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

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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 and often inconsistent and inadequate 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 paper argues that such barriers not only fail to advance these public 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 the centralized authority of the federal government; this position is consistent with the U.S. Constitution and other governing principles. Finally, this paper

observes that the U.S. experience has 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.

I. 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.”

Barak Obama
Remarks to Joint Session of Congress on Health
Care¹

The hardship that the United States President Barak Obama (President Obama) denounced in his address to a 2009 Joint Session of Congress on Health Care is the plight of over 30 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 37th in the world for health

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

² *Id.*

³ *Id.*

⁴ *Id.*

care system performance.⁵ Specifically, the U.S. ranks 39th in infant mortality, 43rd for adult female mortality, 42nd for adult male mortality, and 36th for life expectancy.⁶

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, 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 different location.⁷ Hawaii is one of the few states who 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."⁸ As this Hawaiian statute indicates, these technological advances are known as telemedicine and have the capabilities to provide for health care delivery at reduced costs while maintaining or increasing the quality of treatment and services.⁹ The existence and potential of telemedicine in resolving problems in the U.S. health care system and the stalled progress on legislative reform underscore the continuing importance of examining the role

⁵ AJAY TANDON, CHRISTOPHER J.L. MURRAY JEREMY A LAUER & DAVID B EVANS, WORLD HEALTH ORGANIZATION, MEASURING OVERALL HEALTH SYSTEM PERFORMANCE FOR 191 COUNTRIES, <http://www.who.int/healthinfo/paper30.pdf>.

⁶ Christopher J.L. Murray & Julio Frenk, *Ranking 37th — Measuring the Performance of the U.S. Health Care System*, NEW ENG. J. OF MED, Jan. 6, 2010, <http://healthcarereform.nejm.org/?p=2610>.

⁷ Susan E. Volkert, *Telemedicine: RX for the Future of Health Care*, 6 MICH. TELECOMM. & TECH. L. REV. 147, 153 (2000).

⁸ Haw. Rev. Stat. § 453-2 (2005) (telemedicine exception permitted 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").

⁹ See Volkert, *supra* note 7, at 151.

telemedicine plays in improvements to health care systems, not only of the U.S. but 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 have addressed the ways in which telemedicine resolves these longstanding concerns in the existing U.S. and foreign health care systems.¹⁰ Such discussions have involved barriers that prevent that realization of telemedicine, which include differing standards and regulatory regimes of sub-national and national governments.¹¹ Because telemedicine is by nature a cross-jurisdictional practice, the majority of scholars conclude that the establishment of a uniform set of standards and regulations is necessary to realize telemedicine's full potential.¹² However, less attention has been given to the reasons for why these barriers exist. This paper 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 II 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 improve such a system.

Part III discusses the barriers to telemedicine in the U.S., which are mainly created and

¹⁰ See, e.g., Volkert, *supra* note 7; 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); Thomas R. McLean, *The Future of Telemedicine & its Faustian Reliance on Regulatory Trade Barriers for Protection*, 16 HEALTH MATRIX 443, 462 (2006); 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 Development, Uses And Problems Facing International Telemedicine Programs*, 11 IND. INT'L & COMP. L. REV. 183 (2000).

¹¹ *Id.*

¹² *Id.*

enforced by individual states with little or no involvement by the federal government. Part IIV questions the justifications for these barriers, and concludes that state authority over the health care is unconstitutional. Building upon such a conclusion, Part V determines that the federal government has the constitutional right to regulate health care. Part VI offers proposals for a national telemedicine regime, and part VII applies such proposals on a global scale.

II. THE ROLE OF TELEMEDICINE IN HEALTH CARE REFORM

According to the World Health Organization, telemedicine is

The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies in 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 interests of advancing the health of professionals and their communities.¹³

As the above definition indicates, telemedicine covers all areas and practices of the health care industry.¹⁴ Current applications and potential future uses of telemedicine have 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 will play an instrumental role in resolving current the health care crises that plague countries such as the United States.¹⁵

¹³ INFORMATION TECHNOLOGY IN SUPPORT OF HEALTH CARE, WORLD HEALTH ORGANIZATION, <http://www.who.int/eh/en/InformationTech.pdf>.

¹⁴ See Volkert, *supra* note 7, 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”).

¹⁵ See, e.g., Blum, *supra* note 10; McLean (2006) *supra* note 10; Gulick, *supra* note 10.

A review of the rising costs and failings of the U.S. health care system, as well as the ways in which telemedicine resolves these problems, is instructive to demonstrate 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.¹⁶ A 2007 Congressional report comparing the U.S. with member countries of the Organization for Economic Cooperation and Development (OECD) concludes that “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.”¹⁷ These prices have been rising for several years.¹⁸ The total health expenditures equaled \$2.3 trillion in 2008, which was 16.2 percent of the nation’s Gross Domestic Product (GDP).¹⁹ To put this in perspective, such expenditures exceed spending on all other government services, including defense, education, and pensions.²⁰ This share of GDP increased from 15.9 percent in 2007.²¹ In comparison, health care spending amounted to \$714

¹⁶ CHRIS L. PETERSON & RACHEL BURTON, U.S. HEALTH CARE SPENDING: COMPARISON WITH OTHER OECD COUNTRIES, summary, http://assets.opencrs.com/rpts/RL34175_20070917.pdf.

¹⁷ *Id.*

¹⁸ The Kaiser J. Family Foundation, U.S. Health Care Costs, http://www.kaiseredu.org/topics_im.asp?imID=1&parentID=61&id=358#1t (last visited January 15, 2010).

¹⁹ CENTERS FOR MEDICARE AND MEDICAID SERVICES, OFFICE OF THE ACTUARY, NATIONAL HEALTH STATISTICS GROUP, NATIONAL HEALTH EXPENDITURES 2008 HIGHLIGHTS, <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/highlights.pdf>.

²⁰ U.S. Government Spending.Com, Total Budgeted Government Spending 2008, <http://www.usgovernmentspending.com/> (last visited January 15, 2009).

²¹ *Id.*

billion in 1990 and \$253 billion in 1980.²² Such costs increases have made it difficult for governments, employers, and consumers to afford health care services.²³

Second, many individuals lack access to health care. These populations include those who require home health care, are confined to correctional facilities,²⁴ and reside in rural communities.²⁵ 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.”²⁶ Trauma centers are largely situated in urban areas, thus rural residents incur great costs of travel and time to seek medical attention.²⁷ Furthermore, the scarcity of trauma centers impacts the entire U.S. population regardless of residence, as a 2007 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.²⁸ This translates into car accident mortality rates being twice as high in rural areas than in urban areas.²⁹

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

²² Kaiser J. Family Foundation, *supra* note 18.

²³ *Id.*

²⁴ Volkert, *supra* note 7, at 156.

²⁵ Joy Elizabeth Matak, *Telemedicine: Medical Treatment Via Telecommunications Will Save Lives, But Can Congress Answer The Call?: Federal Preemption of State Licensure Requirements Under Congressional Commerce Clause Authority & Spending Power*, 22 VT. L. REV. 231, 236 (1997).

²⁶ *Id.*

²⁷ *Id.* at 237.

²⁸ R. Latifi et al., *Telemedicine and Telepresence for Trauma and Emergency Care Management*, 96 SCANDINAVIAN J. OF SURGERY 281, 282 (2007).

²⁹ *Id.*

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.³⁰ 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.³¹ Additionally, the use of video-conferencing by physicians to treat state prisoners has led to less travel time and security risks.³² In particular, the Arizona Telemedicine Program, which began in 1998, has reported that its use of telemedicine in the state’s prisons have lowered transportation costs by more than one million dollars.³³

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.³⁴ For example, advances in information technology (IT) security will resolve current concerns about breaches in security and patient privacy.³⁵ IT networks will transform the delivery of health care

³⁰ Volker, *supra* note 7, at 153.

³¹ Gulick, *supra* note 10, at 192.

³² Volkert, *supra* note 7, at 156.

³³ *Innovative Programs in Telemedicine: The Arizona Telemedicine Program*, 11(6) TELEMEDICINE & E-HEALTH 633, 639 (2005).

³⁴ Amar Gupta, *Prescription for Change*, THE WALL STREET JOURNAL, Oct. 20, 2008, <http://online.wsj.com/article/SB122426733527345133.html>.

