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THE CONSTITUTIONALITY OF CURRENT LEGAL BARRIERS TO TELEMEDICINE IN THE UNITED STATES: ANALYSIS AND FUTURE DIRECTIONS OF ITS RELATIONSHIP TO NATIONAL AND INTERNATIONAL HEALTH CARE REFORM

Amar Gupta[†] and Deth Sao^{††}

ABSTRACT

The current health care crisis in the United States compels a consideration of the crucial role that telemedicine could play towards deploying a pragmatic solution. The nation faces rising costs and difficulties in access to and quality of medical services. Telemedicine can potentially help to overcome these challenges, as it can provide new cost-effective and efficient methods of delivering health care across geographic distances. The full benefits and future potential of telemedicine, however, are constrained by overlapping, inconsistent, and inadequate legal and regulatory frameworks, as well as the repertoire of standards imposed by state governments and professional organizations. Proponents of these barriers claim that they are necessary to protect public health and safety, and that the U.S. Constitution gives states exclusive authority over health and safety concerns. This Article argues that such barriers not only fail to advance these public

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policy goals, but are unconstitutional when they restrict the practice of telemedicine across state and national borders. Furthermore, the interstate and international nature of telemedicine calls for increasing the centralized authority of the federal government; this position is consistent with the U.S. Constitution and other governing principles. Finally, this Article observes that the U.S. experience bears some similarities to that of other nations, and represents a microcosm of the international community's need and struggle to develop a uniform telemedicine regime. Just as with state governments in the U.S., nations are no longer able to view health care as a traditional domestic concern and must consider nontraditional options to resolve the dilemmas of rising costs and discontent in the delivery of health care to their people.

INTRODUCTION

"We are the only democracy—the only advanced democracy on Earth — the only wealthy nation—that allows such hardship for millions of its people."

-- Barack Obama

-- Remarks to Joint Session of Congress on Health Care¹

The hardship that the United States President Barack Obama (President Obama) denounced in his address to a 2009 Joint Session of Congress on Health Care is the plight of over thirty million U.S. citizens who lack health care coverage.² In calling for health care reform, President Obama cited rising costs as one of the primary obstacles.³ His observation that the nation spends one and one half times more per person on health care than any other country without any resulting improvements⁴ is supported by the World Health Organization's (WHO) dismal ranking of the nation at thirty-seventh among 191 member nations for health care system performance.⁵ Although

¹ U.S. President Barak Obama, Remarks by the President to the Joint Session of Congress on Health Care (Sept. 9, 2009), *available at* http://www.whitehouse.gov/the_press_office/remarks-by-the-president-to-a-joint-session-of-congress-on-health-care/ (last visited Jan. 29, 2010).

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ Ajay Tandon et al., *Measuring Overall Health System Performance For 191 Countries* 18 (WHO, GPE Discussion Paper Series: No. 30), *available at* <http://www.who.int/healthinfo/paper30.pdf> (last visited Oct. 14, 2010).

the WHO published these rankings in 2000,⁶ the U.S. continues to lag behind its counterparts to the present day. In 2006, the U.S. ranked thirty-ninth in infant mortality, forty-third for adult female mortality, forty-second for adult male mortality, and thirty-sixth for life expectancy.⁷ In a 2010 study of industrialized countries, the U.S. was last in “quality, efficiency, access to care, equity and the ability to lead long, healthy, productive lives.”⁸ The U.S. Central Intelligence Agency’s 2011 estimates affirm such a result, placing the U.S. forty-sixth for infant mortality⁹ and fiftieth in life expectancy among other countries.¹⁰

This dilemma of rising costs and the corresponding lack of quality and access to health care forces one to question whether this is an avoidable and incongruous result, especially given recent advances in technology and medical knowledge that have transformed the health care industry. For instance, the development of electronic communications has enabled remote consultations and real-time examination, treatment, and diagnosis of a patient’s symptoms by a physician in a different location.¹¹ Hawaii is one of the few states that have taken advantage of such innovations by permitting out-of-state licensed physicians to engage in “actual consultation, including in-person, mail, electronic, telephonic, fiber-optic, or other telemedicine consultation. . . .”¹² These advances in telecommunications, which represent

⁶ As of the writing of this Article, the WHO has yet to update these findings. See Press Release, World Health Organization, World Health Organization Assesses the World’s Health Systems (June 21, 2000), available at <http://www.who.int/inf-pr-2000/en/pr2000-44.html>.

⁷ Christopher J. L. Murray & Julio Frenk, *Ranking 37th—Measuring the Performance of the U.S. Health Care System*, 362 NEW ENG. J. OF MED 98, 98 (2010).

⁸ Mary Mahon & Bethanne Fox, *U.S. Ranks Last Among Seven Countries on Health System Performance Based on Measures of Quality, Efficiency, Access, Equity, and Healthy Lives*, COMMONWEALTH FUND (June 23, 2010), <http://www.commonwealthfund.org/Content/News/News-Releases/2010/Jun/US-Ranks-Last-Among-Seven-Countries.aspx>. Six other countries in the 2010 Commonwealth Fund study include: Australia, Canada, Netherlands, New Zealand, and United Kingdom. *Id.*

⁹ *The World Factbook Country Comparison: Infant Mortality Rate*, CENT. INTELLIGENCE AGENCY, <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html> (last visited Mar. 16, 2011).

¹⁰ *The World Factbook Country Comparison: Life Expectancy at Birth*, CENT. INTELLIGENCE AGENCY, <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2102rank.html> (last visited Mar. 16, 2011).

¹¹ See Susan E. Volkert, *Telemedicine: Rx for the Future of Health Care*, 6 MICH. TELECOMM. & TECH. L. REV. 147, 153 (2000).

¹² HAW. REV. STAT. § 453-2 (West 2010) (permitting a telemedicine exception provided out-of-state physician does “not open an office, or appoint a place to meet patients in th[e] State, or receive calls within the limits of the State”).

a few of the innovative technologies in the emerging field of telemedicine, offer the capabilities to provide for health care delivery at reduced costs while maintaining or increasing the quality of treatment and services.¹³ The existence and potential of telemedicine in helping to resolve problems in the U.S. health care system and the tardy progress on legislative reform underscore the continuing importance of examining the role telemedicine plays in improvements to health care systems, not only that of the U.S. but those of all nations.

As the experience of the U.S. demonstrates, telemedicine remains a timely and relevant topic. It continues to impact current political, economic, and public policy concerns of quality and access to health care discussed above. Earlier works address the ways in which telemedicine helps to resolve these longstanding concerns in the existing U.S. and foreign health care systems.¹⁴ Such discussions involve surmounting of barriers that prevent the full realization of the benefits of telemedicine, which include differing standards and regulatory regimes of sub-national and national governments.¹⁵ Because telemedicine is by nature a cross-jurisdictional practice, several scholars and medical professionals conclude that the establishment of a uniform set of standards and regulations is necessary to realize telemedicine's full potential.¹⁶ However, less attention has been given to the reasons for why these barriers exist. This Article seeks to build upon the earlier works and conclusions of these scholars, and go beyond the existing analysis to specifically critique the long-held and fiercely defended rationales for barriers to telemedicine. Part I discusses the crucial role of telemedicine in health care reform, and offers the current U.S. system as an instructive example of how telemedicine may address the escalating healthcare crisis. Part II discusses the barriers to telemedicine in the U.S., which have been largely created by individual states with little or no involvement by the federal government. Part III ques-

¹³ See Volkert, *supra* note 11, at 155.

¹⁴ See, e.g., John D. Blum, *The Role of Law in Global E-Health: A Tool for Development and Equity in a Digitally Divided World*, 46 ST. LOUIS U. L.J. 85 (2002); P. Greg Gulick, *E-Health and the Future of Medicine: The Economic, Legal, Regulatory, Cultural, and Organizational Obstacles Facing Telemedicine and Cybermedicine Programs*, 12 ALB. L.J. SCI. & TECH. 351 (2002); Thomas R. McLean, *The Future of Telemedicine & Its Faustian Reliance on Regulatory Trade Barriers for Protection*, 16 HEALTH MATRIX 443, 462-63 (2006); Kristen Rabe Smolensky, *Telemedicine Reimbursement: Raising the Iron Triangle to a New Plateau*, 13 HEALTH MATRIX 371 (2003); see generally Amar Gupta & Michael McHugh, *Keeping Up with Industry Development in Telemedicine*, in TELEMEDICINE FOR TRAUMA, EMERGENCIES, AND DISASTER MANAGEMENT 373-388 (Rifat Latifi ed., 2010); Volkert, *supra* note 11.

¹⁵ See Volkert, *supra* note 11, at 156.

¹⁶ See *id.* at 158-59.

tions the justifications for these barriers, and concludes that state authority over the health care is unconstitutional. Building upon such a conclusion, Part IV determines that the federal government has the constitutional right to regulate health care. Part V offers proposals for a national telemedicine regime, and Part VI examines the feasibility of applying such proposals on a global scale.

I. THE ROLE OF TELEMEDICINE IN HEALTH CARE REFORM

The WHO defines telemedicine as:

[t]he delivery of health care services, where distance is a critical factor, by health care professionals using information and communications technologies for the exchange of valid information for diagnosis, treatment and prevention of diseases and injuries, research and evaluation, and for the continuing education of health care providers, all in the interest of advancing the health of individuals and their communities.¹⁷

As the above definition indicates, telemedicine covers all areas and practices of the health care industry.¹⁸ Current applications and potential future uses of telemedicine hold the promise of reducing health care costs, and increasing both quality and access to health care services. As several scholars in this field maintain, the unrestricted utilization of telemedicine has the capacity to play an instrumental role in resolving current the health care crises that plague countries such as the United States.¹⁹

A review of the rising costs and failings of the U.S. health care system and the ways in which telemedicine resolves these problems demonstrates the importance of telemedicine in reaching a solution. First, health care spending in the U.S. is the highest among all the most economically advanced countries.²⁰ A 2007 Congressional report comparing the U.S. with member countries of the Organization for Economic Cooperation and Development (OECD) concludes that

¹⁷ WORLD HEALTH ORG., INFORMATION TECHNOLOGY IN SUPPORT OF HEALTH CARE 1, <http://www.who.int/eh/en/InformationTech.pdf> (last visited Sept. 15, 2010).

¹⁸ See Volkert, *supra* note 11, at 152 (“Telemedicine providers are expanding and cover the entire spectrum of health care practices, from cardiology to trauma medicine, from dentistry to toxicology, and from gynecology to ophthalmology.”).

¹⁹ See, e.g., Blum, *supra* note 14; Gulick, *supra* note 14, at 353; McLean, *supra* note 14, at 443-45; Smolensky, *supra* note 14.

²⁰ CHRIS L. PETERSON & RACHEL BURTON, CONG. RESEARCH SERV., RL 34175, U.S. HEALTH CARE SPENDING: COMPARISON WITH OTHER OECD COUNTRIES I (2007).

“there is no doubt that U.S. prices for medical care commodities and services are significantly higher than in other countries and serve as a key determinant of higher overall spending.”²¹ These prices have been rising for several years.²² The total health expenditures equaled \$2.3 trillion in 2008, which was 16.2 percent of the nation’s Gross Domestic Product (GDP).²³ To put this in perspective, such expenditures exceed spending on all other government services, including defense, education, and pensions.²⁴ This share of GDP increased from 15.9 percent in 2007.²⁵ In comparison, health care spending amounted to \$714 billion in 1990 and \$253 billion in 1980.²⁶ Such costs increases have made it difficult for governments, employers, and consumers to afford health care services.²⁷

Second, many individuals lack access to health care. These populations include those who require home health care, are confined to correctional facilities,²⁸ and reside in rural communities.²⁹ For example, those residing in rural areas “have limited health care delivery systems due to a scarcity of health care professionals, specialists, and modern medical technology.”³⁰ Trauma centers are largely situated in urban areas, thus rural residents incur great costs of travel and time to seek medical attention.³¹ Furthermore, the scarcity of trauma centers impacts the entire U.S. population regardless of residence: a 2007

²¹ *Id.* at 16 (quoting Elizabeth Docteur et al., *The US Health System: An Assessment and Prospective Directions for Reform* 22-23 (OECD Econ. Dept., Working Paper No. 350), available at http://www.oecdwash.org/PDFFILES/us_health_ecowp350.pdf).

²² *U.S. Health Care Costs*, HENRY J. KAISER FAMILY FOUND., http://www.kaiseredu.org/topics_im.asp?imID=1&parentID=61&id=358#1t (last visited Jan. 15, 2010) (citing CTR. FOR MEDICARE & MEDICAID SERV., DEP’T OF HEALTH & HUMAN SERV. UPDATED NHE HISTORICAL PROJECTIONS (1965-2019), available at https://146.123.140.205/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp).

²³ *National Health Expenditures 2009 Highlights*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/highlights.pdf> (last visited Mar. 31, 2011).

²⁴ U.S. CENSUS BUREAU, CONSOLIDATED FEDERAL FUNDS REPORT FOR FISCAL YEAR 2008 xx (2009) <http://www.census.gov/prod/2009pubs/cffr-08.pdf>.

²⁵ *National Health Expenditures 2009 Highlights*, *supra* note 23.

²⁶ *U.S. Health Care Costs*, *supra* note 22.

²⁷ *Id.*

²⁸ Volkert, *supra* note 11, at 156.

²⁹ Joy Elizabeth Matak, *Telemedicine: Medical Treatment Via Telecommunications Will Save Lives, But Can Congress Answer the Call?*, 22 VT. L. REV. 231, 236 (1997).

³⁰ *Id.*

³¹ *Id.* at 237.

study found that over half of car accident deaths occur in rural areas even though only approximately 25 percent of the U.S. population lives in rural areas.³² This translates into car accident mortality rates being twice as high in rural areas than in urban areas.³³

Telemedicine offers the ability to reduce health care expenditures and deliver health care to the above underserved populations by offering treatment at a distance. This form of “distance medicine” includes, but is not limited to, use of the following applications: online communications between physician and patient; consultations via electronic communications between patients’ primary care physicians and tertiary care specialists; and real-time examination, treatment, and diagnosis through interactive television and emergency centers where physicians remotely evaluate a patient’s symptoms.³⁴ For example, websites enabling patients at home to upload personal health data for review by health professionals have resulted in huge cost savings and shorter hospital stays.³⁵ Additionally, the use of video-conferencing by physicians to treat state prisoners has led to less travel time and security risks.³⁶ In particular, the Arizona Telemedicine Program, which began in 1998, reported that its use of telemedicine in the state’s prisons lowered transportation costs by more than one million dollars.³⁷

In addition to such existing capabilities, telemedicine has the potential to further reduce costs, and facilitate greater access to and improve the quality of health care in a variety of ways. One promising development involves innovations in networking and communications.³⁸ For example, advances in information technology (IT) security will resolve current concerns about breaches in security and patient privacy.³⁹ IT networks will transform the delivery of health care by enabling secure cross-border transfers of confidential health information, thus allowing greater opportunities to engage in interstate and offshore delivery of telemedicine.⁴⁰

³² R. Latifi et al., *Telemedicine and Telepresence for Trauma and Emergency Care Management*, 96 SCANDINAVIAN J. OF SURGERY 281, 282 (2007).

³³ *Id.*

³⁴ Volkert, *supra* note 11, at 153.

³⁵ Gulick, *supra* note 14, at 358.

³⁶ Volkert, *supra* note 11, at 156.

³⁷ Kevin Blanchet, *Innovative Programs in Telemedicine: The Arizona Telemedicine Program*, 11 TELEMEDICINE & E-HEALTH 633, 639 (2005).

³⁸ Amar Gupta, *Prescription for Change*, WALL ST. J., Oct. 20, 2008, at R6.

³⁹ *Id.*

⁴⁰ *Id.*

Another area of potential is the offshore outsourcing of diagnostic services.⁴¹ Such an approach will improve the quality of health care by re-distributing workloads and lowering costs.⁴² An instructive example is the area of teleradiology, as x-rays are increasingly taken in one location and transmitted to another location for evaluation.⁴³ This arrangement helps to resolve the growing demand for teleradiology services, thus lowering costs, and allowing for improved quality in service by ensuring that alert radiologists will evaluate the images at all hours.⁴⁴

Despite the above-demonstrated benefits of present and potential uses of telemedicine, the subsequent sections of this Article will build upon earlier scholarship to show that the U.S. and other nations are impeding the full realization of these benefits by promulgating conflicting regulations and technical standards for the delivery of health care.⁴⁵ To better understand the implications and consequences of such impediments, an examination of the situation in the U.S. is instructive. Similar to the challenges telemedicine providers face in the international community, telemedicine providers must comply with a multitude of varying and often conflicting requirements imposed by different states and professional organizations within the U.S. Analyzing these challenges within the context of the U.S. enables one to glean greater insight into how to find workable solutions to the unrestricted use of telemedicine on a global platform.

