congress may have the freedom to return power over benefit design and other similar issues to the states. Technology may facilitate similar opportunities for federalism in taxation.<sup>212</sup>

### G. Genomics

If any area of health care technology calls for international regulation, it is genetically modified organisms. Modifications to food product germplines may escape into the environment or contaminate unrelated crops,<sup>213</sup> with unknown consequences. Genetically modified soybeans account for about half of the soybeans grown in the United States in 2000.<sup>214</sup> The release of genetically modified salmon may be imminent,<sup>215</sup> and yet there are serious questions to be answered:

One hypothetical area for regulation is illustrated here: you may have seen pictures of these salmon on the front page of the *New York Times* a few days ago [May 2000]. Some of these may be more inspiring to fisherman [sic] than to others. This salmon on the right carries a transgene, an extra gene in its germline that expresses a growth hormone from another fish. At 14 months of size, the wild-type salmon and the transgenic salmon are remarkably different in size, although their ultimate size is about the same. Some people wonder what would happen if these fish were to escape into the vast seas — could their presence change population dynamics? Others are concerned that these fish might be dangerous to eat, although there is no evidence for that.

The story raises some interesting questions about what we should do. Should we just let this happen? Should we have some kind of penalty for companies that raise such fish if damages occur? Should we ask the FDA to prove that these fish are safe to eat? Should we require that these fish be tagged so that if a tagged fish is found in the open seas the company that grew it can be penalized? Or perhaps, least likely of all, should we prevent the

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<sup>211</sup> See, e.g., PeopleSoft, Inc., *HRMS Product Brochure* (visited May 7, 2001) <<http://www.peoplesoft.com/en/us/virtuallibrary>> (copy on file with author).

<sup>212</sup> See Shaviro, *supra* note 122, at 921 (1992) (discussion of administrative costs of interstate divergence in tax rules).

<sup>213</sup> See Andrew Pollack, *Farmers Joining State Efforts Against Bioengineered Crops*, N.Y. TIMES, Mar. 24, 2001, available at <<http://www.nytimes.com/2001/03/24/health/24DAKO.html>>.

<sup>214</sup> See *id.*

<sup>215</sup> See Andrew Pollack, *Moratorium on Alteration of Salmon*, N.Y. TIMES, May 9, 2001, available at <<http://www.nytimes.com/2001/05/09/science/09FISH.html>>.

use of Federal funding for research on these fish?<sup>216</sup>

Once the germline of wild salmon are altered by an accidental release anywhere in the world, the change may be irreversible. In this situation, some have called for a "Treaty to Protect the Genetic Common"<sup>217</sup> and in 2000 the World Trade Organization adopted a "Biosafety Protocol," taking the first steps towards international regulation of genetically modified organisms.<sup>218</sup> In the absence of federal law, the states are rushing to fill the void.<sup>219</sup> One could conceive of a Commerce Clause challenge to many of these proposed state laws, along the lines of *Dean Milk Co.*<sup>220</sup> More practically, since any genetic modification anywhere has the potential to spread globally, mere state (or national) regulation seems foolhardy.

## VI. CONCLUSION

Some tentative conclusions may be drawn from this study of the interaction between health care, technology and federalism. First, describing health care as a police power may have more to do with the historical practice of medicine as a local art than any inherent definition of the phrase. The advance of technology, first with scientific medicine and the automobile, and today with the Internet, weakens the presumption that there is something uniquely local about health care, although in most cases, care is still delivered locally.

Second, technological growth has supported an expansion of federal power, both in the Commerce Clause and in the Spending Power. Technology has traditionally permitted proponents of an expansive Commerce Clause to identify a relationship to interstate and foreign commerce that permits federal regulation. Technology's gift to the Spending Power probably lies in the ability of the federal government to collect significant taxes that are not limited to import duties. These funds, in turn, are distributed with conditions embodying the policy choices of Congress.