³⁵ *Id.*

by enabling secure cross-border transfers of confidential health information, thus allowing greater opportunities to engage in interstate and offshore delivery of telemedicine.³⁶

Another area of potential is the offshore outsourcing of diagnostic services.³⁷ Such an approach will improve the quality of health care by re-distributing work loads and lower costs.³⁸ An instructive example is the area of teleradiology, as x-rays may be taken in one location and then transmitted to another location for evaluation.³⁹ This arrangement will help to resolve the growing demand for teleradiology services, thus lowering costs, and allowing for improved quality in service by ensuring that an alert radiologist will evaluate the images at all hours.⁴⁰

Despite the above demonstrated benefits of present and potential uses of telemedicine, the subsequent sections of this paper will 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.⁴¹ To better understand the implications and consequences of such impediments, an examination of 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

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *See, e.g.,* Gulick, *supra* note 10; Thomas R. McLean (2006), *supra* note 10.

U.S. thus enables one to glean greater insight into how to find workable solutions to the unrestricted use of telemedicine on a global platform.

III. 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.⁴² 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 regulations and standards, all of which are not uniform. 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 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.

⁴² Volkert, *supra* note 7, at 156.

A. Licensing Requirements

Every state has the authority to regulate health professionals who practice in their territories.⁴³ 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.⁴⁴ These state statutes require a physician to be licensed in the state in which the physician is practicing medicine.⁴⁵ These statutes also delegate regulatory authority to a state medical board.⁴⁶ The importance of locality in licensing is further underscored in other aspects of these statutes, as they have significant variations among them.⁴⁷ These variations may include differences in the following: definition of the practice of medicine; what constitutes the unlawful practice of medicine; and licensure and

⁴³ In 1889, the Supreme Court held in *Dent v. West Virginia* 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.

129 U.S. 114, 117-18 (1889).

⁴⁴ Federation of State Medical Boards, The Role of the State Medical Board, http://www.fsmb.org/grpol_talkingpoints1.html (last visited January 8, 2010) [hereinafter Federation of State Medical Boards].

⁴⁵ The category of health professionals subject to regulation is too huge in number to warrant individual analysis for the purposes of this paper (e.g., nurses, dentists). With the purpose of highlighting 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 players in this industry must undergo licensure/approval requirements (e.g., hospitals), but these discussions are beyond the scope of this article.

See, e.g., Alaska Stat §08.64.170; Colorado Rev. Stat. §12-36-106; 24 Del. Code §1702; Florida Stat. §458.327; Hawaii Rev. Stat. §453-2; Idaho Code §54-1804; Kansas Stat. Ann. §65-2803; La. Rev. Stat. Ann. §1271; Miss. Code Ann. §73-25-1; Nev. Rev. Stat. §630.160; 59 Okl. Stat. §§491, 492(C)(2)(b); S.C. Code Ann. §40-47-60.

⁴⁶ Federation of State Medical Boards, *supra* note 44.

⁴⁷ *Id.*

re-registration requirements.⁴⁸ 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.⁴⁹ 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.⁵⁰

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 physicians to practice without a license.⁵¹ 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.⁵² This exception, however, is not a successful strategy, as most states require consultations to be infrequent or that the in-state physician make the final medical decision.⁵³

⁴⁸ *Id.*

⁴⁹ Volkert, *supra* note 7, at 168.

⁵⁰ McLean (2006), *supra* note 10, at 462 (2006); *see also* Matak, *supra* note 25, 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”).

⁵¹ Linda Gobis, *An Overview of State Laws and Approaches to Minimize Licensure Barriers*, 5 *Telemedicine Today Magazine* 6, ¶ 11 <http://www2.telemedtoday.com/statelawguide/index.shtml> (last visited July 13, 2009).

⁵² *Id.*

⁵³ Laura Keidan Martin, *Not So Fast, It’s Regulated Some Warnings For The E-Health Biz*, *BUS. L. TODAY* 14, 11 (Sept. / Oct. 2000).

Second, many states have enacted laws regulating telemedicine licensure. Since 2006, twenty-five states require out-of-state physicians to obtain a full license from the state in which the service is being provided.⁵⁴ A minority of states allow for reciprocity or endorsement.⁵⁵ As of the writing of this paper, only the state of Washington allows out-of-state physicians to practice medicine.⁵⁶ Washington permits out-of-state physicians to practice medicine provided they do not open an office or designate a meeting place for patients or receiving calls in-state.⁵⁷ 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, but the board has yet to exercise that authority.⁵⁸ 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 1996.⁵⁹ The FSMB is a national non-profit association that represents seventy state

⁵⁴ Telemedicine Information Exchange, Law and Policy in Telemedicine The State of Licensure in the U.S., http://tie.telemed.org/legal/state_data.asp?type=licensure (last visited January 9, 2010) [hereinafter Telemedicine Information Exchange].

⁵⁵ See, e.g., S.D. Codified Laws § 36-4-19 (1996) (reciprocity if another state's or country's requirements are not less stringent); Tenn. Code Ann. § 63-6-211(a) (1996) (reciprocity if another state's or country's requirements are not less stringent); N.M. Stat. Ann. § 61-6-13 (Michie 1996) (licensure by endorsement if physician meets its state-based Medical Practice Act requirements).

⁵⁶ Wash. Rev. Code §18.71.030(6) (1996).

⁵⁷ Wash. Rev. Code §18.71.030(6) (1996).

⁵⁸ Cal. Bus. & Prof. Code §2052.5(a)(1) (West 2008).

⁵⁹ 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*, http://www.fsmb.org/pdf/1996_grpol_Telemedicine.pdf [hereinafter FSMB Model Act].

medical licensing and disciplinary boards.⁶⁰ The special purpose license was created by FSMB as part of its 1996 Model Guidelines for the Appropriate Use of the Internet in Medical Practice.⁶¹ This license is intended for physicians who practice medicine across state lines by electronic or other means.⁶² License holders are subject to the jurisdiction of the medical board in the state of issuance for all matters.⁶³ Thus far, only seven states have adopted this license.⁶⁴ This approach fails to provide an effective solution, as evidenced by its rejection by most states and its deference to state authority on licensing matters.

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.⁶⁵ The federal government has affirmed such delegation of state power through passage of the McCarran-Ferguson Act.⁶⁶ A state's insurance

⁶⁰ Federation of State Medical Boards, *supra* note 44.

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Paul v. Virginia*, 75 U.S. 168, 183-184 (1869).

⁶⁶ 15 U.S.C. §§1011- 1013 (2000). In *Life Partners, Inc. v. Morrison*, the Fourth Circuit court explained that the McCarran-Ferguson Act explicitly granted states with the authority to regulate the business of insurance and protects such authority from any constitutional challenge based on the Commerce Clause (1) any state law that "relates to the regulation of the business of insurance," or (2) any state law "enacted for the purpose of regulating the business of insurance." 484 F.3d, 284, 286 (2007).

code essentially regulates every aspect of the health insurance within its borders.⁶⁷ While there is overlap between state insurance codes, each state has its own unique definitions, coverage schemes, and procedures.⁶⁸ Most require that a health professional must obtain medical malpractice coverage for a state's territory before receipt of medical license.⁶⁹ Several scholars argue that such a requirement for state-specific coverage for telemedicine providers who operate on an interstate platform creates system inefficiencies that significantly increase transaction costs.⁷⁰ 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.⁷¹ Listed among the barriers to entering the medical malpractice market include regulatory constraints, which bar “[m]ost medical malpractice insurers [from] sell[ing] across state lines without filing for license or authorization. Rates and forms must be adjusted to local requirements.”⁷² 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.⁷³ Given the requirements to comply with

⁶⁷ See, e.g., Ky. Rev. Stat. Ann. §304.40-250 to 320 (West 2009); MASS. GEN. LAWS ANN. ch. 17F (West 2007).

⁶⁸ *Id.*

⁶⁹ See, e.g., Kan. Stat. Ann. §65-2809(c) (2005).

⁷⁰ 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).

⁷¹ ERIC NORDMAN, DAVIN CERMAK & KENNETH MCDANIEL, *MEDICAL MALPRACTICE INSURANCE REPORT: A STUDY OF MARKET CONDITIONS AND POTENTIAL SOLUTIONS TO THE RECENT CRISIS* (2004), 6 http://www.naic.org/documents/topics_med_mal_rpt_final.pdf.

⁷² *Id.* at 37.