II. BARRIERS TO TELEMEDICINE IN THE UNITED STATES

The present and potential uses of telemedicine are constrained by overlapping and often inconsistent and inadequate regulatory frameworks and technical standards imposed by governments and professional medical organizations.⁴⁶ As this section will demonstrate, these barriers raise transaction costs and prevent or impede patients from receiving the best quality of care available. In the U.S., telemedicine providers are subject to each state's differing regulations and standards. Many states have yet to address the interstate and global nature of telemedicine, and inappropriately impose requirements tailored for delivery and practice of health care on a local level. Furthermore, such

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ See, e.g., Gulick, *supra* note 14, at 378-79; McLean, *supra* note 14., at 461-63.

⁴⁶ See Volkert, *supra* note 11, at 156-57.

inability to recognize and resolve these new challenges is underscored by the limited role the federal government currently plays in the area of regulation of telemedicine. In the few areas where the federal government does regulate, it often does not pre-empt state power and allows states to impose stricter standards.

The following categories of health regulation constitute the main barriers that telemedicine faces: (1) licensing requirements, (2) medical malpractice coverage, (3) legal liability, (4) privacy of information, and (5) payment of services. An examination of each of these categories shows how overlapping, inconsistent, and inadequate obligations imposed by governments and professional organizations impede the practice and growth of telemedicine.

A. Licensing Requirements

Every state has the authority to regulate health professionals who practice in their territories.⁴⁷ Each state has its own version of a “Medical Practice Act,” created and enacted by that state’s legislature, to govern the practice of medicine.⁴⁸ These state statutes require a physician to be licensed in the state in which the physician is practicing medicine.⁴⁹ These statutes also delegate regulatory authority to a state medical board.⁵⁰ The importance of locality in licensing is further

⁴⁷ See *Dent v. West Virginia*, 129 U.S. 114, 122-23 (1889), where the Supreme Court held that a state’s interest in protecting its citizens included the regulation of medical licensure:

Few professions require more careful preparation by one who seeks to enter it than that of medicine... Every one may have occasion to consult [the health professional], but comparatively few can judge of the qualifications of learning and the skill which he possesses. Reliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect, that he possesses the requisite qualifications.

⁴⁸ *The Role of the State Medical Board*, FED’N OF STATE MED. BDS., http://www.fsmb.org/grpol_talkingpoints1.html (last visited Jan. 8, 2010) [hereinafter FED’N OF STATE MED. BDS.].

⁴⁹ See, e.g., ALASKA STAT. §08.64.170; COLORADO REV. STAT. §12-36-106 (2010); 24 DEL. CODE ANN. tit. 24, § 1702 (2008); FLA STAT. ANN. § 458.327 (West 2010); HAWAII REV. STAT. §453-2; IDAHO CODE §54-1804; KANSAS STAT. ANN. §65-2803(West 2010); LA. REV. STAT. ANN. § 37:1271 (2010); MISS. CODE ANN. §73-25-1; NEV. REV. STAT. §630.160; 59 OKL. STAT. §§491, 492(C)(2)(b); S.C. CODE ANN. § 40-47-30 (2009). The number of categories of health professionals subject to regulation is too large to warrant individual analysis for the purposes of this Article (e.g., nurses, dentists). In order to highlight common issues within an industry as diverse as health care, this Article will only focus on a few examples. It should also be noted that other parties in this industry, like hospitals, must undergo licensure/approval requirements (e.g., hospitals), but these discussions are beyond the scope of this Article.

⁵⁰ FED’N OF STATE MED. BDS., *supra* note 48.

underscored in other aspects of these statutes, as they have significant variations among them.⁵¹ These variations may include differences in the following: definition of the practice of medicine; what constitutes the unlawful practice of medicine; and licensure and re-registration requirements.⁵² Such state-specific requirements force a telemedicine practitioner or provider to incur higher business costs to meet compliance, as telemedicine is often and intended to be practiced across state borders. These scenarios include: (1) physician and patient are located in different states, (2) physician and patient are in same state but consulting physician is out-of-state, or (3) patient, physician, and consulting physician are in different states.⁵³ Thus, the effect of compliance with these varying state specific requirements is higher costs of conducting interstate business and the creation of a monopoly for in-state health care providers.⁵⁴

Current measures to address telemedicine licensure offer no solution. A review of each of these measures will reveal their weaknesses. First, a majority of states offer a consultation exception that allows out-of-state licensed physicians to practice in very limited situations without the particular state's license in question.⁵⁵ This exception allows out-of-state licensed physicians to consult on patients provided that they work with or offer services at the request of an in-state physician.⁵⁶ This exception, however, is not a successful strategy, as most states require consultations to be infrequent or that the in-state physician or physicians make the final medical decision.⁵⁷

Second, many states have enacted laws regulating telemedicine licensure. Since 2006, twenty-four states require out-of-state physicians to obtain a full license from the state in which the service is being provided.⁵⁸ A minority of states allow for reciprocity or endorse-

⁵¹ *Id.*

⁵² *Id.*

⁵³ Volkert, *supra* note 11, at 168.

⁵⁴ McLean, *supra* note 14, at 462; *see also* Matak, *supra* note 29, at 242 ("Requiring teledoctors to obtain a license in every possible state to which they may transmit treatment will inhibit the use of telemedicine since '[e]ach state's requirements are minutely different, and the expense and time involved in receiving licensure . . . in more than one or two states makes it prohibitive, if not impossible, to achieve'" (quoting 104 CONG. REC. 141, 18185 (1995))).

⁵⁵ Linda Gobis, *An Overview of State Laws and Approaches to Minimize Licensure Barriers*, TELEMEDICINE TODAY, Dec. 1997, at 14, 15.

⁵⁶ *Id.*

⁵⁷ Laura Keidan Martin, *Not So Fast, It's Regulated: Some Warnings for the E-Health Biz*, BUS. L. TODAY, Sept.-Oct. 2000, at 10, 10.

⁵⁸ *Law and Policy in Telemedicine: The State of Licensure in the U.S.*, TELEMEDICINE INFO. EXCH., http://tie.telemed.org/legal/state_data.asp?type=licensure (last updated Nov. 15, 2006) [hereinafter TELEMEDICINE INFO. EXCH.].

ment.⁵⁹ As of the writing of this Article, very few states allow out-of-state physicians to practice medicine.⁶⁰ Examples of states in this minority category include Hawaii and Washington, which permit out-of-state physicians to practice medicine provided they do not open an office or designate a meeting place for patients or receive calls in-state.⁶¹ Another potential outlier is California, as it has enacted legislation giving the medical board authority to develop a registration program to permit licensed out-of-state physicians to register with the board to practice medicine,⁶² but the board has yet to exercise that authority.⁶³ Thus, by virtue of the variations in these state laws, such measures to address telemedicine licensure fail to resolve the geographical limitations imposed by traditional licensure requirements.

Third, the Federation of State Medical Boards (FSMB) proposed a special purpose license in 1996.⁶⁴ The FSMB is a national non-profit association that represents seventy state medical licensing and disciplinary boards.⁶⁵ The special purpose license was created by FSMB as part of its evaluation and recommendations for regulation of telemedicine to state medical boards.⁶⁶ This license is intended for physicians who practice medicine across state lines by electronic or other

⁵⁹ See, e.g., N.M. STAT. ANN. § 61-6-13 (LexisNexis 2008) (enabling licensure by endorsement if physician meets its state-based Medical Practice Act requirements); S.D. CODIFIED LAWS § 36-4-19 (2010) (providing that reciprocity is available if another state's or country's requirements are not less stringent); TENN. CODE ANN. § 63-6-211(a) (West 2010) (allowing reciprocity if another state's or country's requirements are not less stringent).

⁶⁰ HAW. REV. STAT. § 453-2 (West 2010); WASH. REV. CODE § 18.71.030(6) (2010).

⁶¹ *Id.*

⁶² CAL. BUS. & PROF. CODE §2052.5(a)(1) (West 2010).

⁶³ See *Practicing Medicine Through Telemedicine Technology*, MED. BD. OF CAL., <http://www.medbd.ca.gov/licensee/telemedicine.html> (last visited Jan. 12, 2011) ("California has no telemedicine registration program. In 1996, the Board sought legislation to obtain the regulatory authority to develop a program for physicians in other states to become registered in California, without requiring full licensure. The legislation was unsuccessful in obtaining regulatory authority, and, instead, added Section 2052.5 of the Business & Professions Code. This code has been the source of some confusion, as it outlines the original proposal for the registration program, but requires the Board to seek legislation to place a future program in statute. Those unfamiliar with the law's history assume that the Board has a program or the authority to implement one—the Board has neither.").

⁶⁴ FED'N OF STATE MED. BDS., REPORT OF THE AD HOC COMMITTEE ON TELEMEDICINE FEDERATION OF THE STATE MEDICAL BOARDS OF THE UNITED STATES, A MODEL ACT TO REGULATE THE PRACTICE OF MEDICINE ACROSS STATE LINES (1996), available at http://www.fsmb.org/pdf/1996_grpol_Telemedicine.pdf [hereinafter FSMB MODEL ACT].

⁶⁵ FED'N OF STATE MED. BDS., *supra* note 48.

⁶⁶ FSMB MODEL ACT, *supra* note 64, § 1.

means.⁶⁷ License holders are subject to the jurisdiction of the medical board in the state of issuance for all matters.⁶⁸ Thus far, few states have adopted this proposal.⁶⁹ This approach is unlikely to provide an effective solution as each state still has the authority to determine its own fees, and requirements and standards for issuance, thus resulting in variations in state laws.⁷⁰ Although the FSMB offers guidelines, a state's medical board has discretion to define what constitutes the practice of medicine⁷¹ and to determine the grounds upon which to grant or deny this license.⁷² This cautious approach towards implementation and deference to state authority indicates that the FSMB proposal primarily represents states' interests, and not necessarily what is the most optimal approach in facilitating the practice of telemedicine. A comparison of the FSMB's proposal with that of other nations in addressing the need for cross-border licensing of health professionals affirms this observation. For example, unlike the FSMB's state-by-state approval process, the European Union (EU) requires its member states to grant legal effect to the diplomas of physicians obtained in other member states as long these diplomas meet the minimum training requirements listed in the EU's "Doctor's Directive 93/16."⁷³ This Directive serves to satisfy the policy goals of "full free movement" and "guarantee[ing] the quality of the entrants to the profession."⁷⁴

⁶⁷ *Id.* § 4.

⁶⁸ *Id.* § 6.

⁶⁹ These states include: Alabama, Minnesota, Montana, New Mexico, Nevada, Oregon, Tennessee, and Texas. *See* TELEMEDICINE INFO. EXCH., *supra* note 58; *see also State Telemedicine Statute Summary*, CTR. FOR TELEHEALTH AND E-HEALTH LAW, http://www.telehealthlawcenter.org/loadattachment.php?attachmentid=174_1744_327 (last visited Mar. 6, 2010) (summarizing state telemedicine licensure provisions in select states).

⁷⁰ *See* FSMB MODEL ACT, *supra* note 64, § 5. An example of variations in state laws can be seen between Alabama and Minnesota. Alabama will only issue a special license to those physicians located in states that allow Alabama-based physicians to practice medicine across state lines, whereas Minnesota has no such requirement. ALA. ADMIN. CODE 540-X-16-.02 (7)(a); MINN. STAT. § 147.032 (2008).

⁷¹ FSMB MODEL ACT, *supra* note 64, § 8.

⁷² *Id.* § 5.

⁷³ Council Directive 93/16/EEC, of the Council of the European Communities of 5 April 1993 to Facilitate the Free Movement of Doctors and the Mutual Recognition of Their Diplomas, Certificates and Other Evidence of Formal Qualifications 93/16/EEC, (1993) O.J. (L 165) 1, 1-24.

⁷⁴ M. Peeters, *Free Movement of Medical Doctors in the EU*, 26 *MED. & L.* 231, 235 (2007).

B. Malpractice Insurance Coverage

In addition to local licensing requirements, telemedicine is limited by difficulties in obtaining medical malpractice coverage. Telemedicine insurers face the challenges of compliance with states' medical malpractice insurance coverage requirements and legal liability in different jurisdictions. Just as with the licensing process, states have the authority to establish and regulate insurance for health care providers.⁷⁵ The federal government has affirmed such delegation of state power through passage of the McCarran-Ferguson Act.⁷⁶ A state's insurance code essentially regulates every aspect of the health insurance within its borders.⁷⁷ While there is overlap between state insurance codes, each state has its own unique definitions, coverage schemes, and procedures.⁷⁸ Most require that a health professional obtain medical malpractice coverage for a state's territory before receipt of medical license.⁷⁹ Such a requirement for state-specific coverage for telemedicine providers who operate on an interstate platform creates system inefficiencies that significantly increase transaction costs.⁸⁰ Such an assertion is supported by the findings of a 2004 report sponsored by the National Association of Insurance Commissioners (NAIC), which investigated the causes for the scarcity of national insurers and the increased cost of coverage on a national basis.⁸¹ Listed among the barriers to entering the medical malpractice market are regulatory constraints, which bar "[m]ost medical malpractice insurers [from] sell[ing] across state lines without filing for license or

⁷⁵ See *Paul v. Virginia*, 75 U.S. (8 Wall) 168, 183-84 (1869).

⁷⁶ 15 U.S.C. §§ 1011-1013 (2006). In *Life Partners, Inc. v. Morrison*, the Fourth Circuit explained that the McCarran-Ferguson Act explicitly granted states the authority to regulate the business of insurance and protected such authority from any constitutional challenge based on the Commerce Clause to any state law (1) that "'relate[s] to the regulation of the business of insurance,'" or (2) "enacted 'for the purpose of regulating the business of insurance.'" 484 F.3d 284, 286, 287 (4th Cir. 2007) (quoting 15 U.S.C. § 1012).

⁷⁷ See, e.g., KY. REV. STAT. ANN. § 304.40-250 to -320 (West 2009).

⁷⁸ See, e.g., KY. REV. STAT. ANN. ch. 304.01; see generally Daniel Schwarcz, *Redesigning Consumer Dispute Resolution: A Case Study Of The British And American Approaches To Insurance Claims Conflict*, 83 TUL. L. REV. 735, 750 (2009) (discussing the varying dispute resolution procedures for insurance coverage claims among the states).

⁷⁹ See, e.g., KAN. STAT. ANN. §65-2809(c) (West 2010).

⁸⁰ See Edward P. Richards & Thomas R. McLean, *Administrative Compensation for Medical Malpractice Injuries: Reconciling the Brave New World of Patient Safety and the Torts System*, 49 ST. LOUIS U. L.J. 73, 77 (2004).

⁸¹ ERIC NORDMAN ET AL., MEDICAL MALPRACTICE INSURANCE REPORT: A STUDY OF MARKET CONDITIONS AND POTENTIAL SOLUTIONS TO THE RECENT CRISIS 6 (2004), available at http://www.naic.org/documents/topics_med_mal_rpt_final.pdf.

authorization. Rates and forms must be adjusted to local requirements.”⁸² Another cited barrier related to local-based regulation is the lack of specialty market experience. For a potential insurer to enter a new market, it must have “specialized and local knowledge” to successfully underwrite, price, and defend claims.⁸³ Given the requirements to comply with multiple insurance codes and local nuances, state insurance laws have acted as longstanding barriers to the national practice of telemedicine.⁸⁴

C. Legal Liability Considerations

The need to develop a standardized approach to obtaining medical malpractice coverage further highlights related legal considerations a telemedicine provider must address before doing business across state borders. Jurisdiction and choice of law present new challenges in malpractice adjudication, as telemedicine providers are often foreign or based in a different state than the opposing party(ies). Jurisdiction empowers a government to exercise authority over all persons and property within its territory, including the power to prescribe, adjudicate, and enforce judgments.⁸⁵ Once jurisdiction is established, the next issue to be resolved is which law applies to the case in question. When parties are based in different states and countries, these otherwise established rules of civil procedure become dilemmas. As an examination of these legal issues for (1) U.S.-based providers and (2) foreign-based providers operating in the U.S. demonstrate below, it is crucial to consider uniform procedures and standards in dealing with tort liability issues.

1. Legal Liability Considerations for U.S.-based Telemedicine Providers

Currently, the dearth of case law and legislation on both federal and state levels reveal much uncertainty and provide little guidance on jurisdiction and choice of law determinations involving telemedicine providers based in the U.S.⁸⁶ Several scholars anticipate jurisdiction in

⁸² *Id.* at 37.

⁸³ *Id.*

⁸⁴ See McLean, *supra* note 14, at 466.

⁸⁵ RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 401 (1987).

