

Enabling Globalization of Health Care in the Information Technology Era: *Telemedicine and the Medical World Wide Web*

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ABSTRACT

Information technology (IT) and accompanying medical breakthroughs may facilitate promising global opportunities for better and more accessible health care. This possibility derives from the border-free characteristic of Internet-based communication, technical advances, and a prominent trend of outsourcing expensive medical services to less expensive, international providers through what might be collectively called “electronic medical tourism.” However, full realization of the potential benefits of these trends remains contingent upon harmonizing cross-national requirements and standards. Current legal regimes exert a chilling effect on the development of digital medicine as a global health facilitator for both developing and developed countries. To expedite IT dissemination as a vehicle for global health promotion, a concerted action aimed at establishing an international consortium on Internet-based Medical-WWW is presented, and some of its salient features are discussed along with their legal ramifications. Cyberspace has become a most important territory, and the pace of change requires effective adaptation of health-care law.

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I. INTRODUCTION

This Article aims at drawing more attention to the beneficial contribution of *information technology* to the *globalization of health care*, terms I wish to clarify on the outset. By “information technology” (IT), I refer to the spectrum of applications that arise from the advent and continuous progress of the computing and communication sciences and applications. This includes the Internet (e-health); social networks; “smart” cellular/mobile communication (known as “m-health” in medical contexts); electronic health/medical records; medical databases; and the emerging telemedicine industry in its expansive meaning, such as telecare (e.g., telesurgery or telepsychiatry), telemonitoring (such as for patients with chronic diseases), and professional education. The dominant and tangible example of telemedicine (TM) will serve below as the case study in reviewing legal and regulatory responses in the IT arena. While a significant body of literature has dealt with the legal implications of TM,¹ only limited space has been devoted to the potential of IT/TM to propel the globalization of health care as a top-down policy goal.²

¹ See generally Jon D. Blum, *Internet Medicine and the Evolving Legal Status of the Physician–Patient Relationship*, 24 J. LEGAL MED. 413 (2003); Melissa M. Goldstein, *Health Information Technology and the Idea of Informed Consent*, 38 J.L. MED. & ETHICS 27 (2010); Thomas R. McLean, *The Future of Telemedicine & Its Faustian Reliance on Regulatory Trade Barriers for Protection*, 16 HEALTH MATRIX 443 (2006); 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 (1997); Shannon S. Venable, *A Call to Action: Georgia Must Adopt New Standard of Care, Licensure, Reimbursement, and Privacy Laws for Telemedicine*, 54 EMORY L.J. 1183 (2005); Peter Zawadski, *International Outsourcing plus Inexpensive, Quality Healthcare: Binding Arbitration Makes This Telemedical Dream a Reality*, 18

The term “globalization” could have different meanings to different audiences. For some the term is associated with positive aspirations to shared knowledge and efficient, open access to goods within and among nations. To others, it offers the prospect of a global market³—in the health care arena, a global market for medical services, especially medical tourism and telemedicine. The term would carry a negative meaning for others who perceive increasing global economic and social integration as a conspiracy by the rich and powerful to exploit the poor and underprivileged.⁴ While this Article does not entirely dismiss such negative claims in the sense that we need to assure that all stand to benefit from proposed progress,⁵ throughout this Article the former sanguine interpretations are the basic premise, as the aim is to pinpoint legal and political instruments needed to increase the provision of better, cost-saving health care to those in need. Under such an understanding, globalization of health care comes close to the “access to care” discussion, and thus is pertinent to developed countries as well as developing ones—disparities in health outcomes and availability of medical services has been documented in the former countries as well.⁶ Therefore, this Article aims to make the case for the United States and other international parties to further invest in IT in order to promote the globalization of health care both for internal and external arenas. Since regulatory and legal barriers seem to be a major impediment to such evolution, resolving these obstacles carries the promise of health care to underserved strata in our domicile as well as our global world. This paper is by no means the first introduction of the benefits of health-related IT to health systems—on the American front, the list of federal bodies that have already identified and invested in IT/TM is impressive,⁷ and similar initiatives have started or are being promulgated in this area internationally.⁸ However, this Article seeks to accentuate a different perspective, namely the need for framing IT as a principal vehicle for globalization of health care, and the need for corollary investments in the needed institutions and infrastructure in order to realize this promise.

Notably, the more familiar aspect of globalization in health care that relates to common threats to public health that emerge from the development of the world into one global village⁹ are not dealt with here, even though IT has much to offer¹⁰ on this front (e.g., data collection and

HEALTH MATRIX 137 (2008); Amar Gupta & Deth Sao, *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*, SELECTED WORKS OF DETH SAO (April 2010), http://works.bepress.com/cgi/viewcontent.cgi?article=1001&context=deth_sao.

² See generally Jon 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); Leah B. Mendelsohn, *A Piece of the Puzzle: Telemedicine as an Instrument to Facilitate the Improvement of Healthcare in Developing Countries*, 18 EMORY INT’L L. REV. 151 (2004).

³ Thomas R. McLean, *The Global Market for Health Care: Economics and Regulation*, 26 WIS. INT’L L.J. 591, 593 (2008).

⁴ See generally JOSEPH E. STIGLITZ, *GLOBALIZATION AND ITS DISCONTENTS* (2003).

⁵ See Zahra Meghani, *A Robust, Particularist Ethical Assessment of Medical Tourism*, 11 DEVELOPING WORLD BIOETHICS 16, 23–24 (2011) (demonstrating how current medical tourism deprives disadvantaged groups in developing countries).