⁷³ *Id.*

multiple insurance codes and local nuances, state insurance laws have acted as longstanding barriers to the national practice of telemedicine.⁷⁴

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.⁷⁵ 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.. Several scholars anticipate jurisdiction in these situations will be established in accordance with the Supreme Court's "minimum contacts"

⁷⁴ Mclean (2006), *supra* note 10, at 466.

⁷⁵ Restatement (Third) of Foreign Relations Law of the United States § 401 (1987).

test of personal jurisdiction over interstate claims.⁷⁶ 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.⁷⁷ The Court has interpreted foreseeability to mean that a defendant expects that its product will be purchased by the state’s citizens.⁷⁸ 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.⁷⁹ 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.⁸⁰ 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.⁸¹

⁷⁶ See, e.g., Thomas R. McLean, *The Offshoring of American Medicine: Scope, Economic Issues and Legal Liabilities*, 14 ANNALS HEALTH L. 205, 247 (2005).

⁷⁷ *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 471-79 (1985); *Hanson v. Denckla*, 357 U.S. 235, 251-53 (1958); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 291-98 (1980).

⁷⁸ *World-Wide Volkswagen Corp.*, 444 U.S. at 295 (finding no foreseeability because the plaintiff purchased defendant’s 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).

⁷⁹ *Id.* (finding no purposeful availment because defendant dealer did not sell cars, advertise, or cultivate customer base in forum state).

⁸⁰ *Keeton v. Hustler*, 465 U.S. 770, 777 (1984) (finding defendant purposefully availed itself of chance to engage in in-state activities by distributing magazines in state).

⁸¹ *World-Wide Volkswagen Corp.*, 444 U.S. at 292.

Applying the “minimum contacts” test employed by the Court to telemedicine, it appears likely that interstate telemedicine providers will be subject to jurisdiction of the state in which they do business. First, most states have long-arm statutes allowing for personal jurisdiction.⁸² 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 also 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 above 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 sometimes act to divest the State of its power to render a valid judgment.⁸³

⁸² See, e.g., Ala.Code 1975 § 8-19C-10; AS § 09.05.015; A.R.S. § 14-7652; A.C.A. § 4-70-304; West’s Ann.Cal.C.C.P. § 410.10; C.R.S.A. § 5-1-203; C.G.S.A. § 1-101oo; West’s F.S.A. § 48.193.

⁸³ World-Wide Volkswagen Corp., 585 P.2d at 294.

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.⁸⁴ 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.⁸⁵ 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,⁸⁶ the same uncertainties voiced above regarding the validity of such assertion apply here. The requirement that personal jurisdiction does not violate “traditional notions of fair play and substantial justice” is extended in the international context in following ways. First, the Court’s consideration of collective U.S. states’ interests “calls for a court to consider the

⁸⁴ See *Haag v. Barnes*, 175 N.E.2d 441, 443 (N.Y. 1961); Restatement (Second) of Conflict of Laws § 145 (1971) (“The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state...”).

⁸⁵ 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. See FSMB Model Guidelines; 10 Colo. Code Regs. § 2505-10 (2004).

⁸⁶ See, e.g., *Asahi Metal Indust. Co. v. Superior Court*, 480 U.S. 102 (1987).

procedural and substantive policies of *other nations* whose interests are affected by the assertion of the jurisdiction of [a state court].”⁸⁷ Second, the federal government’s interest in its foreign policies will also play a factor.⁸⁸ Third, the interests of the defendant has “significant weight in assessing the reasonableness 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.”⁸⁹

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 paper, there are no international agreements concerning telemedicine.⁹⁰ There are notable exceptions where telemedicine law has been more fully developed and comprehensive, such as Malaysia.⁹¹ Overall, however, telemedicine providers who engage in business in the United States and globally face significant uncertainty as to their scope and extent of their legal liability exposure.

⁸⁷ *Asahi Metal Indus.*, 480 U.S. at 115 [emphasis added].

⁸⁸ *Id.*

⁸⁹ *Id.* at 102.

⁹⁰ See, e.g., John D. Blum, *The Role of Law in Global E-Health: A Tool for Development and Equity in Digitally Divided World*, 46 ST. LOUIS U. L.J. 85, 95, (2002); Leah B. Mendelsohn, *A Piece of the Puzzle: Telemedicine as an Instrument to Facilitate the Improvement of Healthcare in Developing Countries?*, 18 EMERY INT’L L. REV. 151, 153 (2004).

⁹¹ See *infra*, Part VIII.

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.⁹² HIPAA applies to health information via electronic media in connection with most financial and administrative transactions.⁹³ Unauthorized disclosures may result in criminal and civil penalties.⁹⁴

The HIPAA requires states to follow the federal standards set forth under this Act, but allows states and other federal agencies to set forth and impose stricter security measures.⁹⁵ Such overlapping regulations force telemedicine providers to comply with both federal and state standards, a process that is expensive, difficult, and time-consuming.⁹⁶ 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

⁹² 42 U.S.C. § 1320(d) to (d)-8 (2000).

⁹³ See 42 U.S.C. § 1320d-2(a)(2); 45 C.F.R. § 160.103 (2001); 63 Fed. Reg. 43, 248 (1998); 64 Fed. Reg. 59, 932-33 (1999).

⁹⁴ 42 U.S.C. § 1320d-6(b).

⁹⁵ 42 U.S.C. § 1320d-2; See 63 Fed. Reg. at 43,258.

⁹⁶ 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*, American Health Information Management Association, http://library.ahima.org/xpedio/groups/public/documents/ahima/bok3_005197.hcsp?dDocName=bok3_005197#side_bar (last visited Jan. 10, 2009).

afforded by authorization; and providing greater privacy protection for the person who is the subject of the individually identifiable health information.⁹⁷

E. Payment of 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 pay for some services under limited circumstances.⁹⁸ A review of each of these insurers will show the ways in which current billing processes impede the practice of telemedicine.

(1) Medicare

Medicare, a federal insurer for the aged and disabled,⁹⁹ has geographic and services limitations for reimbursement. Eligible services include “office and other outpatient visits, professional consultation, psychiatric diagnostic interview examination, individual psychotherapy, and pharmacologic management furnished by an interactive telecommunications system.”¹⁰⁰ Excluded services that “do not meet the definition of an interactive telecommunications system” are “[t]elephones, facsimile machines, and electronic mail systems.”¹⁰¹ Geographically, reimbursement is limited to an originating site. This means “the

⁹⁷ *Id.*

⁹⁸ DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH RESOURCES AND SERVICES ADMIN., 2001 REPORT TO CONGRESS ON TELEMEDICINE: PAYMENT ISSUES (2001), <ftp://ftp.hrsa.gov/telehealth/report2001.pdf>. [hereinafter 2001 REPORT TO CONGRESS ON TELEMEDICINE].

⁹⁹ Medicare, General Enrollment and Eligibility, <http://www.medicare.gov/MedicareEligibility/Home.asp?dest=NAV\Home\GeneralEnrollment#TabTop> (last visited Feb. 1, 2009).

¹⁰⁰ 42 C.F.R. § 410.78(b) (2003).

¹⁰¹ 42 C.F.R. § 410.78(a)(3).

site where the patient is located, 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.”¹⁰² These sites must be a Rural Health Professional Shortage Area, a non-Metropolitan Statistical Area, or part of a federal telemedicine project.¹⁰³ Furthermore, home health care requires face-to-face visits and telemedicine may not be substituted in place of these visits.¹⁰⁴

(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.¹⁰⁵ This means that each state determines which telemedicine services, if any, are eligible for reimbursement.¹⁰⁶ Currently, only eighteen states thus far compensate for telemedicine services, while two others are developing plans to cover telemedicine.¹⁰⁷

¹⁰² 42 C.F.R. § 410.78(b)(3).

¹⁰³ 2001 REPORT TO CONGRESS ON TELEMEDICINE *supra* note 98, at 17-18.

¹⁰⁴ Centers for Medicaid & Medicare Services, Telemedicine and Telehealth, <http://www.cms.hhs.gov/Telemedicine/> (last visited Jan. 10, 2009).

¹⁰⁵ Centers for Medicaid & Medicare Services, Medicaid Program – General Information, <http://www.cms.hhs.gov/MedicaidGenInfo/> (last visited Jan. 10, 2009).

¹⁰⁶ Telemedicine Information Exchange, Telemedicine and Telehealth Funding, <http://tie.telemed.org/funding/default.asp?return=record&type=program&genus=Federal&id=21> (last visited Jan. 10, 2009).