⁸⁶ See generally Nathan Cortez, *Patients Without Borders: The Emerging Global Market for Patients and the Evolution of Modern Health Care*, 83 IND. L.J. 71, 78 (2008); Deth Sao, David A. Gantz & Amar Gupta, *Disputes Related to Healthcare Across National Boundaries: The Potential for Arbitration*, 42 GEO. WASH. INT’L L. REV. (forthcoming 2011).

these situations will be established in accordance with the Supreme Court's "minimum contacts" test of personal jurisdiction over interstate claims.⁸⁷ This test requires a finding of the following three elements: (1) the state has a long-arm statute allowing for personal jurisdiction; (2) the defendant has minimum contacts with the state, as evidenced by foreseeability of liability and "purposeful availment" of the privileges and protections of the laws of that state; and (3) the exercise of personal jurisdiction is reasonable and does not violate "traditional notions of fair play and substantial justice" guaranteed under the Due Process Clause of the Fourteenth Amendment.⁸⁸ The Court has interpreted foreseeability to mean that a defendant expects that its product will be purchased by the state's citizens.⁸⁹ As to "purposeful availment," the defendant must make a deliberate choice to relate to the state in a meaningful way before being made to bear the burden of defending there.⁹⁰ Notably, the defendant is not required to have a physical presence in the state as long as the defendant's efforts are directed towards the state.⁹¹ Finally, in considering whether personal jurisdiction is reasonable, the Court looks to the following factors: burden of litigation on defendant, interests of the forum state, interests of the plaintiff, the interstate judicial system's interests in the most efficient resolution, and shared states' interests in furthering fundamental substantive social policies.⁹²

When applying the "minimum contacts" test to telemedicine, it appears likely that interstate telemedicine providers will be subject to

⁸⁷ See, e.g., Archie A. Alexander, III, *American Diagnostic Radiology Moves Offshore: Is this Field Riding "The Internet Wave" Into a Regulatory Abyss?*, 20 J.L. & HEALTH 199, 232-36 (2006-07); Mark S. Kopson, *Medical Tourism: Implications for Providers & Plans*, 3 J. HEALTH & LIFE SCI. L. 147, 182-83 (2010); Thomas R. McLean, *The Offshoring of American Medicine: Scope, Economic Issues and Legal Liabilities*, 14 ANNALS HEALTH L. 205, 247 (2005); Lisa Rannefeld, *The Doctor Will Email You Now: Physicians' Use of Telemedicine to Treat Patients Over the Internet*, 19 J.L. & HEALTH 75, 90 (2004-05).

⁸⁸ *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 471-78 (1985); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 291-98 (1980) (citing *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)); *Hanson v. Denckla*, 357 U.S. 235, 251-53 (1958).

⁸⁹ *World-Wide Volkswagen Corp.*, 444 U.S. at 295-98 (finding no foreseeability because the plaintiff purchased defendant dealer's car in a state other than forum state, and defendant had no knowledge plaintiff would be using car to travel to forum state).

⁹⁰ *Id.* at 295 (finding no purposeful availment because defendant dealer did not sell cars, advertise, or cultivate customer base in forum state).

⁹¹ *Keeton v. Hustler Magazine Inc.*, 465 U.S. 770, 777, 781 (1984) (finding defendant purposefully availed itself of chance to engage in in-state activities by distributing magazines in state).

⁹² *World-Wide Volkswagen Corp.*, 444 U.S. at 292.

jurisdiction of the state in which they provide medical treatment and/or services. First, most states have long-arm statutes allowing for personal jurisdiction.⁹³ Second, the interstate nature of telemedicine compels a provider to acknowledge foreseeability of suit in any state in which that provider does business. Furthermore, a telemedicine provider also purposefully avails itself of the benefits and protections of the forum state by engaging in commerce in that state.

On the other hand, the “minimum contacts” test reveals that the state’s assertion of personal jurisdiction in this context may be invalid. It is questionable whether the last requirement that personal jurisdiction be reasonable will be met. Given the above-listed factors the Court considers to evaluate this requirement, it is debatable whether an individual state’s judicial system is an appropriate forum to adjudicate an issue that involves parties, transactions, and public policy concerns on such comprehensive national and global levels. These concerns go the heart of the Court’s considerations of the interstate judicial system’s interests in the most efficient resolution and the shared states’ interests in furthering fundamental substantive social policies. According to the Court, these considerations promote the principles of interstate federalism, which is paramount to all other elements of the test:

Even if the defendant would suffer minimal or no inconvenience from being forced to litigate before the tribunals of another State; even if the forum State has a strong interest in applying its law to the controversy; even if the forum State is the most convenient location for litigation, the Due Process Clause, acting as an instrument of interstate federalism, may

⁹³ See, e.g., ALA.CODE § 8-19C-10 (LexisNexis 2009); ALASKA STAT. § 09.05.015 (2010); ARIZ. REV. STAT. ANN. § 25-1221 (2010); ARK. CODE ANN. § 16-4-101 (2010); CAL. CIV. PROC. CODE § 410.10 (West 2010); COLO. REV. STAT. § 13-1-124 (2010); CONN. GEN. STAT. ANN. § 1-101oo (West 2010); FLA. STAT. ANN. § 48.193 (West 2010); GA. CODE ANN. § 9-10-91 (2010); 735 ILL. COMP. STAT. ANN. 5/2-209 (West 2010); KY. REV. STAT. ANN. § 454.210 (West 2009); LA. REV. STAT. ANN. § 13:3201 (2010); ME. REV. STAT. ANN. tit. 14 § 704-A (2010); MASS. GEN. LAWS ch. 223A § 2 (2010); MICH. COMP. LAWS ANN. § 600.701, .711, .721 (West 2010); NEB. REV. STAT. ANN. § 25-536 (Lexis Nexis 2010); NEV. STAT. ANN. § 14.065 (West 2010); N.M. STAT. ANN. § 38-1-16 (West 2010); N.Y. C.P.L.R. § 302 (McKINNEY 2010); N.C. GEN. STAT. § 1-75.4 (2009); OHIO REV. CODE ANN. § 2307.382 (West 2010); 42 PA. CONS. STAT. ANN. § 5322 (West 2010); R.I. GEN. LAWS ANN. § 9-5-33 (West 2010); S.D. CODIFIED LAWS § 15-7-2 (2010); TENN. CODE ANN. § 20-2-214 (West 2010); TEX. CIV. PRAC. & REM. CODE ANN. § 17.042 (Vernon 2010); UTAH CODE ANN. § 78B-3-205 (West 2010); VA. CODE ANN. § 8.01-328.1 (2010); WASH. REV. CODE ANN. § 4.28.185 (2010); WIS. STAT. ANN. § 801.05 (West 2008).

sometimes act to divest the State of its power to render a valid judgment.⁹⁴

Here, it is doubtful whether adjudicating an interstate telemedicine claim in one forum state is the most efficient resolution to the interstate judicial systems' best interests or advances the states' social policies. For example, telemedicine implicates health and safety standards and regulations of more than one state, which are issues that a forum state is arguably not qualified to unilaterally adjudicate. This is especially true when the forum state will likely apply its own laws for cases involving tort liability.⁹⁵ Furthermore, telemedicine is an unsettled and ambiguous area of legal liability. The standard of care for online treatment by physicians in a medical malpractice case is still undefined by many states.⁹⁶ Thus, given these concerns, it is worth considering a national forum for adjudication as an alternative to state courts.

2. Liability Considerations for Foreign-based Telemedicine Providers

Just as with U.S.-based telemedicine providers, there is little guidance on jurisdiction and choice of law determinations for foreign-based telemedicine providers. While the Supreme Court has applied the "minimum contacts" test to determine personal jurisdiction over alien defendants,⁹⁷ the same uncertainties voiced above regarding the validity of such an assertion apply here. The requirement that personal jurisdiction not violate "traditional notions of fair play and substantial justice" is extended in the international context in the following ways. First, the Court's consideration of collective U.S. states' interests "calls for a court to consider the procedural and substantive policies of *other nations* whose interests are affected by the assertion of [the jurisdiction of a state court]."⁹⁸ Second, the federal government's interest in its foreign policies will also play a factor.⁹⁹ Third, the interests of the defendant have "significant weight in assessing the reasonable-

⁹⁴ *World-Wide Volkswagen Corp.*, 444 U.S. at 294 (citing *Hanson v. Denckla*, 357 U.S. 235, 251, 254 (1958)).

⁹⁵ See *Haag v. Barnes*, 175 N.E.2d 441, 443 (N.Y. 1961); RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 145(1) (1971) ("The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state . . .").

⁹⁶ Some states follow the FSMB's view that online treatment warrants the same standard of care as in-person treatment, and that sole use of an online questionnaire is unacceptable. FSMB MODEL ACT, *supra* note 64, §3.

⁹⁷ See, e.g., *Asahi Metal Indus. Co. v. Superior Court*, 480 U.S. 102 (1987).

⁹⁸ *Id.* at 115 (emphasis added).

⁹⁹ *Id.*

ness of stretching the long arm of the personal jurisdiction over national borders," as "unique burdens [are] placed upon one who must defend oneself in a foreign legal system."¹⁰⁰

Here, the global nature of the telemedicine industry necessarily involves other nations' interests and foreign policy implications for the federal government. Thus, the Court's reluctance to apply a bright line rule of jurisdiction over foreign defendants and its expressed desire to honor the interests of the federal government and other nations lends support to the need for an inclusive global framework for determining such international rules of civil procedure. A review of existing international legal mechanisms to address the practice of telemedicine underscores this need. As of the writing of this Article, there are no international agreements concerning telemedicine.¹⁰¹ There are notable exceptions where telemedicine law has become more fully developed and comprehensive, such as Malaysia.¹⁰² Overall, however, telemedicine providers who engage in business in the U.S. and the global marketplace face significant uncertainty as to the scope and extent of their exposure to legal liability.

D. Privacy of Information

Unlike the ambiguities of telemedicine law, there are layers of regulation at both the federal and state levels for privacy protection of health care information in the United States.

At the federal level, the 1996 Health Insurance Portability and Accountability Act (HIPAA) imposes an obligation to maintain the confidentiality of individually identifiable health information on health plans, health care clearinghouses, and health care providers that transmit health information electronically.¹⁰³ HIPAA applies to health information via electronic media in connection with most financial and administrative transactions.¹⁰⁴ Unauthorized disclosures may result in criminal and civil penalties.¹⁰⁵

¹⁰⁰ *Id.* at 114.

¹⁰¹ See, e.g., Blum, *supra* note 14, at 85; Leah B. Mendelsohn, *A Piece of the Puzzle: Telemedicine as an Instrument to Facilitate the Improvement of Healthcare in Developing Countries?*, 18 EMORY INT'L L. REV. 151, 153 (2004).

¹⁰² See *infra* Part V.

¹⁰³ 42 U.S.C. § 1320d (2006).

¹⁰⁴ Mary Beth Johnston, *HIPAA Administrative Simplification Privacy, Security, and Transaction Standards*, 2 HEALTH LAW. 9, 9 (2002) ("The HIPAA transaction standards and requirements apply, unless otherwise specified, to health plans, health care clearinghouses, and any health care provider that transmits or maintains any health information via electronic media in connection with a covered transaction. Covered transactions include, among others, health claims or equivalent encounter information, health claims attachments, enrollment and disenrollment in a health plan,

HIPAA requires states to follow the federal standards it sets forth, but it allows states and other federal agencies to set forth and impose stricter security measures.¹⁰⁶ Such overlapping regulations force telemedicine providers to comply with both federal and state standards, a process that is expensive, difficult, and time-consuming.¹⁰⁷ Furthermore, the telemedicine provider faces additional costs of compliance where state laws are more stringent. Examples of such state laws include: granting a person greater rights to see, copy, or amend his or own health information; increasing privacy protections afforded by authorization; and providing greater privacy protection for the person who is the subject of the individually identifiable health information.¹⁰⁸

E. Payment for Telemedicine Services

In addition to the above-listed obstacles, the practice of telemedicine is impeded by the health care reimbursement process in the United States. The three main health care insurers, Medicare, Medicaid, and private entities, do not pay for telemedicine services or only pay for some services under limited circumstances.¹⁰⁹ A review of each of these insurers will show the ways in which current billing processes impede the practice of telemedicine.

eligibility for a health plan, health care payment and remittance advice, health plan premium payments, first report of injury, health claim status, and referral certification and authorization”); see 42 U.S.C. § 1320d-2(a)(2) (2006); 45 C.F.R. § 160.103 (2009).

¹⁰⁵ 42 U.S.C. § 1320d-6(b).

¹⁰⁶ § 1320d-7(a).

¹⁰⁷ The American Health Information Management Association, a nonprofit association of health information professionals, published an advisory article to businesses interested in HIPAA compliance that provided the following price estimates of the process: from approximately \$500 for a single state study conducted by that state’s bar to \$5,000–\$10,000 by another entity for a single state’s analysis, depending on the complexity of the state’s laws. Joy Pritts, *Preemption Analysis Under HIPAA—Proceed with Caution*, 11 IN CONFIDENCE 4 (2003), available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok3_005197.hcsp?dDocName=bok3_005197#sidebar.

¹⁰⁸ *Id.*

¹⁰⁹ U.S. DEP’T OF HEALTH AND HUMAN SERV., 2001 TELEMEDICINE REPORT TO CONGRESS 1 (2001), available at <ftp://ftp.hrsa.gov/telehealth/report2001.pdf> [hereinafter 2001 TELEMEDICINE REPORT TO CONGRESS].

1. Medicare

Medicare, a federal insurer for the aged and disabled,¹¹⁰ has geographic and services limitations for reimbursement. Eligible services include “office and other outpatient visits, professional consultation, psychiatric diagnostic interview examination, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one visit per month to examine the access site), individual medical nutrition therapy, the neurobehavioral status exam, and follow-up telehealth consultations furnished by an interactive telecommunications system.”¹¹¹ Excluded services that “do not meet the definition of an interactive telecommunications system” are “[t]elephones, facsimile machines, and electronic mail systems.”¹¹² Geographically, reimbursement is limited to an originating site. The Code of Federal Regulations defines an originating site as “the site where the patient is located [, which] must be the office of a physician or practitioner, a critical access hospital, a rural health clinic, a federally qualified health center, or a hospital.”¹¹³ These sites must be a Rural Health Professional Shortage Area, a non-Metropolitan Statistical Area, or part of a federal telemedicine project.¹¹⁴ Furthermore, home health care requires face-to-face visits and telemedicine may not be substituted in place of these visits.¹¹⁵

2. Medicaid

Medicaid, a federal insurer of low-income and disabled populations, further complicates the billing process by allowing states to run their own Medicaid programs.¹¹⁶ This means that each state determines which telemedicine services, if any, are eligible for reimburse-

¹¹⁰ See *Medicare Eligibility Tool*, MEDICARE.GOV, <http://www.medicare.gov/MedicareEligibility/Home.asp?dest=NAV|Home|GeneralEnrollment#TabTop> (follow “What is Medicare?” hyperlink) (last updated Sept. 17, 2008).

¹¹¹ 42 C.F.R. § 410.78(b) (2009).

¹¹² § 410.78(a)(3).

¹¹³ § 410.78(b)(3).

¹¹⁴ 2001 TELEMEDICINE REPORT TO CONGRESS, *supra* note 109, at 17-18.

¹¹⁵ *Telemedicine and Telehealth*, CTRS. FOR MEDICAID & MEDICARE SERVS., U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.cms.hhs.gov/Telemedicine/> (last visited Jan. 10, 2009).

¹¹⁶ *Medicaid Program—General Information*, CTRS. FOR MEDICAID & MEDICARE SERVS., U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.cms.gov/MedicaidGenInfo/> (last visited Mar. 25, 2011).

ment.¹¹⁷ Currently, only eighteen states compensate for telemedicine services, while two others are developing plans to cover telemedicine.¹¹⁸

3. Private Insurers

In general, private insurers rarely compensate for telemedicine services.¹¹⁹ A combination of doubt regarding telemedicine's efficacy and concerns with costs of and compliance with states' regulatory insurance requirements are likely responsible for denial of coverage.¹²⁰ In instances where insurers do provide coverage, intrastate services are more likely to be covered than interstate services because of the premium differentials among states.¹²¹ Only recently have some private insurers begun to provide limited telemedicine coverage.¹²² One of the main reasons for this change in policy is because some states have begun to require private insurers to provide reimbursement.¹²³ While there is some movement towards coverage, such overwhelming reluctance contributes to the difficulties faced by telemedicine practitioners in treating their patients.

III. THE (IL)LEGITIMACY OF STATE AUTHORITY OVER POLICE POWERS IN TELEMEDICINE

As the above section demonstrates, the existing state-by-state regulatory framework is ill equipped to resolve the challenges of the health care industry on a national and global scale. The effects of the aforementioned barriers prompt a consideration of national and international alternatives to establish standards and regulations involving out-of-state parties and transactions. In justifying the need for these

¹¹⁷ See *Telemedicine and Telehealth Funding*, TELEMEDICINE INFO. EXCH., <http://tie.telemed.org/funding/default.asp?return=record&type=program&genus=Federal&id=21> (last updated Nov. 1, 2005).