Neither of these first two conclusions requires the abandonment of state regulation of health care. With regard to the police power, the presumption may be weakened, and yet there may be compelling policy reasons to retain state or

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<sup>216</sup> Harold E. Varmus, M.D., *The Challenge of Making Laws on the Shifting Terrain of Science*, 28 J.L. MED. & ETHICS 46, 47-48 (2000) (Selected Proceedings of "Genes and Society: Impact of New Technologies on Law, Medicine, and Policy," May 10-12, 2000).

<sup>217</sup> *America's Next Ethical War*, ECONOMIST, Apr. 12, 2001, available at <[http://www.economist.com/science/displayStory.cfm?Story\\_ID=568825](http://www.economist.com/science/displayStory.cfm?Story_ID=568825)> (citing the efforts of Jeremy Rifkin).

<sup>218</sup> *Caution Needed*, ECONOMIST, Feb. 3, 2000, available at <[http://www.economist.com/PrinterFriendly.cfm?Story\\_ID=279360&approval=3804712993404](http://www.economist.com/PrinterFriendly.cfm?Story_ID=279360&approval=3804712993404)>.

<sup>219</sup> See Pollack, *supra* note 213 (more than 40 state bills to regulate genetically modified organisms have been introduced this year).

<sup>220</sup> See *supra* note 5.

concurrent jurisdiction. While technology may have fueled the growth of federal power, technology can cut both ways.<sup>221</sup> Technology may provide enhanced opportunities to distribute responsibility back to the states, or to exercise it more efficiently in situ.

Third, the fact that states retain any authority at all in the face of near-omnipotent federal power may suggest that Wechsler's political federalism is functioning. Of course, this statement is merely descriptive rather than normative, and, if accepted, effectively abandons the field from constitutional review.

Fourth, one gets the sense when reading the new federalism cases and literature that the court is probing for limits on federal power. To the extent that the Tenth or Eleventh Amendments are successfully invoked, the states may gain some power over health care regulation that is now held by the federal government, although this project faces formidable opponents. Without giving short shrift to the power of the Commerce Clause, the Spending Power is the true Goliath, due to the federal financial role in health care.

Finally, it seems to me that one critical juncture in the history of health care jurisprudence before the court was the *Slaughter House Cases*.<sup>222</sup> While it may be important for states to have rights in health care matters, it is perhaps more important for individuals to have rights in this intensely personal area.<sup>223</sup> In the *Slaughter House Cases*, a majority of the court did not find a violation of the Privileges or Immunities Clause of the Fourteenth Amendment, on technical grounds relating to the definition of citizenship.<sup>224</sup> If that decision were revisited, perhaps a David could be found to champion individual health care rights in the face of plenary federal power.<sup>225</sup>

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<sup>221</sup> See E. David Elliott, *Symposium on Biomedical Technology and Health Care: Social and Conceptual Transformations: Comments: Against Ludditism: An Essay on the Perils of the (Mis)Use of Historical Analogies in Technology Assessment*, 65 S. CAL. L.R. 279 (1991).

<sup>222</sup> 83 U.S. (Wall.) 36 (1872); see also *supra* note 56.

<sup>223</sup> A few recent cases involving personal liberty in health care matters have reached the Court without analysis under the Privileges or Immunities Clause of the Fourteenth Amendment. See, e.g., *United States v. Oakland Cannabis Buyers' Cooperative*, 121 S.Ct. 1352 (2001) (cannabis cooperative established under California law to provide for the medical needs of its citizens ruled illegal); *Kansas v. Hendricks*, 521 U.S. 346 (1997) (upholding civil commitment of predatory child sexual offender; see *supra* note 22); *Washington v. Glucksberg*, 521 U.S. 702 (1997) (no Constitutional right to die; see *supra* notes 125-26). Of these cases, *Glucksberg* is more supportive of personal liberty - and federalism - since persons desiring assisted suicide may relocate from Washington to Oregon. But this freedom in *Glucksberg* is endangered by the Supremacy Clause should Congress decide to outlaw assisted suicide, much as Congress foreclosed the medical use of cannabis in *Oakland Cannabis Buyers' Cooperative*.

<sup>224</sup> 83 U.S. (Wall.) 36.

<sup>225</sup> Most of the articles cited *supra* at note 56 are attempts to limit or channel the possible expansion of the Privileges and Immunities Clause.