¹⁰⁷ 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. Telemedicine Information Exchange, Telemedicine and Telehealth Funding, <http://tie.telemed.org/funding/default.asp?return=record&type=program&genus=Federal&id=21> (last visited Jan. 10, 2009).

Private Insurers

In general, private insurers rarely compensate for telemedicine services.¹⁰⁸ 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.¹⁰⁹ 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.¹¹⁰ Only recently have some private insurers have begun to provide limited telemedicine coverage.¹¹¹ One of the main reasons for this change in policy is because some states have begun to require private insurers to provide reimbursement.¹¹² While there is some movement towards coverage, such overwhelming reluctance contributes to the difficulties faced by telemedicine practitioners in treating their patients.

IV. 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.

¹⁰⁸ Alissa R. Spielburg, *Online without a Net: Physician-Patient Communication by Electronic Mail*, 25 AM. J.L. & MED. 267, 290 (1999) (private insurers doubt that telemedicine is a "cost-effective and reliable therapeutic modality that deserves reimbursement").

¹⁰⁹ *See id.*

¹¹⁰ Lisa Rannefeld, *The Doctor Will E-Mail You Now: Physicians' Use of Telemedicine To Treat Patients Over the Internet*, 19 J.L. & HEALTH 75, 91 (2004-2005).

¹¹¹ *See* 2001 REPORT TO CONGRESS ON TELEMEDICINE, *supra* note 98, at 19.

¹¹² *See, e.g.*, Colo. Rev. Stat. § 10-16-123(2) (2002); La. Rev. Stat. Ann. § 22:657(F) (West. Supp. 2003); Tex. Ins. Code Ann. art. 21.53F, § 3(a) (2001).

In justifying the need for these 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 industry¹¹³ 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 Inherently 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.¹¹⁴ Because health and safety issues have “local peculiarities,” the state is most qualified to tailor a solution for its citizenry.¹¹⁵ In the context of health care, this point of view is valid from a historical perspective. Up until recently, health care was only practiced at a local level and limited to parties and transactions within a state’s territory.¹¹⁶ But this point of view is no longer valid now. As this paper has demonstrated, recent advancements in technology and medical knowledge enabled health care to

¹¹³ See Volkert, *supra* note 10, at 179-180 (“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”).

¹¹⁴ See Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 156-157 (2004).

¹¹⁵ *Id.*

¹¹⁶ *Id.*

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.

(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...”¹¹⁷ The prevalence and reoccurrence of infectious disease in colonies and the available medical knowledge and technologies to combat such diseases in colonies helped to dictate the distribution of powers between states and the federal government.¹¹⁸ Because of these circumstances,

The regulation of health care was, of practical necessity, a municipal function during the Colonial period, remaining so during the first century of the Republic ... [M]unicipal regulation of health care was a reflection of the era, rather than an immutable Constitutional principle of federalism.¹¹⁹

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

¹¹⁷ Kevin Outterson, *Health Care, Technology and Federalism*, 103 W. Va. L. Rev. 503, 504 (2001).

¹¹⁸ 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).

¹¹⁹ Outterson, *supra* note 117, at 515.

control infectious disease outbreaks.¹²⁰ As most citizens in the colonies lived near rivers, they were vulnerable to mosquito-borne diseases such as malaria and yellow fever.¹²¹ Because these diseases were transmitted face-to-face or via local contact, a local response was required.¹²² To prevent contagion and infection, local authorities implemented quarantine measures as a solution.¹²³ These outbreaks occurred and solutions were applied at such a localized level that the first regulatory efforts were mainly municipal initiatives.¹²⁴ The first boards of health were also municipal.¹²⁵ The first hospital was established by the city of Philadelphia.¹²⁶ Thus, just like the federal government, states played no role in health care during the nation's early formative years.

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.¹²⁷ During the seventeenth and eighteenth centuries, medical treatment made no significant difference in a person's survival.¹²⁸ Widely practiced treatments were more harmful than beneficial, and included the following: purges, bleeding, and unsanitary habits by

¹²⁰ *Id.*

¹²¹ Richards, *supra* note 118, at 203-204.

¹²² Outterson, *supra* note 117, at 506.

¹²³ Richards, *supra* note 118, at 205.

¹²⁴ Outterson, *supra* note 117, at 505-507.

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ Outterson, *supra* note 117, at 515.

¹²⁸ Richards, *supra* note 118, at 206

physicians who spread germs by contact.¹²⁹ Because of such ineffectiveness, “in the minds of the populace and legislatures, there was no justification for setting some physicians up with a state-enforced monopoly through licensing them.”¹³⁰

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.¹³¹

(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.¹³² Discoveries such as anesthesia and modern germ theory enabled physicians to provide successful treatments and cures.¹³³ Such gains in medical knowledge also offered a basis on which to set standards for health professionals and types of treatment,¹³⁴ thus prompting the formation of state medical boards and their petitioning to states for stricter licensing laws.¹³⁵ Thus, the evolution from municipal to state regulation in response to advances to technology and medical knowledge show that expansion of jurisdiction in this

¹²⁹ *Id.*

¹³⁰ *Id.* at 207.

¹³¹ Outterson, *supra* note 117, at 511.

¹³² Richards, *supra* note 118, at 209.

¹³³ *Id.* at 209-210.

¹³⁴ Outterson, *supra* note 117, at 512.

¹³⁵ *Id.*

area has already occurred, and that these advances in embodied in the form of telemedicine indicate a further expansion on national and international scales.

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, as it is a federal consumer protection agency charged with protecting the public health by regulating safety and efficacy of drugs and medical devices.¹³⁶ Just as with 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, 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.¹³⁷ Congress granted such regulatory power to the FDA,¹³⁸ which originally began as the Chemical Division of the United States Department of Agriculture (“USDA”) in

¹³⁶ 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, 890 (1996).

¹³⁷ *Id.* at 890.

¹³⁸ James Robert Dean, Jr., *FDA at War: Securing the Food that Secured Victory*, 53 FOOD AND DRUG L.J. 453, 461 (1998).

1862.¹³⁹ Through the Food and Drug Act, the FDA was established as a federal agency with a mission of consumer protection.¹⁴⁰ To carry out such a goal, the “FDA developed a regulatory model based on frequent seizures and criminal prosecutions of adulterated products.”¹⁴¹ The reach of the FDA authority extended only to banning “adulterated” and “misbranded” foods and drugs that were placed in interstate commerce.¹⁴² Such authority was further bounded by the absence of any requirement that these regulated products be tested or approved for safety before being marketed.¹⁴³ Finally, the FDA had no authority over medical devices.¹⁴⁴ Few such instruments existed during this time,¹⁴⁵ 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.¹⁴⁶ This prompted a public outcry for reform of

¹³⁹ *Id.* at 456.

¹⁴⁰ *Id.* at 461.

¹⁴¹ *Id.* at 456.

¹⁴² Walsh & Pyrich, *supra* note 136, at 890.

¹⁴³ *Id.* at 892.

¹⁴⁴ *Id.* at 890.

¹⁴⁵ 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), <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL3282603232005.pdf>.

¹⁴⁶ Walsh & Pyrich, *supra* note 136, at 893.

federal drug laws.¹⁴⁷ Furthermore, so-called “quack” devices were being sold to consumers that posed health risks to consumers.¹⁴⁸ For example, in the 1940s, \$90 lamps were marketed as cure-alls for diseases such as diabetes, cancer, tuberculosis, and syphilis.¹⁴⁹

These harms to the consumers’ health and pocketbook prompted the enactment of the 1938 Act.¹⁵⁰ 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.¹⁵¹ For medical devices, the FDA had new authority to ban devices entering interstate commerce, impose labeling requirements,¹⁵² and seize misbranded and fraudulent devices.¹⁵³ Significantly, the FDA gained greater power under the 1938 Act’s transformation of the agency into an administrative 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.”¹⁵⁴ 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.¹⁵⁵ Finally, the FDA’s transfer from the USDA to

¹⁴⁷ *Id.*

¹⁴⁸ Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (codified as amended in scattered sections of 21 U.S.C.); S. Rep. No. 33, 94th Cong., 1st Sess. 3 (1975). [hereinafter Federal Food Drug and Cosmetic Act].

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* Full implementation of 1938 Act delayed by statute until July 1, 1940. *See* Pub. L. No. 76-511, 53 Stat. 853 (1939).

¹⁵¹ Walsh & Pyrich, *supra* note 136, at 894.

¹⁵² *Id.* at 895.