¹¹⁸ *Id.* The following states provide for telemedicine reimbursement: Arkansas, California, Georgia, Iowa, Illinois, Kansas, Louisiana, Montana, Nebraska, North Carolina, North Dakota, Oklahoma, South Dakota, Texas, Utah, Virginia, and West Virginia. States that are in the process of incorporating telemedicine services in their plan include: Kentucky and Maine. *Id.*

¹¹⁹ Alissa R. Spielberg, *Online Without a Net: Physician-Patient Communication by Electronic Mail*, 25 AM. J.L. & MED. 267, 290 (1999) (explaining that private insurers doubt that telemedicine is a "cost-effective and reliable therapeutic modality that deserves reimbursement . . .").

¹²⁰ See *id.*

¹²¹ Rannefeld, *supra* note 87, at 91.

¹²² See 2001 Telemedicine Report to Congress, *supra* note 109, at 19.

¹²³ See, e.g., COLO. REV. STAT. § 10-16-123(2) (2010); LA. REV. STAT. ANN. § 22:1821(F) (2009).

alternatives, it is first necessary to demonstrate the following: (1) the reasons behind the traditional belief that local authorities are in the best position to police the health care industry¹²⁴ are no longer valid in the context of telemedicine; (2) the existing state system is not the best solution available, as national standards and regulations for health and safety are currently in place for other aspects of public health and safety; (3) because of these two reasons, in addition to the interstate commercial nature of telemedicine, the state does not have exclusive constitutional authority over health regulation; and (4) for these same reasons, state regulation of telemedicine is unconstitutional. This section will argue each of these assertions in turn below.

A. State Regulation of Health Care Is a Result of Historic and Political Realities, Not Because Health Care is an Intrinsically Local Concern

Proponents of the state policing system maintain that issues surrounding health and safety are inherently local in nature, and thus warrant local control.¹²⁵ Because health and safety issues have “local peculiarities,” the state is most qualified to tailor a solution for its citizenry.¹²⁶ In the context of health care, this point of view is valid from a historical perspective. Until recently, health care was only practiced at a local level and limited to parties and transactions within a state’s territory.¹²⁷ But this point of view is no longer valid. As this Article has demonstrated, recent advancements in technology and medical knowledge enabled health care to transcend state borders, thus no longer making health care a local activity and by extension, an exclusive local concern.

To demonstrate that health care is not an intrinsically local concern, it is instructive to examine the historical development of state power over health care regulation in the United States. Such an examination will show that, rather than resulting from immovable “local peculiarities” of a community, state regulation arose and expanded in response to the prevailing medical knowledge and technology at the time.

¹²⁴ See Volkert, *supra* note 11, at 179-80 (“States have historically done an excellent job at policing, and there is no data to suggest a national system would work as well as the existing state systems.”).

¹²⁵ See Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 156-157 (2004).

¹²⁶ *Id.* at 156.

¹²⁷ Thomas R. McLean, *The Global Market for Health Care: Economics and Regulation*, 26 WIS INT’L L.J. 591, 591, 625 (2008).

1. Colonial Period: Health Care Regulation Limited to Infectious Disease Control

In colonial times, the regulation of health care became a province of the states because it was “a rational response to the technological level of the eighteenth century . . .”¹²⁸ The prevalence and reoccurrence of infectious disease in colonies and the available medical knowledge and technologies to combat such diseases in colonies helped dictate the distribution of powers between states and the federal government.¹²⁹ Because of these circumstances:

[t]he regulation of health care was, of practical necessity, a municipal function during the Colonial period, remaining so during the first century of the Republic. . . . [M]unicipal regulation of health care was a reflection of the era, rather than an immutable Constitutional principle of federalism . . .¹³⁰

From these circumstances arose the beginnings of state regulation in health care, as medical knowledge at the time dictated that states were in the best position to monitor and control infectious disease outbreaks.¹³¹ As most citizens in the colonies lived near rivers, they were vulnerable to mosquito-borne diseases such as malaria and yellow fever.¹³² Because these diseases were transmitted face-to-face or via local contact, a local response was required.¹³³ To prevent contagion and infection, local authorities implemented quarantine measures as a solution.¹³⁴ These outbreaks occurred and solutions were applied at such a localized level that the first regulatory efforts were mainly municipal initiatives.¹³⁵ The first boards of health were also municipal.¹³⁶ The first hospital was established by the city of Philadelphia.¹³⁷ Thus, just as with the federal government, states played no role in health care during the nation’s early formative years.

¹²⁸ Kevin Outterson, *Health Care, Technology and Federalism*, 103 W. VA. L. REV. 503, 504 (2001).

¹²⁹ 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 ANNALS HEALTH L. 201, 203 (1999).

¹³⁰ Outterson, *supra* note 128, at 515.

¹³¹ *Id.*

¹³² Richards, *supra* note 129, at 203-05.

¹³³ Outterson, *supra* note 128, at 506.

¹³⁴ See Richards, *supra* note 129, at 205.

¹³⁵ See Outterson, *supra* note 128, at 506.

¹³⁶ *Id.* at 507.

¹³⁷ *Id.* at 506-07.

At the same time that available medical knowledge dictated that states regulate infectious diseases, the lack of medical knowledge in other areas of health prevented states from regulating the practice of medicine.¹³⁸ During the Seventeenth and Eighteenth Centuries, medical treatment made no significant difference in a person's survival.¹³⁹ Widely practiced treatments were more harmful than beneficial, and included the following: purges, bleeding, and unsanitary habits by physicians who spread germs by contact.¹⁴⁰ Because of such ineffectiveness, "in the minds of the populace and the legislatures, there was no justification for setting some physicians up with a state-enforced monopoly through licensing them, and excluding other physicians."¹⁴¹

It is important to note here another theory for why states did not regulate the practice of medicine at this time, as it lends further support to the argument that health care is determined by political concerns rather than "local peculiarities." Legal scholar Kevin Outterson observes that such lack of regulation reflected the political views of the Revolution and Jacksonian era, which opposed the British practice of granting monopolies by requiring licensures of professionals.¹⁴²

2. Post-Civil War Period: Expansion of Health Care Regulation

By 1880, advances in medical knowledge and technology triggered state involvement in health care regulation. Developments in science finally reached the point where medical treatments began to be effective.¹⁴³ Discoveries such as anesthesia and modern germ theory enabled physicians to provide successful treatments and cures.¹⁴⁴ Gains in medical knowledge, like these, also offered a basis on which to set standards for health professionals and types of treatment,¹⁴⁵ which prompted the formation of state medical boards and their petitioning of states for stricter licensing laws.¹⁴⁶ Thus, the evolution from municipal to state regulation in response to advances in technology and medical knowledge shows that expansion of jurisdiction in this area has already occurred. That these advances are embodied in the form of telemedicine indicate the need for a further expansion on national and international scales.

¹³⁸ *Id.* at 515.

¹³⁹ Richards, *supra* note 129, at 206.

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 207.

¹⁴² Outterson, *supra* note 128, at 511.

¹⁴³ Richards, *supra* note 129, at 209.

¹⁴⁴ *Id.* at 209-10.

¹⁴⁵ Outterson, *supra* note 128, at 512.

¹⁴⁶ *Id.*

B. National Regulation of Health and Safety: Lessons from the Federal Drug Agency

In addition to the historical evolution of state regulation over health care, the development of the Federal Drug Agency (FDA) also lends support to the proposition that an overarching layer of governance is required when health and safety concerns involve interstate parties and transactions. The FDA is a prime example of such a national policing system because it is a federal consumer protection agency charged with protecting the public health by regulating the safety and efficacy of drugs and medical devices.¹⁴⁷ Just as with this Article's section on the growth of state regulation of health care, this section will show that the establishment and expansion of the FDA's responsibilities was also a response to developments in technology and medical knowledge. Furthermore, this section will show that national regulation promulgated by the FDA was the appropriate response, as the relevant health and safety concerns involved populations across state borders, and not just citizens within a particular territory.

1. The Establishment of the FDA: The Pure Foods and Drug Act

The interstate sale of drugs prompted the Congressional enactment of the Pure Foods and Drug Act in 1906 (Food and Drug Act), which was the first attempt towards national regulation of drugs.¹⁴⁸ Congress granted such regulatory power to the FDA,¹⁴⁹ which originally began as the Chemical Division of the United States Department of Agriculture (USDA) in 1862.¹⁵⁰ Through the Food and Drug Act, the FDA was established as a federal agency with a mission of consumer protection.¹⁵¹ To carry out such a goal, the "FDA developed a regulatory model based on frequent seizures and criminal prosecutions of adulterated products."¹⁵² The reach of the FDA authority extended only to banning "adulterated" and "misbranded" foods and drugs that were placed in interstate commerce.¹⁵³ Such authority was further bounded by the absence of any requirement that these regulated prod-

¹⁴⁷ Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS. L. REV. 883, 886 (1996).

¹⁴⁸ *Id.* at 890.

¹⁴⁹ James Robert Dean, Jr., *FDA at War: Securing the Food that Secured Victory*, 53 FOOD & DRUG L.J. 453, 461 (1998).

¹⁵⁰ *Id.* at 455.

¹⁵¹ *Id.* at 461.

¹⁵² *Id.* at 456.

¹⁵³ Walsh & Pyrich, *supra* note 147, at 892.

ucts be tested or approved for safety before being marketed.¹⁵⁴ Finally, the FDA had no authority over medical devices.¹⁵⁵ Few such instruments existed during this time,¹⁵⁶ and thus likely had too little an impact on interstate commerce and citizens' health and safety to warrant federal attention.

2. The Federal Food, Drug & Cosmetic Act of 1938

The emergence and interstate sale of dubious medical devices and widespread injuries and deaths resulting from untested drugs prompted Congress to expand the limited powers of the FDA under the Federal Food Drug & Cosmetic Act of 1938 (1938 Act). In 1937, over 100 people died and others were severely injured by the drug Elixer Sulfanilamide, which was never tested for safety before entering the market.¹⁵⁷ This prompted a public outcry for reform of federal drug laws.¹⁵⁸ Furthermore, so-called "quack" devices were being sold to consumers that posed health risks to consumers.¹⁵⁹ For example, in the 1940s, ninety dollar lamps were marketed as cure-alls for diseases such as diabetes, cancer, tuberculosis, and syphilis.¹⁶⁰

Such harmful impacts on consumers' health and pocketbooks prompted the enactment of the 1938 Act.¹⁶¹ To address drug safety concerns, the 1938 Act required all new drugs to undergo testing by the manufacturer and FDA safety review prior to sale.¹⁶² For medical devices, the FDA had new authority to ban devices entering interstate commerce, impose labeling requirements,¹⁶³ and seize misbranded and fraudulent devices.¹⁶⁴ Significantly, the FDA gained greater power under the 1938 Act's transformation of the agency into an adminis-

¹⁵⁴ *Id.* at 891-92.

¹⁵⁵ *Id.*

¹⁵⁶ See MICHELE SCHOONMAKER, CRS REPORT FOR CONGRESS: THE U.S. APPROVAL PROCESS FOR MEDICAL DEVICES: LEGISLATIVE ISSUES AND COMPARISON WITH THE DRUG MODEL 7 (2005), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL3282603232005.pdf>.

¹⁵⁷ Walsh & Pyrich, *supra* note 147, at 893.

¹⁵⁸ *Id.*

¹⁵⁹ S. REP. NO. 94-33, at 3 (1975), reprinted in 1976 U.S.C.C.A.N. 1070, 1072-73 (detailing Congress's concerns about "quack" medical devices).

¹⁶⁰ *Id.*

¹⁶¹ *Id.* at 6, reprinted in 1976 U.S.C.C.A.N. at 1075. The 1938 Act's effective date was delayed by statute until July 1, 1940. See Act of June 23, 1939, Pub. L. No. 76-151, 53 Stat. 853.

¹⁶² Walsh & Pyrich, *supra* note 147, at 894.

¹⁶³ *Id.* at 895.

¹⁶⁴ Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

trative authority. The 1938 Act “provided for the replacement of a traditional police force with an independent regulatory body empowered to create and enforce the law.”¹⁶⁵ The scope of such authority ranged from the beginning of the regulated product’s development (e.g., factory inspections where products are made) to the procurement of injunctions in federal courts and pursuit of criminal prosecutions of violators.¹⁶⁶ Finally, the FDA’s transfer from the USDA to the Federal Security Agency in 1940 affirmed its mandate as a national regulator of health and safety issues. In approving such a transfer, President Franklin D. Roosevelt wrote in his 1939 Reorganizational Plan that it was “necessary and desirable to group in a Federal Security Agency those agencies of the Government, the major purposes of which are to promote social and economic security, educational opportunity and the health of the citizens of the Nation.”¹⁶⁷

3. The 1962 Amendments

In addition to developments in drugs and medical devices in the United States, the power of the FDA was also influenced by such developments abroad. In Europe, the drug Thalidomide, which was used to relieve morning sickness in pregnant women, was discovered to cause serious birth defects.¹⁶⁸ While this drug was popular in Europe, it was never approved for U.S. use. However, this incident “provided the single most visible justification for increasing the power of the FDA to regulate drugs.”¹⁶⁹ U.S. residents’ fears of this incident occurring domestically thus “framed the FDA policy toward review of drugs approved for use outside the United States.”¹⁷⁰ In response, Congress enacted the 1962 Amendments, which expanded FDA power to include: (1) determining that a drug was safe before sale, (2) determining whether new drugs did what they proposed to do, and (3) providing approval for clinical testing in humans.¹⁷¹

¹⁶⁵ Dean, *supra* note 149, at 457.

¹⁶⁶ Walsh & Pyrich, *supra* note 147, at 895-96.

¹⁶⁷ The President Presents Plan No. I to Carry Out the Provisions of the Reorganization Act (Apr. 24, 1939) at 252, available at <http://www.socialsecurity.gov/history/pdf/fdr.pdf>.

¹⁶⁸ Walsh & Pyrich, *supra* note 147, at 896.

¹⁶⁹ *Id.* at 896 n.37.

¹⁷⁰ *Id.* (quoting Joseph Contrera, *The Food and Drug Administration and the International Conference on Harmonization: How Harmonious Will International Pharmaceutical Regulations Become?*, 8 ADMIN. L.J. AM. U. 927, 936 (1994)).

¹⁷¹ Walsh & Pyrich, *supra* note 147, at 897. The 1962 Amendments were also motivated by widespread complaints of deceptive advertising by drug manufacturers. To address this problem, the Amendments granted the FDA authority over: (1) drug advertising and promotional activities, (2) inspections of drug manufacturing facili-

4. The Medical Devices Amendments of 1976

While the aforementioned legislation provided the FDA even greater authority in response to interstate and global health and safety concerns, it was not until the passage of the Medical Device Amendments of 1976 (MDA) that “the FDA achieved jurisdiction over nearly every commercial implement or substance used in the treatment or diagnosis of disease.”¹⁷² Just as with past legislation, the MDA was enacted in response to technological developments in the medical field. In the 1960s, newly invented medical devices such as heart pacemakers and kidney dialysis units were introduced.¹⁷³ Widespread reports of injuries and death resulting from use of these devices prompted Congress to fill gaps in existing FDA regulation,¹⁷⁴ thereby making devices subject to the same pre-approval process applied to drugs.¹⁷⁵ Furthermore, given the wide scope and seriousness of the health and safety concerns involved, Congress sought to ensure that the FDA’s medical regulations would pre-empt any conflicting state regulations by including the following express pre-emption clause in the MDA:

[N]o State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.¹⁷⁶

Thus, as both the historical development of state regulation and the FDA authority demonstrate, the expansion and uniformity of regulation is required to ensure that new technologies and knowledge in the health care industry are safely distributed to the public.

ties, (3) establishing manufacturing practices, and (4) removal of drugs from market in event of regulatory violation. *Id.* at 901.

¹⁷² *Id.* at 903.

¹⁷³ S. REP. NO. 94-33, at 5 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1074.

¹⁷⁴ Walsh & Pyrich, *supra* note 147, at 903; *see also id.* at 6-7, *reprinted in* 1976 U.S.C.C.A.N. at 1076 (describing the results of a 1970 study that revealed 10,000 injuries due to medical devices and the resulting public opinion regarding medical device legislation).

¹⁷⁵ SCHOONMAKER, *supra* note 156, at 7.

¹⁷⁶ 21 C.F.R. § 808.1(b) (1994).

C. States Do Not Have the Constitutional Right to Exclusive Domain Over Health Regulation

Because there are no “local peculiarities” in the delivery of health care with respect to telemedicine and the FDA provides a real-world example of a workable and successful alternative to state regulation, there exists no justifiable basis for a state policing system for telemedicine. These observations further support the following assertion that a state has no constitutional basis to claim exclusive authority over health regulation.