¹⁵³ Federal Food Drug and Cosmetic Act, *supra* note 148, at 3.

¹⁵⁴ Dean, *supra* note 138, at 461.

¹⁵⁵ Walsh & Pyrich, *supra* note 136, at 985-986.

the Federal Security Agency in 1940 affirmed its mandate a national regulator of health and safety issues. In approving such a transfer, President Roosevelt “found it desirable to group together those agencies of the government whose major purpose was to promote social and economic security, educational opportunity, and the health of the citizens of the Nation.”¹⁵⁶

(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, thus prompting the 1962 Amendments. In Europe, the drug Thalidomide, which was used to relieve morning sickness in pregnant women, was discovered to cause serious birth defects.¹⁵⁷ 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.”¹⁵⁸ 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.”¹⁵⁹ 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.¹⁶⁰

¹⁵⁶ Dean, *supra* note 138, at 456.

¹⁵⁷ Walsh & Pyrich, *supra* note 136, at 896.

¹⁵⁸ *Id.* at 896.

¹⁵⁹ *Id.* at 897.

¹⁶⁰ *Id.* at 901. 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 facilities; (3) establishing manufacturing practices; and (4) removal of drugs from market in event of regulatory violation. *Id.*

(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.”¹⁶¹ 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.¹⁶² Widespread reports of injuries and death resulting from use of these devices thus prompted Congress to fill gaps in existing FDA regulation,¹⁶³ thereby making devices subject to the same pre-approval process applied to drugs.¹⁶⁴ 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.¹⁶⁵

¹⁶¹ Walsh & Pyrich, *supra* note 136, at 903.

¹⁶² Federal Food Drug and Cosmetic Act, *supra* note 148, at 5.

¹⁶³ Walsh & Pyrich, *supra* note 136, at 903; *see* Federal Food Drug and Cosmetic Act, *supra* note 148, at 5. (referencing a 1970 study that concluded medical devices contributed to 10,000 injuries).

¹⁶⁴ SCHOONMAKER, *supra* note 145, at 7 ; MDA; P.L. 94-29.

¹⁶⁵ 21 C.F.R. § 808.1(b) (1994).

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.

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 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,¹⁶⁶ 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.”¹⁶⁷ 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 Constitution, nor prohibited by it to the states, are reserved respectively, or to the people.”¹⁶⁸ In U.S. Supreme Court

¹⁶⁶ Federation of State Medical Boards, *supra* note 44.

¹⁶⁷ *Id.*

¹⁶⁸ U.S. CONST. amend. X.

(“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.¹⁶⁹

Indeed, the history of legal challenges to the police power and health care regulation has resulted in overwhelming support for state authority.¹⁷⁰ Notwithstanding such support, the Court rejects that view 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.¹⁷¹ In reaching its conclusion, the Court explained:

That 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

¹⁶⁹ See *Gibbons v. Odgen*, 22 U.S. 1, 203 (1824) (defining police powers of the states under the Tenth Amendment to include an “immense mass of legislation, which embraces every thing within the territory of a State, not surrendered to the general government: all which can be most advantageously exercised by the States themselves. Inspection laws, quarantine laws, health laws of every description, as well as laws for regulating the internal commerce of a State...”).

¹⁷⁰ See, e.g., *Dent v. W. Virginia*, 129 U.S. 114 (1889) (under the police power, a state can impose regulation for the general welfare even if it prevents a person from practicing his profession); *Hawker v. New York*, 170 U.S. 189 (1898) (state had broad discretion in describing qualifications necessary to practice medicine in state); *Watson v. Maryland*, 218 U.S. 173 (1910) (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 small pox vaccinations); *McNaughton v. Johnson*, 242 U.S. 344 (1917) (state regulation upheld and ophthalmologist defeated on a Fourteenth Amendment claim); *Semler v. Oregon State Bd. of Dental Examiners*, 294 U.S. 608 (1935) (state has discretion to regulate the practice of dentistry).

¹⁷¹ *Hamilton v. Kentucky Distilleries & Warehouse Co.*, 251 U.S. 146, 156 (1919).

the same incidents which attend the exercise by a state of its police power, or that it may tend to accomplish a similar purpose.¹⁷²

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.”¹⁷³ Such reasoning was also applied to uphold the federal Labor Standards Act of 1938 in *United States v. Darby*, which contravened traditional authority over labor relations by banning the shipment of interstate commerce of goods made by employees paid less than minimum wage.¹⁷⁴

Mirroring the reasoning in *Hamilton*, the Court observed:

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.¹⁷⁵

¹⁷²*Id.*

¹⁷³ *Id.* at 155 (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”)

¹⁷⁴ *United States v. Darby*, 312 U.S. 100, 113 (1941).

¹⁷⁵ *Id.* at 114, 123, 124; *see also* *Champion v. Ames*, 188 U.S. 321 (1903) (upholding federal law penalizing the interstate transportation of lottery tickets); *Hoke v. United States*, 227 U.S. 308 (1913) (upholding federal law banning interstate transportation of women for immoral purposes); *Brooks v. United States*, 267 U.S. 432 (1925) (upholding federal law regulating stolen automobiles); *Thornton v. United States*, 271 U.S. 414 (1926) (upholding federal law regulating tick-infected cattle); *Roth v. United States*, 354 U.S. 476 (1957) (upholding federal law banning the mailing of obscene matter).

In the context of health regulation, this basis for federal interference was applied by the Third Circuit in *Pharm. Mfrs. Ass'n v. FDA*.¹⁷⁶ The Third Circuit upheld FDA regulation requiring that patients receive certain information for drugs containing estrogen.

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.¹⁷⁷

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

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.¹⁷⁸ For example, Medicare legislation declares: "Nothing in this title 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."¹⁷⁹ To defeat this claim, Professor Lars Noah notes that the legislative records for these statutes offers little explanation for these provisions, as "...the similarity of their language

¹⁷⁶ *Pharm. Mfrs. Ass'n v. FDA*, 484 F. Supp. 1179, 1187-88 (D. Del), *aff'd* 634 F.2d 106 (3d Cir. 1980).

¹⁷⁷ *Id.* at 1187-88.

¹⁷⁸ Noah, *supra* note 114, at 167.

¹⁷⁹ Medicare Statute, Pub. L. No. 89-97, § 102(a), 79 Stat. 290, 291 (1965) (codified at 42 U.S.C. § 1395 (2000)).

suggests that they have become essentially boilerplate.”¹⁸⁰ 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 the field.”¹⁸¹

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.¹⁸² 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.¹⁸³

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.¹⁸⁴ Also, the Food, Drug and Cosmetic Act regulates technologies associated with health care delivery.¹⁸⁵

¹⁸⁰ Noah, *supra* note 114, at 167.

¹⁸¹ *Id.*

¹⁸² 42 U.S.C. § 300k, et seq. (1976).

¹⁸³ See 42 USC §1395x(e) (2001) (hospitals); 42 USC §1395x(m) (home health services); 42 CFR §§484.1-484.55 (2001) (various types of providers).

¹⁸⁴ 42 U.S.C.A. § 263b.

D. Current State Regulation Is Unconstitutional under the Dormant Commerce Clause.

Finally, the exclusivity and legitimacy of state authority over telemedicine regulation is further undermined by its 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.¹⁸⁶ 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; they also advertise services that attract both local and distant customers.¹⁸⁷ 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 “the power . . . [t]o regulate Commerce with foreign Nations, and among several States, and with the Indian Tribes...”¹⁸⁸

¹⁸⁵ 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)).

¹⁸⁶ *See supra* Part II.

¹⁸⁷ Noah, *supra* note 114, at 170.

¹⁸⁸ U.S. CONST. art. I, § 8.

The Supreme Court interprets the Commerce Clause to mean that Congress has the sole authority to engage in interstate and foreign commercial regulation.¹⁸⁹ 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.¹⁹⁰ In barring such discrimination, 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.¹⁹¹

(b) Violation under the Dormant Commerce Clause

One of the functions of the Commerce Clause is to invalidate state and local laws because they place an undue burden on interstate commerce.¹⁹² Although the Constitution does not expressly state this doctrine, the Supreme Court has interpreted Article I, § 8, to confer this power to Congress.¹⁹³ This doctrine, known as the Dormant Commerce Clause, is invoked as a

¹⁸⁹ *Gibbons v. Ogden*, 22 U.S. 1, 26 (1824).