Many proponents of a state policing system claim that the federal government is constitutionally barred from health regulation, as police powers are the exclusive domain of states under the Tenth Amendment. The FSMB, mentioned earlier as the representative voice of state medical licensing boards,¹⁷⁷ asserts that “[u]nder the 10th Amendment of the U.S. Constitution, states have the authority to regulate the activities that affect health, safety, and welfare of their citizens.”¹⁷⁸ While the Tenth Amendment does not explicitly state that health care is an enumerated state power, such power is ostensibly rooted in the following language of the Amendment: “The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”¹⁷⁹ In U.S. Supreme Court decisions, these powers have been interpreted to mean “police” powers that were best exercised locally by a state in order to protect its citizens’ public health, safety and welfare.¹⁸⁰

Indeed, the history of legal challenges to the police power and health care regulation has resulted in overwhelming support for state authority.¹⁸¹ Notwithstanding such support, the Court rejects the view

¹⁷⁷ FED’N OF STATE MED. BDS., *supra* note 48.

¹⁷⁸ *Id.*

¹⁷⁹ U.S. CONST. amend. X.

¹⁸⁰ *See* *Gibbons v. Odgen*, 22 U.S. (9 Wheat.) 1, 203 (1824) (defining police powers of the states under the Tenth Amendment to include an “immense mass of legislation, which embraces everything 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. . . .”).

¹⁸¹ *See, e.g., Semler v. Oregon State Bd. of Dental Exam’rs*, 294 U.S. 608 (1935) (holding that a state has discretion to regulate the practice of dentistry); *McNaughton v. Johnson*, 242 U.S. 344 (1917) (upholding state regulation defeating ophthalmologist on a Fourteenth Amendment claim); *Watson v. Maryland*, 218 U.S. 173 (1910) (holding that a state statute barring practice of medicine without state registration does not violate Fourteenth Amendment); *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (upholding state law allowing boards of health to require mandatory

that the Tenth Amendment grants states exclusive authority over police powers. The Court has historically upheld federal measures in areas traditionally regarded as responsibilities of the states in instances where Congress has the concurrent right to regulate under its enumerated constitutional powers. In its 1919 *Hamilton v. Kentucky Distilleries* decision, the Court upheld the federal War-Time Prohibition Act, which was challenged under Tenth Amendment grounds because its ban on sale of liquor contravened the state police power to regulate liquor traffic.¹⁸² In reaching its conclusion, the Court explained:

[t]hat the United States lacks the police power, and that this was reserved to the states by the Tenth Amendment, is true. But it is none the less true that when the United States exerts any of the powers conferred upon it by the Constitution, no valid objection can be based upon the fact that such exercise may be attended by the same incidents which attend the exercise by a state of its police power, or that it may tend to accomplish a similar purpose.¹⁸³

Even though the War-Time Prohibition Act interfered with a state police power, it was valid because Congress's implied war powers under, Article I, § 8, clause 18 of the Constitution, authorized Congress "to 'make all laws . . . necessary and proper for carrying into execution' the war powers expressly granted."¹⁸⁴ Such reasoning was also applied to uphold the federal Labor Standards Act of 1938 in *United States v. Darby*, which contravened traditional state authority over labor relations by banning the shipment of interstate commerce of goods made by employees paid less than minimum wage.¹⁸⁵ Mirroring the reasoning in *Hamilton*, the *Darby* Court observed:

small pox vaccinations); *Hawker v. New York*, 170 U.S. 189 (1898) (determining that state had broad discretion in describing qualifications necessary to practice medicine in state); *Dent v. West Virginia*, 129 U.S. 114 (1889) (holding that under the police power, a state can impose regulation for the general welfare even if it prevents a person from practicing his profession).

¹⁸² *Hamilton v. Kentucky Distilleries & Warehouse Co.*, 251 U.S. 146, 153-54, 156 (1919).

¹⁸³ *Id.* at 156.

¹⁸⁴ *Id.* at 155 (citation omitted) (noting that federal legislation was a justifiable contravention of state police power authority because it advanced the war powers in "guard[ing] and promot[ing] the efficiency of the men composing the army and the navy and of the workers engaged in supplying them with arms, munitions, transportation and supplies.").

¹⁸⁵ *United States v. Darby*, 312 U.S. 100, 121 (1941).

The power of Congress over interstate commerce 'is complete in itself, may be exercised to its utmost extent, and acknowledges no limitations other than are prescribed in the Constitution.' That power can neither be enlarged nor diminished by the exercise or non-exercise of state power. . . . It is no objection to the assertion of the power to regulate interstate commerce that its exercise is attended by the same incidents which attended the exercise of the police power of the states. . . . Our conclusion is unaffected by the Tenth Amendment which . . . states but a truism that all is retained which has not been surrendered.¹⁸⁶

In the context of health regulation, this basis for federal interference was applied by the District Court of Delaware in *Pharmaceutical Manufacturers Association v. Food and Drug Administration*, and was subsequently affirmed by the Third Circuit.¹⁸⁷ In upholding a FDA regulation requiring that patients receive certain information for drugs containing estrogen, the District Court of Delaware reasoned:

To the extent that the plaintiffs' claim of unconstitutional interference with the right to practice medicine is founded on a notion of federalism which reserves all rights over such regulation to the states, it is without merit. It is undisputed that the practice of medicine is subject to the exercise of state police power where such regulation furthers a legitimate state interest. But that assumption does not imply an absence of federal jurisdiction over the same area, where the federal regulation constitutes a reasonable exercise of a power vested in Congress under the Constitution.¹⁸⁸

Thus, given such history of legal validity of federal police power concurrent with state police power, the claim that states have exclusive jurisdiction over health concerns is rendered invalid.

¹⁸⁶ *Id.* at 114, 123, 124 (citation omitted); *see also* *Roth v. United States*, 354 U.S. 476, 492 (1957) (upholding federal law banning the mailing of obscene matter); *Thornton v. United States*, 271 U.S. 414, 424 (1926) (upholding federal law regulating tick-infected cattle); *Brooks v. United States*, 267 U.S. 432, 436-37 (1925) (upholding federal law regulating stolen automobiles); *Hoke v. United States*, 227 U.S. 308, 323 (1913) (upholding federal law banning interstate transportation of women for immoral purposes); *Champion v. Ames (The Lottery Case)*, 188 U.S. 321, 363-64 (1903) (upholding federal law penalizing the interstate transportation of lottery tickets).

¹⁸⁷ *Pharm. Mfrs. Ass'n v. FDA*, 484 F. Supp. 1179, 1187-88 (D. Del.), *aff'd* 634 F.2d 106 (3d Cir. 1980).

¹⁸⁸ *Id.* at 1187 (citation omitted).

Furthermore, Congressional involvement in various aspects of health care undermines any argument of state exclusivity in this area. To counter this assertion, several proponents of exclusive state authority point to language in a variety of state statutes expressing Congressional intent of noninterference in this area.¹⁸⁹ For example, Medicare legislation declares: “Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided”¹⁹⁰ To defeat this claim, Professor Lars Noah notes that the legislative records for these statutes offers little explanation for these provisions, as “. . . the similarity in their language suggests that they have become essentially boilerplate.”¹⁹¹ These provisions also “endorse deference to professional autonomy rather than the primacy of state regulation” and “appear to represent a concession to the political pressure exerted by organized medicine rather than any admission of possible constitutional limitations on the power of Congress to regulate in the field.”¹⁹²

The following examples of current federal regulation of health care underscore Professor Noah’s observations. First, in accordance above with the Supreme Court’s allowance of concurrent federal police power regulation under an enumerated constitutional power, Congress has invoked the Spending Clause to impose limited regulation of health care under its power to spend for the general welfare. For example, the National Health Planning and Resources Development Act of 1974 requires states to adopt certificate of need laws related to health facility planning.¹⁹³ Other examples include Medicare and Medicaid participation requirements, which among other things, impose operational standards and accreditation rules on health care providers in exchange for funding.¹⁹⁴

Second, Congress has imposed regulations even in the absence of a Spending Clause justification. For example, in 1992, Congress enacted the Mammography Quality Standards Act, which requires that all facilities performing mammographies be certified by the FDA.¹⁹⁵

¹⁸⁹ Noah, *supra* note 125, at 169.

¹⁹⁰ 42 U.S.C. § 1395 (2006).

¹⁹¹ Noah, *supra* note 125, at 167.

¹⁹² *Id.*

¹⁹³ National Health Planning and Resources Development Act, 42 U.S.C. § 300n-1 (2006).

¹⁹⁴ See 42 U.S.C. § 1395x(e) (2006) (defining ‘hospital’ within the context of Medicare regulations); 42 U.S.C. § 1395x(m) (defining ‘home health services’ within the context of Medicare regulations); 42 C.F.R. § 484.1-.55 (2001) (regulating various types of providers).

¹⁹⁵ 42 U.S.C. § 263b(b)(1).

Also, the Food, Drug and Cosmetic Act regulates technologies associated with health care delivery.¹⁹⁶

D. Current State Regulation Is Likely Unconstitutional Under the Dormant Commerce Clause

Finally, the exclusivity and legitimacy of state authority over telemedicine regulation is further undermined by its arguable unconstitutionality under the Dormant Commerce Clause. The emergence and growth of health care into a national and international commercial industry currently places state regulation of this area in conflict with the Federal Commerce Power. As discussed earlier, advances in technology and medical knowledge have transformed the health industry from a local to a global commercial activity.¹⁹⁷ The increasing discoveries and uses of advanced technologies not only allow for health professionals to remotely provide services but also prompt patients to travel across state and national borders for innovative procedures not available. Many health professionals work with large managed care networks or national hospital chains;¹⁹⁸ they also “advertise services that attract both local and distant customers.”¹⁹⁹ Thus, such business operation and transactions constitute activities affecting interstate commerce and intrude upon the Commerce Clause.

Under Article I, §8, of the Constitution, Congress has “. . . [p]ower . . . [t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes . . .”²⁰⁰ The Supreme Court interprets the Commerce Clause to mean that Congress has the sole authority to engage in interstate and foreign commercial regulation.²⁰¹ Because this is an area of enumerated federal concern in the Constitution, a state(s) effectively may not discriminate against goods and services from other states and nations.²⁰² In barring such discrim-

¹⁹⁶ The FDA only has authority to regulate those health-related drugs and devices that meet the federal statutory definition of these products. A medical device is defined to include:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or animals.

21 U.S.C. § 321(h) (2006).

¹⁹⁷ See *supra* Part I.

¹⁹⁸ Noah, *supra* note 125, at 169.

¹⁹⁹ *Id.* at 170.

²⁰⁰ U.S. CONST. art. I, § 8, cl. 3.

²⁰¹ *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 26-27 (1824).

²⁰² See *id.*

ination, the Commerce Clause endeavors to achieve three goals: (1) prevent state laws that interfere with interstate commerce; (2) prevent protectionist legislation in furtherance of the national economy; and (3) ensure equal protection of the laws to citizens of all states.²⁰³

One of the functions of the Commerce Clause is to invalidate state and local laws because they place an undue burden on interstate commerce.²⁰⁴ Although the Constitution does not expressly state this doctrine, the Supreme Court has interpreted Article I, § 8, to confer this power to Congress.²⁰⁵ This doctrine, known as the Dormant Commerce Clause, is invoked as a challenge to state or local actions in areas where Congress has yet to act or where there is no explicit federal law pre-emption.²⁰⁶ In other words, the Commerce Clause grants the judicial branch authority in some circumstances to limit state and local regulation in the absence of Congressional action. The application of the Commerce Clause in such a manner to challenge the constitutionality of state health regulation is appropriate here. As this Article discussed earlier, Congress has intervened in various aspects of the health care industry, but such regulations are silent or ambiguous on pre-emption and states have historically played and still play a principal role in regulating this area.²⁰⁷

In determining whether a police power that burdens interstate commerce should be upheld or invalidated as violating the Dormant Commerce Clause, the Supreme Court has developed and applied at

²⁰³ See *H.P. Hood & Sons, Inc. v. DuMond*, 336 U.S. 525, 539-43 (1949). In *South Carolina Highway Dep't. v. Barnwell Bros., Inc.*, Justice Stone reinforced the establishment of the Dormant Commerce Clause by expressing the Court's distrust of a state's political process to give equal treatment to residents and non-residents who lacked representation:

Underlying the stated rule has been the thought, often expressed in judicial opinion, that when the regulation is of such a character that its burden falls principally upon those without the state, legislative action is not likely to be subjected to those political restraints which are normally exerted on legislation where it affects adversely some interests within the state.

303 U.S. 177, 185 n.2 (1938) (citations omitted).

²⁰⁴ See *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 145 (1970). When the Commerce Clause limits state and local regulation in the absence of Congressional action, the Supreme Court and scholars call this doctrine the "Dormant" or "Negative" Commerce Clause. See generally Donald H. Regan, *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause*, 84 MICH. L. REV. 1091 (1986).

²⁰⁵ See *DuMond*, 336 U.S. at 539, 545.

²⁰⁶ See *Duckworth v. Arkansas*, 314 U.S. 390, 400 (1941) (Jackson, J., concurring) (finding that exercising judicial power to defend the Commerce Clause is required because state and local laws "are individually too petty, too diversified, and too local to get the attention of a Congress hard pressed with more urgent matters.").

²⁰⁷ See *supra* Part III.

least one of the following three tests: (1) national versus local subject matter test (subject matter test), (2) direct versus indirect effects on commerce test (direct-indirect effects test), and (3) balancing test.²⁰⁸ An analysis below of these tests in the context of health protection will show that while state regulation may have been valid in the past, such regulation is likely unconstitutional in light of the health care industry's recent expansion on national and global levels.

1. Failure Under the Subject Matter Test

Under the subject matter test, a state law violates the Dormant Commerce Clause if the law regulates national subject matter but is upheld if it regulates local subject matter.²⁰⁹ The Court defines national subject matter as "demanding a single uniform rule, operating equally on the commerce of the United States in every port," while local subject matter "imperatively demand[s] diversity, which alone can meet the local necessities"²¹⁰ In the context of state health regulation, the distinction between national and local subject matter is further clarified in the following two cases, *Norris v. The City of Boston*, and *Smith v. Turner*, which were argued together and grouped as *The Passenger Cases*.²¹¹ In these cases, Boston and New York had established state public hospitals whose duties included determining if ship passengers landing in their ports were infected with communicable diseases.²¹² To fund these hospitals, the states imposed a head tax on persons landing in their ports.²¹³ The Court held this tax to be an

²⁰⁸ These tests reflect the evolution of Supreme Court jurisprudence in this area, but none of these tests have been overruled and earlier tests have been applied to cases even after later tests were set forth. *See, e.g.*, *Brown-Forman Distillers Corp. v. N.Y. Liquor Auth.*, 476 U.S. 573 (1986) (applying the direct/indirect test to invalidate state regulation of alcohol to the disadvantage of out-of-staters); *California v. Zook*, 336 U.S. 725, 727, 733, 738 (1949) (applying the local/national test to uphold state statute prohibiting the sale or arrangement of any interstate transportation of persons over state highways); *Cooley v. Bd. of Wardens*, 53 U.S. (12 How.) 299, 319-21 (1851) (applying local/national test to uphold state law requiring use of local pilot or payment of fine for ships in Port of Philadelphia).

²⁰⁹ *Cooley*, 53 U.S. 299.

²¹⁰ *Id.* at 319.

²¹¹ *The Passenger Cases*, 48 U.S. (7 How.) 283, 283 (1849). It should be noted that this case precedes *Cooley v. Board of Wardens*, 53 U.S. (12 How.) 299 (1851), the seminal case in which the Court fully articulated the subject matter test and is discussed later in this section. The reader should also be aware that in *The Passenger Cases*, the Court was split five to four in its decision to invalidate a state law on every incoming passenger to pay for the costs of health inspections and treatment, but the holding and reasoning employed by the Court are still good law and thus influence subsequent relevant Supreme Court cases.

²¹² *See id.* at 284-85.

²¹³ *Id.* 393, 409.

impermissible restriction on interstate commerce and foreign trade.²¹⁴ In reaching this conclusion to invalidate the New York tax, Justice McLean noted that while states hold the “power of self-preservation” to maintain the health and safety of its citizenry,²¹⁵ the state has “no power . . . to tax objects not subject to its jurisdiction” absent “peculiar emergencies and to a limited extent.”²¹⁶ Here, the New York tax went beyond the state’s jurisdiction by imposing on instruments of interstate commerce, which included a ship’s officers and crew and foreign passengers.²¹⁷

Given such plenary power accorded to Congress under the Commerce Clause, a state may only exercise any infringing police powers under the following exceptions: (1) there is no less burdensome way to deal with an issue of local concern; or (2) if Congress expressly provided authorization. Such exceptions are illustrated in *Cooley v. Board of Wardens*, which involved a Pennsylvania law requiring all ships accessing the Port of Philadelphia to use a local pilot or pay a fine.²¹⁸ The Court upheld the law because it qualified as local subject matter for two reasons: (1) unique characteristics of ports and the impracticability of making them uniform,²¹⁹ and (2) a 1789 federal law expressly authorizing states to regulate piloting.²²⁰ Even though the Court acknowledged that navigation fell under the Commerce Clause power, the Court came to conclude that ports were local subject matter because of their “local peculiarities” and that implementing changes to these different systems would be so “impracticable” that “it cannot be supposed uniformity was required.”²²¹

Here, the application of the subject matter test and the Court’s reasoning above to state regulation of various aspects of the health care industry likely leads to the conclusion that such regulation is unconstitutional. First, as this Article has demonstrated, interstate telemedicine does not possess “local peculiarities” to warrant exclusive local attention.²²² Second, just as with the head tax in *The Passenger Cases*, many of these regulations impact actors and activities that in-

²¹⁴ *Id.* at 409-10.

²¹⁵ *Id.* at 400.

²¹⁶ *Id.* at 408.

²¹⁷ *Id.* at 408-09.

²¹⁸ *Cooley v. Bd. of Wardens*, 53 U.S. (12 How.) 299, 300 (1852).

²¹⁹ *Id.* at 314.

²²⁰ *Id.* at 319-20.

²²¹ *Id.* at 314 (determining states should be allowed to regulate ports because the “consequent impossibility of having its charges uniform throughout the United States [as] sufficient of itself to prove that they could not have been intended to be embraced within [the Commerce] [C]ause”).

²²² See *supra* Part III.

volve interstate and foreign commerce. Third, these regulations arguably are not directly related to advancing local safety concerns. For example, in medical malpractice cases, a growing number of state courts have rejected the traditional “locality” rule to embrace a national standard of care.²²³ Thus, state borders no longer determine whether a health professional has the skills or competency to treat a state’s residents.²²⁴

Finally, the exceptions allowing a state law to violate the Commerce Power do not apply here. First, there are less burdensome ways to provide for such protection and these ways are not impracticable to implement. For example, several scholars have observed that the framework for the replacement of individual state licensing systems with one national licensure system is already in place.²²⁵ Educational and professional competency requirements for each state are similar in mandating that licensed practitioners graduate from an accredited medical school and pass the United States Medical licensing exam, which is nationally standardized.²²⁶ Specialization in a medical area requires passing another nationally standardized exam to become board certified.²²⁷ The establishment of a National Practitioner Data Bank also streamlines this process, as it collects information about physicians on a nationwide basis, including licensure matters.²²⁸

Furthermore, proponents argue that national licensing alternatives are already successfully implemented by the following federal entities: The Veterans Administration, the Bureau of Indian Affairs, and the U.S. military.²²⁹ Professor Alison Sulentic notes that U.S. military law permits any health professional who holds a state license to practice anywhere in the nation as long as she or he is providing direct patient care in a hospital affiliated with the Department of Defense.²³⁰ This “military license” pre-empts the local standards of the jurisdiction in which the health professional practices by only requiring that the professional comply with the standards of the state in which he or

²²³ Noah, *supra* note 125, at 165.

²²⁴ *See id.*

²²⁵ *See, e.g.,* Alexander, *supra* note 87, at 241-42; McLean, *supra* note 14, at 504-05; Volkert, *supra* note 11, at 177-78.

²²⁶ Volkert, *supra* note 11, at 177-78.

²²⁷ Jeffrey A. Van Detta, *Dialogue with a Neurosurgeon: Toward a Dépeçage Approach to Achieve Tort Reform and Perverse Corrective Justice in Medical Malpractice Cases*, 71 U. PITT. L. REV. 1, 3 n.6 (2009).

²²⁸ Volkert, *supra* note 11, at 178.

²²⁹ Alison M. Sulentic, *Crossing Borders: The Licensure of Interstate: Telemedicine Practitioners*, 25 J. LEGIS. 1, 37 (1999).

²³⁰ *Id.*

she is licensed.²³¹ Given that courts are increasingly adopting a national standard of care in malpractice cases, and medical educational and competency requirements employ nationally standardized procedures, the extension of a “military license” in a civil context seems fitting. Additionally, the FDA’s national regulation of drugs and medical devices discussed earlier demonstrates that federal oversight is a workable alternative as it is practical to regulate diverse aspects of the health care industry.²³² Finally, the need for state authority fails under the last exception because Congress has never expressly authorized states to regulate in this field.

2. Failure Under the Direct-Indirect Effects Test

Under the direct-indirect effects test, a state law that directly interferes with interstate or foreign commerce is invalid but is upheld if such interference has an indirect effect on interstate or foreign commerce.²³³ Direct interference with the Commerce Clause arises when state laws subject interstate market participants to inconsistent obligations in different states.²³⁴ In *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, the state sought to obtain the lowest possible prices for its citizens by requiring alcohol distillers to file a schedule affirming that their selling price in the state was as low as other prices offered in other states.²³⁵ During this time, twenty other states had similar laws.²³⁶ The Court invalidated such a law, in part, because New York contributed to the maze of inconsistent regulations that distillers were subjected to by defining “effective” liquor prices differently from other states.²³⁷ This requirement “effectively force[d]” distillers to drop their promotional allowance program in other states and other states had to alter their own regulations to accommodate New York’s pricing schedule.²³⁸ Such effective interfer-

²³¹ *Id.*

²³² *See supra* Part III.

²³³ *DiSanto v. Pennsylvania*, 273 U.S. 34 (1927), *overruled on other grounds*, *California v. Thompson*, 313 U.S. 109 (1941). In *Thompson*, the Court narrowed the *DiSanto* holding, which deemed a state regulation that affected interstate transportation to be unconstitutional, to permitting such regulations in cases (1) involving local concerns, and (2) where there are no infringements upon matters of national interest and regulatory uniformity. 313 U.S. at 116.

²³⁴ *See Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 572, 582-83 (1986).

²³⁵ *Id.* at 576.

²³⁶ *Id.*

²³⁷ *Id.* at 583-84.

²³⁸ *Id.* at 584.

ence with other states' commerce and regulatory schemes constituted an impermissible violation of the Commerce Clause.²³⁹

Furthermore, it is also important to note here that *Brown-Foreman* highlights the dominance of the Commerce Clause when a state's constitutional rights over certain domains are involved.²⁴⁰ Specifically in this case, the right invoked is the state's Twenty-First Amendment power to regulate the sales of liquor within its territory.²⁴¹ While the Court acknowledges the validity of such a constitutional right, it notes that "[t]he Commerce Clause operates with full force whenever one State attempts to regulate transportation and sale of alcoholic beverages destined for distribution and consumption in a foreign country . . . or another State."²⁴² As the Court's above analysis of the New York law demonstrates, if a state regulation impacts business decisions made by interstate market participants and other states' regulatory schemes, the Commerce Clause invalidates such a regulation.

Here, similar to the New York law in *Brown Foreman*, a variety of state health regulations impermissibly interfere with the Commerce Clause because they subject interstate telemedicine providers to inconsistent regulations. As discussed earlier, state regulations involving licensing, insurance, and information privacy place impose barriers so difficult to overcome that many of these providers are discouraged from conducting interstate business.²⁴³

3. Failure Under the Balancing Test

Under the balancing test, the benefits of a state law are weighed against the burdens it imposes on interstate commerce in order to assess its constitutionality. The Court begins its analysis by determining whether a law facially discriminates against or is facially neutral towards interstate commerce. Facially discriminatory laws textually draw a distinction between in-staters and out-of-staters and are presumed unconstitutional.²⁴⁴ A law is deemed neutral on its face if it

²³⁹ *Id.*

²⁴⁰ *Id.* at 584-85 (noting that the Court's task is to reconcile the interests of conflicting constitutional provisions. The Court states that in case of the Commerce Clause and the Twenty-First Amendment, "each must be considered in light of the other[,] and in the context of the issues and interests at stake in any concrete case" (quoting *Hostetter v. Idlewild Bon Voyage Liquor Corp.*, 377 U.S. 324, 332 (1964)).

²⁴¹ *Id.* at 585.

²⁴² *Id.* (citation omitted).

²⁴³ *See supra* Part II.

²⁴⁴ *See, e.g.*, *Philadelphia v. New Jersey*, 437 U.S. 617, 618, 626-27 (1978) (holding that a state law which prevented importation of waste from out-of-state was facially discriminatory); *Dean Milk Co. v. Madison*, 340 U.S. 349, 354-56 (1951)

applies equally to in-state and out-of-state citizens.²⁴⁵ Facially neutral laws are considered unconstitutional if their purpose and/or effect are discriminatory.²⁴⁶ Both types of laws will be upheld if they serve a legitimate local police power purpose and if it is the least burdensome method on interstate commerce to achieve that purpose.²⁴⁷

A review of the Court's decision in *Dean Milk Co. v. Madison* is instructive in evaluating the ways in which facially discriminatory laws in the context of current health regulation would likely be unconstitutional.²⁴⁸ In *Dean Milk Co.*, a local law required all milk sold in Madison to be pasteurized within five miles of the city.²⁴⁹ According to the Court, this ordinance was facially discriminatory because it prevented milk pasteurized from other states from being sold in the city. The city defended the ordinance by applying its police power to protect the health and safety of its citizens.²⁵⁰ The Court acknowledged the validity of the state's police power, but noted that such a power is only paramount to the Commerce Clause if no less burdensome methods exist to achieve the offending regulations stipulated goals:

In thus erecting an economic barrier protecting a major local industry against competition from without the State, Madison plainly discriminates against interstate commerce. This it cannot do, even in the exercise of its unquestioned power to protect the health and safety of its people, if reasonable nondiscriminatory alternatives, adequate to conserve legitimate local interests, are available.²⁵¹

(deeming a city ordinance requiring milk be pasteurized within five miles of city to be deemed facially discriminatory).

²⁴⁵ See *Dean Milk Co.*, 340 U.S. at 354 (finding that a Madison ordinance, which only permitted the sale of milk that was processed and bottled at an approved Madison pasteurization plant within a five-mile radius of the city is facially neutral because it applies equally to intrastate and interstate milk suppliers).

²⁴⁶ See, e.g., *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 389-95 (1994); see also *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333, 352-53 (1977) (invalidating a facially neutral state law banning the importation of non-USDA grade apples because the law discriminated against interstate commerce and did not advance a legitimate state interest).

²⁴⁷ See *Hunt*, 432 U.S. at 352-53 (stating that court would uphold a discriminatory state commerce law where the State proves a legitimate state interest resulting from the law and the State proves the unavailability of nondiscriminatory alternatives); *Dean Milk Co.*, 340 U.S. at 353-56.

²⁴⁸ See *Dean Milk Co.*, 340 U.S. 349.

²⁴⁹ *Id.* at 350.

²⁵⁰ See *id.* at 354.

²⁵¹ *Id.*

The Court proceeded to find that less burdensome methods existed (e.g., the use of health inspectors), and declared the ordinance invalid because it was “not essential for the protection of local health interests.”²⁵² In cases where no suitable alternative method for such interests exists, the discriminatory law is upheld. For example, in *Maine v. Taylor*, the Court upheld a state statute barring the import of minnows in order to preserve the health of the local minnow population because the state’s marine ecology was endangered and no less restrictive method would yield the same results.²⁵³

Extending this balancing test analysis to facially neutral laws that operate analogously to current state health regulations further underscores the latter’s unconstitutionality. A review of case law concerning state regulation of highways is apt here because the Court has deemed such power to regulate similar to protection of citizens’ health and safety.²⁵⁴ The Court considers such regulation to be a “peculiarly local . . . subject of safety . . . akin to quarantine measures.”²⁵⁵ Given such a deferential view, the Court has historically upheld state laws in this area “despite the fact that they may have an impact on interstate commerce.”²⁵⁶ Notwithstanding such deference, the Court will invalidate such a law if its resulting benefits are minimal and the costs to interstate commerce are great:

Unless [the Court] can conclude on the whole record that ‘the total effect of the law as a safety measure in reducing accidents and casualties is so slight or problematical as not to outweigh the national interest in keeping interstate commerce free from interferences which seriously impede it’ [citation omitted] [the Court] must uphold the statute.²⁵⁷

Applying that balancing test in *Bibb v. Navajo Freight Lines, Inc.*, the Court found the state law requiring curved mudguards on interstate carriers to be an impermissible violation of the Commerce Clause. There, the Court found the benefits of such a safety measure to be questionable at best and the burden on interstate commerce to be excessive.²⁵⁸ This safety requirement imposed excessive costs by prescribing standards that conflict with other states, thus forcing the in-

²⁵² *Id.* at 355-56.

²⁵³ *Maine v. Taylor*, 477 U.S. 131, 141, 150 (1986).

²⁵⁴ *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 523 (1959).

²⁵⁵ *Id.* at 523-24.

²⁵⁶ *Id.* at 523.

²⁵⁷ *Id.* at 524 (quoting *Southern Pacific Co. v. Arizona*, 325 U.S. 761, 775-76 (1945)).

²⁵⁸ *Id.* at 528.

dustry to invest time and money in conforming to these various standards in order to conduct interstate business.²⁵⁹ The Court pointed to the nearby state of Arkansas opposite requirement of straight or conventional mudguards as an example.²⁶⁰

Just as importantly, the burden on interstate may still be held as excessive even if the state law is not inconsistent with other state laws, but imposes great costs to comply with such regulation.²⁶¹ For example, the Court has invalidated several state laws banning interstate carriers of certain sizes and/or weights within their territories because of their speculative benefits and substantial burden on interstate commerce.²⁶² In *Kassel v. Consolidated Freightways Corp.*, the Court invalidated the state's ban on 65-foot double trailers because the "State failed to present any persuasive evidence that 65-foot [trailers were] less safe than 55-foot [trailers]" and the law "substantially burdens [interstate commerce]" by forcing these trucks to avoid the state or to detach the trailers and ship them separately.²⁶³

Here, state health regulations will likely be regarded as facially neutral laws, as they treat in-stater and out-of-staters equally, but deemed unconstitutional because their purpose and/or effect are discriminatory. As an earlier examination of barriers to telemedicine demonstrates, these regulations apply to all parties but their effect is to impede out-of-staters from doing business in a state.²⁶⁴ An application of the balancing test to these regulations also shows that they are unlikely the least burdensome method on interstate commerce to achieve that purpose. An earlier cited example of replacing the state licensing system with a national system is relevant here as well, as national standards are already being used to test the competency and skills of health professionals.²⁶⁵

Overall, an examination of these tests have shown that the Court uses them to ensure that state regulations are not are veiled forms of economic protectionism to help local industries. The application of these tests shows that several forms of state health regulation are un-

²⁵⁹ *Id. But see* South Carolina State Highway Dep't. v. Barnwell, 303 U.S. 177, 179, 196 (1938) (upholding state law barring use of motor and semitrailer trucks on state highways whose width and weight exceeded certain thresholds).

²⁶⁰ *Bibb*, 359 U.S. at 527.

²⁶¹ *See, e.g., Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 671 (1981) (invalidating state law banning sixty-five foot double trailers); *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429, 447 (1978) (invalidating a state law banning double-trailer trucks and trucks exceeding fifty-five feet).

²⁶² *Raymond*, 434 U.S. at 447.

²⁶³ *Kassel*, 450 U.S. at 671, 674.

²⁶⁴ *See supra* Part II.

²⁶⁵ *See supra* Part III(B).

constitutional because the only interests they seem to advance are those of the local industry players at the cost of citizens' health and safety.

IV. FOUNDATIONS FOR A UNIFORM REGULATORY REGIME: THE CONSTITUTIONALITY OF NATIONAL TELEMEDICINE REGULATION

In addition to providing a legal basis for invalidating current forms of health care regulation that involve interstate and foreign commerce, the Constitution provides grounds for Congress to legislate in these areas. First, just as the Commerce Clause may be invoked to limit state and local regulation, it may also be invoked to authorize federal action.²⁶⁶ Second, the Spending Power grants Congress the broad power to spend for the general welfare so long as it does not violate other Constitutional provisions.²⁶⁷

A. Congressional Authority to Regulate under the Interstate Commerce Clause

Congress has the constitutional power to regulate commerce among states if such regulation passes the "Substantial Effect" test established in the seminal 1995 Supreme Court decision in *United States v. Lopez*.²⁶⁸ Under this test, federal legislation is permissible if it falls under one of the following types of activities:

- (1) Regulation of use of channels of interstate commerce;²⁶⁹
- (2) Regulation and protection of instrumentalities of interstate commerce²⁷⁰; or
- (3) Regulation of activities having substantial effect on commerce.²⁷¹

In evaluating whether Congressional action falls under either of these categories, the Court applies rational basis review. Rational ba-

²⁶⁶ *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 195-96 (1824) ("But, in regulating commerce with foreign nations, the power of Congress does not stop at the jurisdictional lines of the several States . . . The power of Congress, then, whatever it may be, must be exercised within the territorial jurisdiction of the several States").

²⁶⁷ *United States v. Butler*, 297 U.S. 1, 66 (1936).

²⁶⁸ *United States v. Lopez*, 514 U.S. 549, 549 (1995).

²⁶⁹ *Id.* at 558.

²⁷⁰ *See Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241, 261 (1964).