¹⁹⁰ *Id.*

¹⁹¹ *H.P. Hood & Sons, Inc. v. DuMond*, 336 U.S. 525, 539-543 (1949). In *South Carolina Highway Dept. 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 out-of-staters 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).

¹⁹² 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 *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970); Donald Regan, *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause*, 84 MICH. L. REV. 1091 (1986); Noel T. Dowling, *Interstate Commerce and State Power*, 27 VA. L. REV. 1 (1940).

¹⁹³ *DuMond*, 336 U.S. at 539.

challenge to state or local actions in areas where Congress has yet to act or where there is no explicit federal law pre-emption.¹⁹⁴ In other words, the Commerce Clause grants the judiciary branch authority 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 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 and still play a principle role in regulating this area.¹⁹⁵

In determining whether a police power burdens interstate commerce should be upheld or invalidated as violating the Dormant Commerce Clause, the Supreme Court has developed and applied at 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.¹⁹⁶ 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.

¹⁹⁴ *Duckworth v. Arkansas*, 314 U.S. 390, 400 (1941) (J. Jackson, concurring) (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”).

¹⁹⁵ *See supra* Part IV.

¹⁹⁶ 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.*, *Cooley v. Board of Wardens*, 53 U.S. 299 (1851) (applying local/national test to uphold state law requiring use of local pilot or payment of fine for ships in Port of Philadelphia); *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573 (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 (1949) (applying the local/national test to uphold state statute convicting defendant of selling interstate transportation of persons over state highways).

(1) Failure under the Subject Matter Test

Under the subject matter test, a state law violates the Dormant Commerce Clause if regulates national subject matter but is upheld if it regulates local subject matter.¹⁹⁷ The Court defined 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...”¹⁹⁸ 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*.¹⁹⁹ 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. To fund these hospitals, the states imposed a head tax on persons landing in their ports. The Court held this tax to be an impermissible restriction on interstate commerce and foreign trade. According to the Court, states have the “solemn duty” to provide safety to its citizens by preventing the introduction of contagious and infectious diseases, but the tax was an ineffective means to do so because it only acts to fund such protection and fails to quarantine against such threats.²⁰⁰ The tax would have been upheld as a valid police power if it were a public measure directly related to the threat of

¹⁹⁷ *Cooley v. Board of Wardens*, 53 U.S. 299.

¹⁹⁸ *Id.* at 319.

¹⁹⁹ *The Passenger Cases*, 48 U.S. 283, 283 (1849). It should be noted that this case precedes *Cooley v. Board of Wardens*, 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 5 to 4 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.

²⁰⁰ *Id.* at 301-302.

the disease, but the effect of the tax would only “destroy the uniformity of taxation upon persons arriving [in the United States] which nothing but an act of Congress can establish, and of which the interest of the country requires.”²⁰¹

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.²⁰² 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 uniform²⁰³; and (2) a 1789 federal law expressly authorizing states to regulate piloting.²⁰⁴ 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.”²⁰⁵

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

²⁰¹ *Id.* at 303.

²⁰² *Id.* at 299.

²⁰³ *Id.* at 314.

²⁰⁴ *Id.* at 319.

²⁰⁵ *Id.* at 314 (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] clause”).

regulation is unconstitutional. First, as this paper has demonstrated, interstate telemedicine does not possess “local peculiarities” to warrant exclusive local attention.²⁰⁶ Second, just as with the head tax in *The Passenger Cases*, many of these regulations impact actors and activities that involve 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.²⁰⁷ Thus, state borders no longer determine whether a health professional has the skills or competency to treat a state’s residents.²⁰⁸

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.²⁰⁹ 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.²¹⁰ Specialization in a medical area requires passing another nationally standardized exam to become board certified.²¹¹ The establishment of a National Practitioner Data Bank also

²⁰⁶ See *supra* Part IV..

²⁰⁷ Noah, *supra* note 114, at 165.

²⁰⁸ *Id.*

²⁰⁹ See, e.g., Volkert *supra* note 7, at 177-78; Gulick, *supra* note 10, at 205.

²¹⁰ Volkert, *supra* note 7, at 177-78.

²¹¹ Gulick, *supra* note 10, at 205.

streamlines this process, as it collects information about physicians on a nationwide basis, including licensure matters.²¹²

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.²¹³ Professor Alison Sulentic notes that U.S. military law permits any health professional who holds a state license and provides direct patient care in a hospital affiliated with the Department of Defense may practice anywhere in the nation.²¹⁴ 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 she is licensed.²¹⁵ Given that courts have come to increasingly adopt 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.²¹⁶ Finally, the need for state authority fails under the last exception, as , Congress has never expressly authorized states to regulate in this field.

²¹² Volkert, *supra* note 7, at 178.

²¹³ Alison M. Sulentic, *Crossing Borders: The Licensure of Interstate: Telemedicine Practitioners*, 25 J. LEGIS. 1, 37 (1999).

²¹⁴ *Id.*

²¹⁵ *Id.*

²¹⁶ *See supra* Part IV.

(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.²¹⁷ Even if a state is able to claim a valid police power justification, a “statute by which its necessary operation directly interferes with or burdens foreign commerce is a prohibited regulation and invalid, regardless of the purpose with which it was passed.”²¹⁸ In *DiSanto v. Pennsylvania*, the state sought to protect its citizens against fraud in the ticket industry by enacting a law requiring a state-issued license to sell tickets for foreign travel.²¹⁹ The licensing process involved providing proof of moral character, paying annual fees, and filing a bond as a security against fraud or misrepresentation.²²⁰ The Court viewed the licensing process as invalid because it directly interferes with foreign commerce by impacting the sale of transportation between the United States and Europe.²²¹ Notably, the Court inferred that Congress’ “complete and paramount authority to regulate foreign commerce” grants it exclusive jurisdiction to develop and enforce police power measures in this area.²²² By invalidating the state law and elaborating upon Congress’ plenary foreign commerce power, the Court expressed that Congress, and not the state, has authority “by appropriate measures, to protect the public against the frauds of those who sell these tickets and orders.”²²³

²¹⁷ *DiSanto v. Pennsylvania*, 273 U.S. 34 (1972).

²¹⁸ *Id.* at 37.

²¹⁹ *Id.* at 35.

²²⁰ *Id.*

²²¹ *Id.* at 36-37.

²²² *Id.* at 37.

²²³ *Id.*

Just as significantly, direct interference with the Commerce Clause arises when state laws subject interstate market participants to inconsistent obligations in different states.²²⁴ 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.²²⁵ During this time, twenty other states had similar laws.²²⁶ 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.²²⁷ Such a requirement “effectively force[d]” distillers to drop their promotional allowance program in other states and other states had to alter their own regulations in order accommodate New York’s pricing schedule.²²⁸ Thus, such effective interference with other states’ commerce and regulatory schemes constituted an impermissible violation of the Commerce Clause.²²⁹

Furthermore, it is also important to note here that *Brown-Forman* highlights the dominance of the Commerce Clause when a state’s constitutional rights over certain domains are involved.²³⁰ Specifically in this case, the right invoked is the state’s Twenty-first Amendment

²²⁴ See *Brown-Forman*, 476 U.S. at 583.

²²⁵ *Brown-Forman*, 476 U.S. at 576.

²²⁶ *Id.*

²²⁷ *Id.* at 584.

²²⁸ *Id.*

²²⁹ *Id.*

²³⁰ *Id.* at 584 (noting that the Court’s task is to reconcile the interests of conflicting constitutional provisions; 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))).

power to regulate the sales of liquor within its territory.²³¹ 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 foreign country [citation omitted] or another State.”²³² 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.²³³

(3) Failure under the Balancing Test

Under the balancing test, the benefits of a state law are weighed against 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.²³⁴ Facially neutral laws treat in-

²³¹ *Id.* at 585.

²³² *Id.*

²³³ *See supra* Part III.

²³⁴ *See, e.g.,* Dean Milk Co. v. Madison, 340 US 349, 354-56 (1951) (city ordinance requiring milk be pasteurized within five miles of city deemed facially discriminatory); Philadelphia v. New Jersey, 437 U.S. 617 (1978) (state law preventing importation of waste from out-of-state to be facially discriminatory).

staters and out-of-staters equally and are deemed unconstitutional if their purpose and/or effect are discriminatory.²³⁵ 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.²³⁶

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.²³⁷ In *Dean Milk Co.*, a local law required all milk sold in Madison to be pasteurized in within five miles of the city.²³⁸ 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.²³⁹ 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

²³⁵ See, e.g., *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383 (1994); *Hunt v. Washington State Apple Advertising Commission*, 432 U.S. 333 (1977) (State law banning import of apples with any grade other than USDA grade is facially neutral but invalid because it discriminated against interstate commerce and lacked a legitimate state interest).