²⁷¹ *Lopez*, 514 U.S. at 558-59.

sis review only requires that Congress choose a means that is reasonably adapted to achieve its goals.²⁷² In addition to the history of case law on interstate commerce and police powers detailed above, an examination below of the Court's interpretation of each of these categories supports the conclusion that Congress has a constitutional right to regulate health care when interstate and foreign actors and activities are involved.

1. Federal Regulation of Health Care Concerns the Use of Channels of Interstate Commerce

This first category requires that the proposed federal regulation in question concerns the use of channels of interstate commerce.²⁷³ To define "channels of interstate commerce," the *Lopez* Court offered the following concrete examples that necessarily involved out-of-state actors and transactions: intrastate coal mining, restaurants using substantial interstate supplies, and hotels serving interstate guests.²⁷⁴ Furthermore, the *Lopez* Court interpreted this element to mean that the federal regulation in question excludes activity not directly economic in nature, even if there are indirect economic consequences.²⁷⁵ For example, in *Lopez*, the Court held that the federal Gun-Free School Zone Act was invalid because possession of a gun in a school zone was too tangentially related to interstate commerce to be within Congressional authority. The Act itself did not regulate commerce, and no formal findings demonstrated a link between commerce and gun possession.²⁷⁶

2. Federal Regulation of Health Care Concerns the Protection of Instrumentalities of Interstate Commerce

This second category requires the proposed federal action "to regulate and protect the instrumentalities of interstate commerce, or persons or things in interstate commerce, even though the threat may come only from intrastate activities."²⁷⁷ The *Lopez* Court offers the following examples of applicable "persons" or "things": destruction of aircraft, thefts from interstate shipments, and regulation of railroads.²⁷⁸

²⁷² *Id.* at 557.

²⁷³ *Id.* at 558.

²⁷⁴ *Id.* at 559.

²⁷⁵ *Id.* at 562.

²⁷⁶ *Id.* at 562-63.

²⁷⁷ *Id.* at 558.

²⁷⁸ *Id.*

3. Federal Regulation of Health Care Concerns Activities Having a Substantial Effect on Interstate Commerce

This third category requires the proposed federal regulation to involve only “those activities that substantially affect interstate commerce.”²⁷⁹ The *Lopez* Court defined “substantial effect” to include intrastate production of a commodity that in the aggregate impacts interstate economic activity.²⁸⁰ There, the Court held that Congress’s commerce authority applies to ban the cultivation and possession of small amounts of home-consumed marijuana despite a state law permitting otherwise.²⁸¹ According to the Court, home production of marijuana in the aggregate would have a substantial effect on interstate commerce because home consumption “would have a substantial influence on price and market conditions.”²⁸²

After a review of each of these categories, it is likely that interstate telemedicine falls under all three categories. Unlike the Gun-Free School Zone Act in *Lopez*, various state health regulations involve direct links to interstate and foreign commerce by allowing or denying a telemedicine provider to conduct business across borders. Furthermore, as an earlier examination of the barriers to telemedicine demonstrates, these regulations undeniably impact the price and market conditions of health care services.²⁸³

B. Congressional Authority to Regulate under the Spending Power Clause

In addition to the Commerce Clause, federal regulation of health care is constitutionally permissible under the Spending Power enumerated in Article 1, Section 8: “Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States.”²⁸⁴

In *United States v. Butler*, the Supreme Court established the scope of Congress’s Spending Power broadly to mean that Congress may spend for the general welfare in furtherance of goals beyond those stipulated in Article I, so long as it does not violate other Con-

²⁷⁹ *Id.* at 559.

²⁸⁰ *Id.* at 561.

²⁸¹ *Gonzales v. Raich*, 545 U.S. 1, 19 (2005).

²⁸² *Id.*

²⁸³ *See supra* Part II.

²⁸⁴ U.S. CONST. art. I, § 8, cl. 1.

stitutional provisions.²⁸⁵ In reaching this interpretation, the Court adopted Alexander Hamilton's view that:

the clause confers a power separate and distinct from those later enumerated, is not restricted in meaning by the grant of them, and Congress consequently has a substantive power to tax and to appropriate, limited only by the requirement that it shall be exercised to provide for the general welfare of the United States.²⁸⁶

Because of the expansive reach of the Spending Power, scholars have argued that this clause provides an ideal basis for Congress to implement concurrent federal regulation of health care.²⁸⁷ This Article has already pointed to instances where Congress has invoked the Spending Power to regulate various aspects of health care.²⁸⁸ As long as each of the following three criteria is met, Congress may regulate:

- (1) The federal regulation in question advances the general welfare;²⁸⁹
- (2) The federal regulation in question is clearly expressed to recipient states and bear some relationship to the spending program;²⁹⁰ and
- (3) The federal regulation is voluntarily accepted by States.²⁹¹

²⁸⁵ 297 U.S. 1, 66 (1936) (holding Congressional regulation of agricultural products through subsidies under the 1933 Agricultural Adjustment Act did not violate the Tenth Amendment as Congress has the constitutional power to tax and spend for the general welfare). Subsequent cases support the Court's view of broad Congressional authority under the taxing and spending clauses. *See, e.g.*, *Sabri v. United States*, 541 U.S. 600, 605-06 (2004) (finding federal criminal law banning bribery of state, local, and tribal officials by entities receiving at least ten thousand dollars in federal funds deemed constitutional); *Helvering v. Davis*, 301 U.S. 619 (1937) (finding the Social Security Act's old age pension program supported by federal taxes was constitutional); *Charles C. Steward Mach. Co. v. Davis*, 301 U.S. 548, 581-83 (1937) (Social Security Act establishing the federal unemployment system deemed constitutional).

²⁸⁶ *Butler*, 297 U.S. at 65-66.

²⁸⁷ *See* Jerry L. Mashaw & Theodore R. Marmor, Commentary, *The Case for Federalism and Health Care Reform*, 28 CONN. L. REV. 115 (1995); Noah, *supra* note 125, at 169 (“[B]ecause the Supreme Court has not yet imposed any meaningful limitations on the spending power, the federal government could regulate health care professionals without ever having to invoke the Commerce Clause.”).

²⁸⁸ *See supra* Part III.

²⁸⁹ *Helvering*, 301 U.S. at 640.

²⁹⁰ *Pennhurst State Hospital v. Halderman*, 451 U.S. 1, 17 (1981); *see* *South Dakota v. Dole*, 483 U.S. 203, 206-07 (1987).

²⁹¹ *See Dole*, 483 U.S. at 207.

An analysis below of these three criteria will demonstrate that the exercise of Spending Power is permissible in the proposal for more extensive federal health regulation.

1. Federal Health Regulation Advances the General Welfare

First, the federal regulation in question must “advance the general welfare” stipulated under the Spending Power. The Court’s broad definition of the Spending Power will likely allow for the inclusion of health care as an acceptable area of federal involvement. The Court has traditionally deferred to Congress on determining what constitutes advancing the general welfare:

The discretion belongs to Congress, unless the choice is clearly wrong, a display of arbitrary power, not an exercise of judgment . . . Nor is the concept of the general welfare static. Needs that were narrow or parochial a century ago may be interwoven in our day with the well-being of the Nation.²⁹²

As a result of such judicial deference, Congress has been able to regulate in areas beyond its enumerated authority under the Constitution to those of exclusive state concern. For example, in *South Dakota v. Dole*, the Court approved Congress’s requirement that states impose a twenty-one year old drinking age in order to receive federal highway funds.²⁹³ The Court reasoned that “[e]ven if Congress might lack the power to impose a national minimum drinking age directly, we conclude that encouragement to state action . . . is a valid use of spending power.”²⁹⁴ Furthermore, Congress has the discretion to decide whatever terms and conditions it deems appropriate in dispensing funds. In *Oklahoma v. Civil Service Commission*, the Court upheld the Hatch Act granting federal funds on the condition that states adopt civil service systems and limit the political activities of government workers.²⁹⁵ In reinforcing the reach of the Spending Power, the Court noted that “[w]hile the United States is not concerned with and has no power to regulate local political activities as such of state officials, it does have power to fix the terms upon which its money allotments to states shall be disbursed.”²⁹⁶ Thus, given such wide discretion accorded to Congress, federal regulation of health care would likely be deemed a valid advancement of the general welfare under the Spending Power.

²⁹² *Helvering*, 301 U.S. at 640-41.

²⁹³ *Dole*, 483 U.S. at 212.

²⁹⁴ *Id.*

²⁹⁵ *See Oklahoma v. Civil Serv. Comm’n*, 330 U.S. 127, 143 (1947).

²⁹⁶ *Id.*

2. Congress Should Ensure that Recipient States Be Aware of the Federal Regulation In Question and that the Regulation Bear Some Relationship to the Purpose of the Spending Program

Second, the only limitations to such plenary power are that Congress clearly inform the recipient states of the regulations in question and that these regulations bear some relationship to the purpose of the spending program. The Court highlighted the importance of informing states of the terms of accepting federal funding in *Pennhurst State School & Hospital v. Halderman*.²⁹⁷ There, the Court noted that Congress may impose regulations via grants to state and local governments as long as these regulations are “unambiguously” stated so that states know the consequences of accepting such funding. As to the second limitation, the Court requires that regulation must promote the objectives of the federal funding initiative. In *Dole*, the Court found that Congress’s twenty-one year old drinking age requirement was directly related to one of the main aims of the federal highway program because it sought to create safe interstate travel.²⁹⁸ Thus, as long as Congress takes care to provide notice of these regulations and pair health objectives with the appropriate regulations in questions, such regulatory initiatives will likely be permissible.

3. Implementation of Federal Health Depends on States’ Voluntary Acceptance of Funds

Finally, states must voluntarily accept these funds in order for them to be bound by the federal requirements in question.²⁹⁹ Here, the federal government already buys substantial portion of physician and clinical services, thus providing the basis on which the Spending Power may be exercised.³⁰⁰ As discussed earlier, Congress has imposed limited regulation under several of its health-related funding programs, such as Medicare and Medicaid.³⁰¹ Congress should consider using existing programs such as these as a basis for establishing more comprehensive and standardized regulation. Even more specifically and to this point, the federal Telecommunications Reform Act of

²⁹⁷ 451 U.S. 1, 17 (1981).

²⁹⁸ *Dole*, 483 U.S. at 208, 212.

²⁹⁹ *Civil Serv. Comm’n*, 330 U.S. at 143 (upholding the Hatch Act granting federal funds to states on the condition that states adopt civil service systems and limit the political activities of government workers); see *Dole*, 483 U.S. at 210, 212 (upholding a federal law establishing a twenty-one year old drinking age by withholding a portion of federal highway funds from any state government that failed to impose such a drinking age).

³⁰⁰ Noah, *supra* note 125, at 169.

³⁰¹ See *supra* Part II.

1996 offers an ideal opportunity in the context of telemedicine.³⁰² This Act ensures that rural health care providers have access to telecommunications service at rates comparable to those enjoyed by their urban counterparts.³⁰³ Thus, the Spending Power offers existing and potential opportunities for uniform standards and regulations in telemedicine.

V. PROPOSALS FOR A UNIFORM REGULATORY REGIME IN THE UNITED STATES

The above establishment of a constitutional basis for Congressional involvement in interstate telemedicine opens the door to the considerations of workable and successful national alternatives to current state regulatory frameworks. Proponents of federal authority note that such a transfer of authority is optimal and feasible for the following reasons: (1) transaction costs and administrative inefficiencies will no longer operate as prohibitive barriers to market entry, (2) uniformity will advance public policy goals that state regulatory systems have been unable to achieve,³⁰⁴ (3) limited de facto national standardization already exists to a certain extent in several areas of health care, and (4) the development and/or implementation of a uniform system for health care delivery in other nations and regions demonstrate that such a model is successful on an operational level. Each of these reasons is analyzed below.

A. Federal Regulation Could Reduce Barriers to Telemedicine by Lowering or Eliminating Transaction Costs and Administrative Inefficiencies

The imposition of national standards in interstate telemedicine could reduce and/or remove transaction costs and administrative inefficiencies that currently dissuade telemedicine providers from operating regionally and/or nationally. To avoid such a predicament, scholars have postulated that a federal system would eliminate the administrative difficulties and costs of obtaining licenses in each state's juris-

³⁰² See 47 U.S.C. § 254 (2006) (requiring the Federal Communications Commission (FCC) to assure that health care providers in rural areas have access to telecommunications services at rates comparable to those found in urban areas); Telecommunications Act of 1996, Pub. L. No. 104-104, 110 Stat. 56 (codified as amended in scattered sections of 47 U.S.C.).

³⁰³ 47 U.S.C. § 254.

³⁰⁴ See P. Greg Gulick, Note, *The Development of a Global Hospital is Closer Than We Think: An Examination of the International Implications of Telemedicine and the Developments, Uses and Problems Facing International Telemedicine Programs*, 11 IND. INT'L & COMP. L. REV. 183, 205-07 (2000).

diction and allow for “a greater degree of flexibility in [the health professional’s] practice with the confidence that his compliance with basic quality standards was assured.”³⁰⁵

Just as importantly, federal regulation of interstate telemedicine has the potential to reduce costs and uncertainty related to legal liability. For instance, the imposition of federal jurisdiction and federal laws governing telemedicine disputes involving citizens of different states may help to resolve jurisdiction and the following choice of law concerns: which state law applies when parties are from different states and whether substantive federal laws should be enacted. In light of the legal principles that presently guide the U.S. judicial system, such a proposition may be considered unworkable and unrealistic at this time and in the short-term future. The Erie Doctrine mandates that citizens from different states may bring a claim in federal court, but such a claim is governed by state law unless it is based upon a federal question to be decided by federal law.³⁰⁶ Under such a legal regime, one may bring a telemedicine dispute in a state court, but such claims may be removed by the defendant to federal court, under the federal court’s diversity jurisdiction.³⁰⁷ Regardless of forum, state law would apply in federal court diversity actions as Congress has yet to enact any telemedicine statutes seeking to modify state jurisdiction or liability rules.³⁰⁸

The U.S. Supreme Court has affirmed that states govern medical malpractice law in noting that “Congress has no power to declare substantive rules of common law applicable in a state whether they be local in their nature or ‘general,’ be they commercial law or part of the law of torts.”³⁰⁹ As long as the telemedicine dispute in question involves a health care provider and a patient within one state, local laws should and do apply. However, when the health care provider and patient are in different states, the appropriate mechanism would be to hold legal proceedings based on federal procedures and substantive laws. As this Article has discussed, the U.S. Supreme Court jurisprudence has upheld concurrent or pre-emptive federal involvement in interstate activities implicating traditionally local concerns.³¹⁰ These instances include upholding the following federal measures: the Labor

³⁰⁵ Sulentic, *supra* note 229, at 36.

³⁰⁶ Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78 (1938).

³⁰⁷ See 28 U.S.C. § 1332(a) (2006).

³⁰⁸ See 28 U.S.C. § 1652 (“The laws of the several states, except where the Constitution or treaties of the United States or Acts of Congress otherwise require or provide, shall be regarded as rules of decision in civil actions in the courts of the United States, in cases where they apply.”).

³⁰⁹ *Erie*, 304 U.S. at 78.

³¹⁰ See *supra* Part III.C.

Standards Act of 1938, which ban the shipment of interstate commerce of goods made by employees paid less than minimum wage;³¹¹ imposing penalties on the interstate transportation of lottery tickets;³¹² banning interstate transportation of women for immoral purposes;³¹³ and banning the mailing of obscene matter.³¹⁴

In light of the inadequacies of the present judicial system and the nation's escalating health care crisis, it behooves Congress to seriously consider adoption of federal measures in interstate telemedicine disputes. As this Article has argued, federal measures are constitutionally permissible.³¹⁵ Even though U.S. jurisprudence has historically allocated health care regulation to states, proposals for broader regulatory authority are not as radical or unworkable as critics are wont to claim for the following reasons. First, the transition from local to more centralized authority is not a novel concept to this nation, as this Article earlier detailed the nation's transformation of health care regulation, albeit on a smaller scale, from a municipal to a state function during the post-Civil War period.³¹⁶ Second, the circumstances that necessitated such a transformation during that time are present today: advances in technology and medical knowledge, and the need to protect and provide for public health and safety as a result of greater access to and quality of health care.³¹⁷

Finally, Congress has long indicated intent in federalizing some aspects of health care, as proposals for federal involvement have been a continuous issue of discussion at least as far back as the late 1960s.³¹⁸ Such discussions first began around that time when the federal government sought to reduce health care expenditures by resolving the crisis of rising costs of medical malpractice litigation.³¹⁹ Federal legislators began submitting proposals for medical malpractice reform throughout the 1970s to the present.³²⁰ This trend has been exhibited by both Republicans and Democrats at different points in time.³²¹ In 1996, Republican Bill Archer introduced the Health Coverage Availability and Affordability Act, which advocated for federal

³¹¹ *United States v. Darby*, 312 U.S. 100, 125-26 (1941).

³¹² *Champion v. Ames (The Lottery Case)*, 188 U.S. 321, 362-64 (1903).

³¹³ *Hoke v. United States*, 227 U.S. 308, 323 (1913).

³¹⁴ *Roth v. United States*, 354 U.S. 476, 492-93 (1957).

³¹⁵ *See supra* Part IV.

³¹⁶ *See supra* Part III.

³¹⁷ *Id.*; *see supra* Part I.

³¹⁸ *See* Abigail R. Moncrieff, *Federalization Snowballs: The Need for National Action in Medical Malpractice Reform*, 109 COLUM. L. REV. 844, 857 (2009).

³¹⁹ *Id.* at 852.

³²⁰ *Id.* at 858-59.

³²¹ *See id.*

damages caps and restrictions on medical malpractice suits.³²² In 2005, then Senators Hillary Clinton and Barack Obama sought to protect physicians from state liability under certain circumstances.³²³ While these proposals have failed to pass into law,³²⁴ it is reasonable to expect that over time federal legislators will come to consensus over common areas of health care. An instance where this has already happened can be seen in the enactment of the federal Mammography Quality Standards Act in 1992, which, as this Article discussed earlier, requires FDA certification for all mammography facilities.³²⁵

Furthermore, the ongoing health care debate indicates movement towards potential consensus over federal control of certain aspects of health care regulation traditionally under state control.³²⁶ For instance, President Obama's health care proposal seeks to establish the Health Insurance Rate Authority (HIRA), which calls for federal involvement in regulation of health insurers.³²⁷ To counteract the rapid rise of premium rates, the HIRA would "provide needed oversight at the Federal level and help States determine how rate review will be enforced and monitor insurance market behavior."³²⁸ Although the establishment of an HIRA remains a point of contention,³²⁹ given the historical roles of federal and state governments in health care, it is very doubtful that the federal incursions of this magnitude would have been proposed or entertained prior to the current crisis of rising health care costs.

As evidenced by Congressional and public reaction to President Obama's proposal, the political climate presently allows for serious consideration of greater federal control in health care. However, as the longstanding Congressional stalemate on medical malpractice reform

³²² Health Coverage Availability and Affordability Act, H.R. 3160, 104th Cong. § 271, 282 (1996) (the proposed caps on damages include: (1) limitations for health care liability actions brought in a State or Federal court against a health care provider, (2) a limitation on the total amount of noneconomic damages which may be awarded to a claimant for losses resulting from an injury, and (3) certain restrictions on punitive damage awards); *see also* H.R. 534, 109th Cong. (2005) (limits noneconomic damages to \$250,000).

³²³ National Medical Error Disclosure and Compensation Act, S. 1784, 109th Cong. (2005) (requirements for indemnification from state liability include admitting to mistakes and entering into settlement negotiations).

³²⁴ *Id.*

³²⁵ 42 U.S.C. § 263(b); Mammography Quality Standards Act of 1992, Pub. L. No. 102-539, 106 Stat. 3547.

³²⁶ *See, e.g.,* Sheryl Gay Stolberg & Robert Pear, *Health Meeting Fails to Bridge Partisan Rift*, N.Y. TIMES, Feb. 26, 2010, at A1.

³²⁷ The White House, The President's Proposal 1 (Feb. 22, 2010), *available at* <http://www.whitehouse.gov/sites/default/files/summary-presidents-proposal.pdf>.

³²⁸ *Id.* at 3.

³²⁹ Stolberg & Pear, *supra* note 326.

described earlier demonstrates, consideration does not automatically result in enactment of the proposals in question. Thus, it is likely that this Article's initial proposal for exclusive federal jurisdiction over both procedural and substantive issues involving interstate telemedicine disputes is a long-term goal. In the short term, it may be realistic to envision limited federal procedural involvement by requiring removal of interstate telemedicine disputes to federal court. Even in this limited form, a federal court would help to reduce legal liability uncertainty and costs by making it more difficult for parties to forum shop in order to gain advantage in litigation. In the long-term, should complete federal authority over interstate telemedicine disputes be realized, the costs of uncertainty and conflicts as to where jurisdiction lies and the treatment of similar issues in different states will be reduced. Such uniformity in other areas of health care touching upon telemedicine will likewise encourage greater interstate delivery of health care. For instance, the requirements of the Joint Commission on Accreditation of Health Care Organizations (JCAHO), a private accreditation organization,³³⁰ may be applied to telemedical credentialing requirements.³³¹ Uniformity may also be achieved by revising the federal HIPAA statute barring states from promulgating stricter standards of data privacy.

B. Federal Regulation Advances Public Policy Goals in the Delivery of Health Care

Uniformity in interstate telemedicine regulations and standards also promotes public policy goals of greater quality and access to health care that existing state regulatory systems are unable to resolve. In the area of licensure, scholars have noted that federal licensure standards promise greater access to health care by enabling health professionals to treat underserved populations, such as rural residents, without requiring these professionals to live in these areas.³³² Professor Alison Sulentic notes that "higher national standards for entry-to-practice may translate to a higher standard of practice through easier access to state markets and enhanced competition."³³³

Uniformity in other areas, such as medical malpractice coverage, further impacts these policy considerations. For example, Professor Noah has observed that differing state insurance requirements influ-

³³⁰ Eleanor D. Kinney, *Private Accreditation as a Substitute for Direct Government Regulation in Public Health Insurance Programs: When is it Appropriate?*, LAW & CONTEMP. PROBS. 47, 52 (1994).

³³¹ See Volkert, *supra* note 11, at 158-59.

³³² Sulentic, *supra* note 229, at 36.

³³³ *Id.* at 37.

ence where health professionals choose to practice, as there is evidence suggesting that they avoid jurisdictions with higher malpractice damage awards and unfavorable procedures.³³⁴

C. Foundations for Federal Regulation are Currently in Place for Interstate Telemedicine

As discussed earlier, the transition from state to federal regulation is feasible because several aspects of the health care industry are already subject to national standards and procedures. The transformation of a state licensing system to a national system offers a prime example, as educational and specialization requirements have come to follow a national standard and existing federal licensing models are in place in limited circumstances.³³⁵ Another related example is accreditation requirements, as Medicare and Medicaid already impose operational standards on health care entities in exchange for funding.³³⁶ In particular, hospitals are subject to the rules of the JCAHO.³³⁷ According to Kevin Outterson, “[t]he uniform national standards of the Joint Commission [JACHO] represent a federalization of hospital licensing standards, enforced upon state licensed hospitals through the vector of Medicare.”³³⁸ Thus, the foundations for a national telemedicine regulatory system are in place in several areas and provide a working model for those areas where there is lack of uniformity.

D. Adoption of Health Care Delivery Models on National and Regional Scales Demonstrate that Domestic Federal Regulation is a Successful Alternative

Finally, the experiences of a few other nations in establishing uniform regulations and standards to telemedicine support the assertion that uniformity in this industry is the optimal solution. As alluded to earlier, Malaysia serves as an instructive example of an overarching telemedicine regime because it is a forerunner in enacting laws that regulate telemedicine.³³⁹ Malaysia’s Telemedicine Act of 1997 grants

³³⁴ Noah, *supra* note 125, at 186.

³³⁵ See *supra* Part III.D.

³³⁶ See 42 U.S.C. § 1395x(e) (2006) (defining ‘hospital’ within the context of Medicare regulations); 42 U.S.C. § 1395x(m) (defining ‘home health services’ within the context of Medicare regulations); 42 C.F.R. § 484.1-.55 (2001) (regulating various types of providers).

³³⁷ See 42 U.S.C. § 1395b(a).

³³⁸ Outterson, *supra* note 128, at 519.

³³⁹ Hsing-Hao Wu, *Evolving Medical Service In The Information Age: A Legal Analysis of Applying Telemedicine Programs In Taiwan*, 27 MED. & L. 775, 784 (2008) (Malaysia’s telemedicine law “specifically addresses legal issues concern-

a certificate to practice telemedicine to physicians who are licensed to practice in that nation and those who are licensed abroad.³⁴⁰ On a regional level, the EU has demonstrated the irrelevance of geographic barriers with regards to ensuring access to and providing quality medical treatment. As discussed earlier,³⁴¹ the EU's "Doctor's Directive 93/16" permits a physician to practice in all member states provided that he or she obtain a diploma from one member state that meets the Directive's minimum training requirements.³⁴² The European Court of Justice (ECJ) further diminished the importance of borders for medical care in its application of the EU's Working Time Directive (WTD) to health services by extending the WTD's restriction on working hour and mandatory rest periods to this sector.³⁴³ While the EU does not directly address telemedicine, the implementation of such measures support the proposition that the development of a cross-jurisdictional approach to the delivery of health care is a more feasible and desirable alternative than geographic based initiatives.

VI. THE POTENTIAL OF TELEMEDICINE AND THE GLOBAL REGULATORY REGIME

The above examples of a national telemedicine regime in the U.S. can provide workable models for an international telemedicine regime. Just as a federal authority over interstate telemedicine offers the most viable solution, the international community should consider an international institution or legal mechanism to regulate and adjudicate issues involving international telemedicine.

As mentioned before, there are no international telemedicine agreements. Some scholars predict that existing multilateral trade agreements pertaining to cross-border services, such the General Agreement on Trade and Services (GATS) or the North American Free Trade Agreement (NAFTA) may evolve to include provisions liberalizing trade in health care services.³⁴⁴ While this may be the case, it is important to caution that the existing frameworks of these agreements are likely ill-equipped to deal with unique health-related barriers addressed in this Article for several reasons. First, the enforcement of GATS provisions under the World Trade Organization's

ing telemedicine, such as licensure, informed consent and telemedicine standard development.".)

³⁴⁰ See Telemedicine Act 1997, Act 564 cl. 3(1) & 4(1) (Malay.).

³⁴¹ See *supra* Part II.

³⁴² Council Directive 93/16/EEC, *supra* note 73, at 1-24.

³⁴³ Scott L. Greer, *Choosing Paths in European Union Health Services Policy: A Political Analysis of a Critical Juncture*, 18 J. EUR. SOC. POL'Y 219, 222 (2008).

³⁴⁴ E.g., McLean, *supra* note 14, at 501.

(WTO) dispute settlement mechanism is an inappropriate and generally unavailable forum for resolving medical malpractice disputes among private parties. The WTO restricts standing to Member governments for a GATS-based violation, and private parties are afforded no legal protection unless they can garner enough political support for a government to bring a claim on their behalf.³⁴⁵ Even when a private party does convince a government to represent her on a claim, the claim may only be made against another government and the only relief available is a prospective remedy of the GATS violation.³⁴⁶ Thus, the inability of private parties to take legal action against other offending private entities and to obtain compensation by injured parties discourages parties from participating in cross-border health care services.³⁴⁷ Second, the WTO offers no recognized authoritative platform by which uniform standards or regulations may be promulgated to member states related to the delivery of health care. Third, dissenting WTO members may invoke the GATS exception clause allowing noncompliance for public health protection under Article XIV.³⁴⁸ Thus, in order for existing multilateral trade agreements such as GATS to be effective, the forums in which they carried and enforced must be re-examined and altered in order to accommodate the unique challenges of international telemedicine.

The difficulties involved in bringing about the above changes prompt a consideration of other feasible alternatives. One such alternative may involve the establishment and/or allocation of an entity or mechanism with an established expertise in the health field to help promulgate supranational regulatory framework and standards.³⁴⁹ For

³⁴⁵ See Thomas R. McLean, *The Offshoring of American Medicine: Scope, Economic Issues and Legal Liabilities*, 14 ANNALS HEALTH L. 205, 248-249 (2005).

³⁴⁶ See Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts 353 (1999), 1869 U.N.T.S. 401, available at http://www.wto.org/english/docs_e/legal_e/28-dsu.pdf.

³⁴⁷ See Jay Lawrence Westbrook, *Legal Integration of NAFTA through Supranational Adjudication*, 43 TEX. INT'L L.J. 349, 351-52 (2003). The lack of legal protection for private persons engaged in cross-border services may be compared with Westbrook's analysis of international investors, as these parties are making financial commitments to projects located in foreign jurisdictions and vulnerable to those foreign states' laws.

³⁴⁸ See Nicolas F. Diebold, *The Morals And Order Exceptions In WTO Law: Balancing The Toothless Tiger And The Undermining Mole*, 11 J. INT'L ECON. L. 43, 43-44 (2008).

³⁴⁹ See generally Amar Gupta & Deth Sao, *Harmonization of International Legal Structure for Fostering Professional Services: Lessons from Early U.S. Federal-State Relations*, 18 CARDOZO J. INT'L & COMP. L. 239 (2010).

example, the WHO is a prime example proponents use to advance this proposal, as it has the global expertise, reputation, and resources to act as an authoritative body with similar responsibilities as the U.S. federal government in the health care field.³⁵⁰ Notably, the WHO comprises of 193 member nations,³⁵¹ one of the largest memberships of an international body or treaty.³⁵² Because the WHO embraces and incorporates more countries than many other organizations, there may be greater acceptance by the international community for WHO-initiated measures in the health care arena.

The WHO would establish and ensure compliance with regulations and standards pertaining to the international practice of telemedicine.³⁵³ For example, the WHO has recent experience in this capacity in promulgating the International Health Regulations (IHR), an international legal instrument that is binding on all WHO member states. Entered into force in 2007, the IHR requires countries to report public health events to the WHO and improve their public health surveillance and response systems.³⁵⁴ Recognizing that there are certain situations where protection of public health is an “inherently multigovernmental concern,” the WHO developed the IHR in response to the global impact of Severe Acute Respiratory Syndrome (SARS) and in preparation for the global spread of the Avian Flu.³⁵⁵ Furthermore, the WHO may ultimately serve as the final arbiter of legal disputes involving healthcare issues that transcend national barriers and involve international parties.³⁵⁶ Thus, in the interests of advancing the policy goals of greater quality and access to health care, nations may be increasingly willing to defer authority in various aspects of transnational healthcare services to global institutions such as the WHO.

CONCLUSION

Telemedicine offers the potential to improve existing health care systems on national and international levels. At the same time that

³⁵⁰ See Blum, *supra* note 14, at 89-91.

³⁵¹ *Governance of WHO*, WORLD HEALTH ORG., <http://www.who.int/about/governance/en/index.html> (last visited Oct. 2, 2010).

³⁵² In comparison, there are 140 signatory countries to the GATS. *The General Agreement on Trade in Services (GATS): Objectives, Coverage and Disciplines*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/serv_e/gatsqa_e.htm#2 (last visited Jan. 13, 2011).

³⁵³ Gulick, *supra* note 304, at 212.

³⁵⁴ *What are the International Health Regulations?*, WORLD HEALTH ORG., <http://www.who.int/features/qa/39/en/index.html> (last visited Jan. 29, 2010).

³⁵⁵ Kumanan Wilson et al., *The New International Health Regulations and the Federalism Dilemma*, PLOS MED., Jan. 2006, at 30, 30.

³⁵⁶ Gulick, *supra* note 304, at 212.

telemedicine provides a feasible and ready solution to health care crises in nations such as the U.S., it motivates reconsideration and realignment of the degree of sovereignty that local, county, state, and national governments have traditionally held or have assumed over the years. The cross-border nature of telemedicine involves opportunities and challenges, as the ability to deliver health care across distances not only achieves public policy goals of greater quality and access to health care, but also creates jurisdictional conflicts within and among nations. The experience of the U.S. shows that such jurisdictional conflicts, if resolved appropriately, could be regarded as a positive rather than a negative consequence of the development of telemedicine. As a study of the development of state authority over health care and the determination of the unconstitutionality of state regulation of telemedicine demonstrates, the need to relinquish local control in favor of a centralized authority is consistent with the provisions of the U.S. Constitution and other governing principles, and does not violate any immutable constitutional or ethical principles.

As we look at the dilemma of health care and mounting costs and poor quality of its delivery, we have to think of more revolutionary changes. This dilemma is similar to the Y2K problem with a fixed date, which forced the financial industry and other companies to embrace nontraditional solutions, such as getting work done abroad or relying on foreign programmers to come to the U.S.³⁵⁷ Until 1999, such practices were frowned upon for reasons ranging from violation of corporate policies to breach of customer data privacy.³⁵⁸ The firm deadline of December 31, 1999, forced the companies to become more flexible.³⁵⁹ As we face a similar dilemma in health care with escalating costs and growing discontent, but with no “very hard deadline” in existence to force cohesive action,³⁶⁰ our policymakers will be increasingly compelled to look at nontraditional options that involve rethinking the status of relationships between state governments and national governments on various facets of health care.

³⁵⁷ Amar Gupta, Raj K. Goyal, Keith A. Joiner, & Sanjay Saini, *Outsourcing in the Healthcare Industry: Information Technology, Intellectual Property, and Allied Aspects*, 21 INFO. RESOURCES MGMT. J. 1, 7-8 (2008).

³⁵⁸ *Id.*

³⁵⁹ *Id.*

³⁶⁰ *See id.* at 7.