²³⁶ *Id.*; *Dean Milk Co.*, 340 US 349.

²³⁷ *Dean Milk Co.*, 340 U.S. 349.

²³⁸ *Id.* at 350.

²³⁹ *Id.* at 354.

nondiscriminatory alternatives, adequate to conserve legitimate local interests, are available.²⁴⁰

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.”²⁴¹ 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.²⁴²

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, as the Court has deemed such power to regulate similar to protection of citizens’ health and safety.²⁴³ Specifically, the Court describes state regulation of highways to be a “peculiarly local . . . subject of safety . . . akin to quarantine measures.”²⁴⁴ 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.”²⁴⁵ Notwithstanding such deference, the Court will invalidate such a law if its resulting benefits are minimal and the costs to interstate commerce are great:

²⁴⁰ *Id.*

²⁴¹ *Id.* at 356.

²⁴² *Maine v. Taylor*, 477 U.S. 131 (1986).

²⁴³ *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 523 (1959).

²⁴⁴ *Id.*

²⁴⁵ *Id.*

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.²⁴⁶

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.²⁴⁷ This safety requirement incurred too great a cost by prescribing standards that conflict with other states, thus forcing the industry to invest time and money in conforming to these various standards in order to conduct interstate business.²⁴⁸ The Court pointed to the nearby state of Arkansas opposite requirement of straight or conventional mudguards as an example.²⁴⁹

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.²⁵⁰ 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.²⁵¹ In *Kassel v. Consolidated*

²⁴⁶ *Id.* at 524 (*quoting* *Southern Pacific Co. v. Arizona*, 325 U.S. 761, 775-776 (1945)).

²⁴⁷ *Id.* at 528.

²⁴⁸ *Id.*; *but see* *South Carolina State Highway Dept. v. Barnwell*, 303 U.S. 177 (1938) (upholding state law barring use of motor and semitrailer trucks on state highways whose width and weight exceeded certain thresholds).

²⁴⁹ *Id.* at 527.

²⁵⁰ *See, e.g.*, *Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 674 (1982) (invalidating state law banning 65-foot double trailers); *Raymond Motor Transp., Inc. v. Rice*, (invalidating state law banning double-trailer trucks and trucks exceeding 55 feet).

²⁵¹ *Id.*

Freightways Corp., the Court invalidated the state’s ban on 65-foot double trailers because the “State failed to present any persuasive evidence that [these] trailers were less safe” and the law “substantially burdens interstate commerce” by forcing these trucks to avoid the state or to detach the trailers and ship them separately.²⁵²

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.²⁵³ 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.²⁵⁴

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

²⁵² Kassel, 40 U.S. at 674.

²⁵³ *See supra* Part III.

²⁵⁴ *See supra* Part IV.

V. 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.²⁵⁵ Second, the Spending Power grants Congress with the broad power to spend for the general welfare so long as it does not violate other Constitutional provisions.²⁵⁶

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*.²⁵⁷ 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;²⁵⁸
- (2) Regulation and protection of instrumentalities of interstate commerce²⁵⁹; or
- (3) Regulation of activities having substantial effect on commerce.²⁶⁰

²⁵⁵ *Gibbons*, 22 U.S. at 19-196 (J. Marshall) (“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”).

²⁵⁶ *United States v. Butler*, 297 U.S. 1, 66 (1936).

²⁵⁷ *United States v. Lopez*, 514 U.S. 549 (1995).

²⁵⁸ *Id.* at 552.

²⁵⁹ *Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241, 558-559 (1964).

²⁶⁰ *Lopez*, 514 U.S. at 559.

In evaluating whether Congressional action falls under either of these categories, the Court applies rational basis review. Rational basis review only requires that Congress choose a means that is reasonably adapted to achieve its goals.²⁶¹ 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.²⁶² 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.²⁶³ 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.²⁶⁴ 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

²⁶¹ *Id.* at 557.

²⁶² *Id.* at 558.

²⁶³ *Id.* at 559.

²⁶⁴ *Id.* at 562.

Act itself did not regulate commerce, and no formal findings demonstrated a link between commerce and gun possession.²⁶⁵

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.”²⁶⁶ The *Lopez* Court offers the following examples of applicable “persons” or “things”: destruction of aircraft, thefts from interstate shipments, and regulation of railroads.²⁶⁷

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.”²⁶⁸ The *Lopez* Court defined “substantial effect” to include intrastate production of a commodity that in the aggregate impacts interstate economic activity.²⁶⁹ For example, the Court held that Congress’ commerce authority applies to ban the cultivation and possession of small amounts of home-consumed marijuana despite a state law permitting otherwise.²⁷⁰ According to the court, home production of marijuana in the

²⁶⁵ *Id.* at 562-563.

²⁶⁶ *Lopez*, at 514 U.S. at 558.

²⁶⁷ *Id.* at 558.

²⁶⁸ *Id.* at 559.

²⁶⁹ *Id.* at 563.

²⁷⁰ *Gonzalez v. Raich*, 545 U.S. 1 (2005).

aggregate would have a substantial effect on interstate commerce because home consumption “would have substantial influence on price and market conditions.”²⁷¹

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.²⁷²

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.²⁷³

In *United States v. Butler*, the Supreme Court established the scope of Congress’ 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 Constitutional provisions.²⁷⁴ In reaching this interpretation, the Court adopted Alexander Hamilton’s view that

²⁷¹ *Id.* at 19.

²⁷² *See supra* Part III.

²⁷³ U.S. CONST. art. I, § 8.

²⁷⁴ *Butler*, 297 U.S. at 66 (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 Steward Machine Co. v. Davis*, 301 U.S. 548 (1937) (Social Security

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.²⁷⁵

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.²⁷⁶

This paper has already pointed to instances where Congress has invoked the Spending Power to regulate various aspects of health care.²⁷⁷ As long as each of the following three criteria are met, Congress may regulate:

- (1) The federal regulation in question advances the general welfare;²⁷⁸
- (2) The federal regulation in question is clearly expressed to recipient states and bear some relationship to the spending program;²⁷⁹ and
- (3) The federal regulation is voluntarily accepted by States.²⁸⁰

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.

Act establishing the federal unemployment system deemed constitutional); *Helvering v. Davis*, 301 U.S. 619 (1937) (Social Security Act's old age pension program supported by federal taxes deemed constitutional); *Sabri v. United States*, 541 U.S. 600 (2004) (Federal criminal law banning bribery of state, local, and tribal officials of entities receiving at least ten thousand dollars in federal funds deemed constitutional).

²⁷⁵ *Id.* at 65.

²⁷⁶ See Jerry L. Mashaw & Theodore R. Marmor, *The Case for Federalism and Health Care Reform*, 28 CONN L.R. 115 (1995); Noah, *Supra* note 114, 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”)

²⁷⁷ See *supra* Part IV.

²⁷⁸ *Helvering v. Davis*, 301 U.S. 619 (1937).

²⁷⁹ *Pennhurst State Hospital v. Halderman*, 451 U.S. 1, 17 (1981); *South Dakota v. Dole*, 483 U.S. 203, 212 (1987).

²⁸⁰ *Oklahoma v. Civil Service Commission*, 330 U.S. 127 (1947).

(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 clearly interwoven in our day with the well-being of the Nation.²⁸¹

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’ requirement that states impose a 21-year old drinking age in order to receive federal highway funds.²⁸² 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.”²⁸³

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.²⁸⁴ In reinforcing the reach of the Spending Power,

²⁸¹ *Helvering*, 301 U.S. at 640-641.

²⁸² *Dole*, 483 U.S. at 212.

²⁸³ *Id.*

²⁸⁴ *Civil Service Commission*, 330 U.S. at 143.

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.”²⁸⁵ 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.

(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*.²⁸⁶ 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’ 21-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.²⁸⁷ 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.

²⁸⁵ *Id.*

²⁸⁶ *Pennhurst State Hospital v. Halderman*, 451 U.S. 1, 17 (1981).

²⁸⁷ *Dole*, 483 U.S. at 212.

(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.²⁸⁸ Here, the federal government already buys a substantial portion of physician and clinical services, thus providing the basis on which the Spending Power may be exercised.²⁸⁹ As discussed earlier, Congress has imposed limited regulation under several of its health-related funding programs, such as Medicare and Medicaid.²⁹⁰ 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 1996 offers an ideal opportunity in the context of telemedicine.²⁹¹ This Act provides rural health care providers with subsidies to the extent that rural rates are higher than urban rates.²⁹² Thus, the Spending Power offers existing and potential opportunities for uniform standards and regulations in telemedicine.

²⁸⁸ Civil Service Commission, 330 U.S. 127 (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); Dole, 483 U.S. 203 (upholding a federal law establishing 21-year old drinking age by withholding a portion of federal highway funds from any state government that failed to impose such a drinking age).

²⁸⁹ Noah, *supra* note 114, at 169.

²⁹⁰ *See supra* Part III.

²⁹¹ 47 U.S.C. § 151 (1996) (Requires 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).

²⁹² 47 U.S.C. § 254 (1996).

VI. 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;²⁹³ (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 are analyzed below.

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

The imposition of national standards in telemedicine will reduce and/or remove transaction costs and administrative inefficiencies that currently dissuade telemedicine providers from operating regionally and/or nationally. For example, to illustrate the degree to which differing state licensing requirements impact a telemedicine provider's ability to conduct its business, it is instructive to consider the predicament of Nighthawks, an Australian-based radiology services company that operates globally. Nighthawks assigns more employees to the

²⁹³ See Gulick, *supra* note 10, at 205, 206-207.

task of getting licensure approval of its radiologists than the total number of radiologists employed by it.²⁹⁴

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 jurisdiction 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."²⁹⁵ Just as importantly, a national licensure system resolves another telemedicine barrier – jurisdiction and choice of law concerns – by imposing federal jurisdiction in disputes involving citizens of different states. In mandating federal jurisdiction, the same law and procedures will be applied to all fifty states. Such uniformity in other areas of health care touching upon telemedicine will likewise encourage greater interstate delivery of health care. These other examples include, among others: applying JCAHO requirements to set telemedical credentialing requirements,²⁹⁶ and 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 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.²⁹⁷ Professor

²⁹⁴ E-mail from Dr. Sanjay Saini, Professor of Radiology, Harvard Medical School, & C.E.O of Partners Radiology, to Deth Sao, Research Assistant to Dr. Amar Gupta, (Feb. 2, 2010, 21:04 MST) (on file with author).

²⁹⁵ Sulentic, *supra* note 213, at 36.

²⁹⁶ *See* Volkert, *supra* note 7, at 159.

²⁹⁷ Sulentic, *supra* note 213, at 36.

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.”²⁹⁸

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 influence where health professionals choose to practice, as there is evidence suggesting that they avoid jurisdictions with higher malpractice damage awards and unfavorable procedures.²⁹⁹

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.³⁰⁰ Another related example is accreditation requirements, as this paper earlier noted that Medicare and Medicaid impose operational standards on health care entities in exchange for funding.³⁰¹ In particular, hospitals are subject to the rules of the Joint Commission on Accreditation of Health Care Organizations (JCAHO), which is a private accreditation organization.³⁰² According to Kevin

²⁹⁸ *Id.* at 37.

²⁹⁹ Noah, *supra* note 136, at 186.

³⁰⁰ *See supra* Part IV.

³⁰¹ *See* 42 USC §1395x(e) (2001) (hospitals); 42 USC §1395x(m) (home health services); 42 CFR §§484.1-484.55 (2001) (various types of providers).

³⁰² *See* 42 USC §1395bb(a)

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.”³⁰³ 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 instructive examples of an overarching telemedicine regime. Malaysia serves as a forerunner in enacting laws that regulate telemedicine.³⁰⁴ For example, Malaysia’s Telemedicine Act of 1997 grants a certificate to practice telemedicine to physicians who are licensed to practice in that nation and those who are licensed abroad.³⁰⁵ On a regional level, the European Union (EU) has demonstrated the irrelevance of geographic barriers with regards to ensuring access to and providing quality medical treatment. The EU’s “Doctor’s Directive 93/16” requires that member states grant legal effect to diplomas of physicians obtained in other member states as long these diplomas

³⁰³ Outterson, *supra* note 117, at 519.

³⁰⁴ 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 concerning telemedicine, such as licensure, informed consent and telemedicine standard development”).

³⁰⁵ Telemedicine Act, Act 564 cl. 4(1) (1997) (Malaysia).

meet the minimum training requirements listed in the Directive.³⁰⁶ Thus, the Directive serves to fulfill the policy goals of “full free movement” and “guarantee[ing] the quality of the entrants to the profession.”³⁰⁷ While the EU does not directly address telemedicine, the implementation of such a measure supports 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.

VII. 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.³⁰⁸ 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

³⁰⁶ Council Directive 93/16/EEC to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications, 5 April 1993, Official Journal L 165, 07.07.1993, p. 1-24.

³⁰⁷ M. Peeters, *Free Movement Of Medical Doctors In The EU*, 26 *Med. & L.* 231, 235 (2007).

³⁰⁸ See, e.g., Mclean, *The Future of Telemedicine & Its Faustian Reliance on Regulatory Trade Barriers for Protection*, 16 *Health Matrix* 443, 501 (2006).

this paper for several reasons. First, the enforcement of GATS provisions under the World Trade Organization's (WTO) dispute settlement mechanism is an inappropriate forum for resolving medical malpractice disputes among private parties. The WTO restricts standing to only 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.³⁰⁹ 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.³¹⁰ 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.³¹¹ 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.³¹² 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.

³⁰⁹Jose E. Alvarez, *The New Dispute Settlers: (Half) Truths And Consequences*, 38 TEX. INT'L L.J. 405, 415 (2003).

³¹⁰World Trade Organization, *Understanding on Rules and Procedures Governing the Settlement of Disputes*, Apr. 15, 1994, available at http://www.wto.org/english/docs_e/legal_e/28-dsu.doc [hereinafter *Settlement of Disputes*].

³¹¹See 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.

³¹²See 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).

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 promulgate and enforce supranational regulatory framework and standards. For example, the World Health Organization (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.³¹³ Notably, the WHO comprises of 194 member nations,³¹⁴ one of the largest memberships of an international body or treaty.³¹⁵ Because the WHO embraces and incorporates more countries than many other organizations, there will likely 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.³¹⁶ 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.³¹⁷ Furthermore, the WHO may serve as the

³¹³ Gulick, *supra* note 10, at 212.

³¹⁴ World Health Organization, What are the International Health Regulations, <http://www.who.int/features/qa/39/en/index.html> (last visited January 29, 2010).

³¹⁵ In comparison, there are 140 signatory countries to the GATS. The World Trade Organization, The General Agreement on Trade in Services (GATS): Objectives, Coverage and Disciplines, http://www.wto.org/english/tratop_e/serv_e/gatsqa_e.htm#2 (last visited Feb. 1, 2009).

³¹⁶ *Id.*

³¹⁷ *Id.*

final arbiter of legal disputes involving international parties.³¹⁸ Thus, rather than relying on nations to coordinate their varying regulatory regimes and standards, it is likely more optimal in the interests of advancing the policy goals of greater quality and access to health care by deferring authority in this area to global institutions such as the WHO.

VIII. CONCLUSION

Telemedicine offers the potential to improve existing health care systems on national and international levels. At the same time that 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 interstate 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, just as with the Y2K problem with a fixed date, which forced the financial industry and other companies to embrace nontraditional

³¹⁸ *Id.*

solutions, such as getting work done abroad or relying on foreign programmers to come to the U.S.³¹⁹ Until 1999, such practices were frowned upon for reasons ranging from “violation of corporate policies” to breach of customer data privacy.³²⁰ The firm deadline of December 31, 1999, forced the companies to become more flexible.³²¹ As we face a similar dilemma in health care with escalating costs and growing discontent, but with no “drop dead date” in existence to force cohesive action,³²² our policymakers will be increasingly compelled to look at nontraditional options that involve rethinking of legacy status of relationships between state governments and national governments on various facets of health care.

³¹⁹ Gupta (2008), *supra* note 34.

³²⁰ Amar Gupta, Raj K. Goyal, Keith A. Joiner, & Sanjay Saini, *Outsourcing in the Healthcare Industry: Information Technology, Intellectual Property, and Allied Aspects*, 21 INFO. RES. MGMT. J. 1, 2008.

³²¹ *Id.*

³²² *See id.*