⁶ See, e.g., David H. Peters et al., *Poverty and Access to Health Care in Developing Countries*, 1136 ANNALS N.Y. ACAD. SCI. 161 (2008), available at <http://onlinelibrary.wiley.com/doi/10.1196/annals.1425.011/pdf>.

⁷ See *infra* Part II.B.

⁸ See *infra* Part II.B.

⁹ See generally MARSHALL McLuhan & BRUCE R. POWERS, *THE GLOBAL VILLAGE: TRANSFORMATIONS IN WORLD LIFE AND MEDIA IN THE 21ST CENTURY* (1992).

¹⁰ A recent example of IT in the global public health front is the South African system using smartphones to help control the spread of tuberculosis (TB). Patients’ homes are located using Google Earth, allowing smartphone-carrying health workers to visit. Then, using the smartphone, the health worker

data mining, reporting and dissemination of information on fast spreading infectious diseases,¹¹ or to resolve collective action problems and sustain public goods via concerted actions).¹²

As for modern *health care*, there are numerous contributing factors to the growing dominance of health care in our lives, including changes in society (patients as consumers), the progress of medicine and science (improved diagnosis, treatment modalities, and computing and information technologies), and the large-scale economic implications of health care (the daunting, growing portion of health-related expenditures of the GDP/GNP). One important insight in this regard is that health-care and health-delivery systems are changing in their very nature, and these changes are not limited to one country or a particular continent but rather represent global trends. Such commonality, therefore, lends itself to multilateral global solutions. One such prospect is to harness IT to address national and international infrastructure deficiencies in existing health-care services. The technical advances in communication have underpinned the advance of globalization in all spheres of the economy, and health should be no exception. On the contrary, IT as a banner can mobilize decision-makers as well as professionals into greater involvement in the somewhat exhausted “globalization of health care” debate. If framed in this way, the promise of IT-globalization has something to offer all parties involved: patients, providers, insurers, national health systems, and the international community.

Various areas of law are thus implicated in this multilayer web—public and private international law, as well as domestic public and private laws and regulations. As a result, the breadth of legal issues that require our attention is breathtaking, and a need to choose some and neglect others is inevitable in this Article. However, while delineating the most central legal issues that must be addressed, my aim here is to argue for a need to converge domestic and international policy efforts to allow for a better and more efficient dissemination and utilization of IT-driven health care. In doing so, a critical review of parochial protectionism currently employed is offered.

The Article proceeds in the following way: Part II delineates some germane features of modern health care as reflected by the parties involved and evolving technologies that bring about some of the current transitions. The introduction of IT to health care allowed for e-health and TM to move from vision to reality, and the driving forces and current barriers are briefly summarized. Part II concludes with some American, European, and other international responses to e-health and TM, illuminating a rather neglected aspect—the possibility to enhance globalization of affordable high quality medical care via a stronger commitment to IT exploitation. Part III takes a close look at current (inhibitory) legal regulation, with a special emphasis on licensure, liability, insurance coverage, and data protection. Part IV offers some directions where more work needs to be done in order to facilitate the contribution of IT to the globalization of health care. I make use of the flourishing medical tourism phenomenon and introduce the concept of “*electronic* medical tourism” as helpful in overcoming contemporary conceptual legal barriers and as a way to propel TM dissemination. In a nutshell, what is permitted or not prohibited in the physical world (e.g.,

can send patients’ information immediately to the health authorities. See *Smartphones to Track TB Patients*, NEWS24.COM, Mar. 24, 2011, <http://www.24.asdfasdfsasf4.com/SouthAfrica/News/Smartphones-to-track-TB-patients-20110324>.

¹¹ David P. Fidler & Lawrence O. Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 34 J.L. MED. & ETHICS 85 (2006); Allyn Taylor & Lawrence O. Gostin, *Global Health Law: A Definition and Grand Challenges*, 1 PUB. HEALTH ETHICS 53 (2008).

¹² See generally Gil Siegal, Neomi Siegal & Richard J. Bonnie, *An Account of Collective Actions in Public Health*, 99 AM. J. PUB. HEALTH 1583 (2009).

traveling to another country for medical care) should be allowed prima facie in the electronic/digital context, legality, safety, and quality requirements notwithstanding.¹³ Suggestions to regulate medical tourism and to guarantee the quality of care and the patients' safety, as well as their legal rights, can be adapted to digital medical tourism, with some added values. Part IV then goes on to call for a more robust dedication of international resources and greater efforts toward concerted action in order to promote IT health-care systems, where all stand to benefit—the contributing and recipient countries and their respective citizenries. To this end, the basic elements of a medical World Wide Web (M-WWW) platform are introduced, including the identification of its possible key leaders; eligibility of potential providers; financing considerations; and assurance of redress for injured patients.

II. THE CHANGING FACE OF MODERN HEALTH CARE

Information technology is one of the most powerful tools to spread the benefits of modern technology, either directly or indirectly, via access to knowledge. Indeed, people today expect to live longer and healthier lives than in the past. Individuals as health consumers, especially in developed countries (but clearly not limited only to those countries), now have better access to information pertaining to their health, various alternative providers or treatments, and information on cutting-edge medical technology that might—although not without price—improve their health conditions or ameliorate current ailments. Thanks to the Internet, such knowledge is generated on a global scale (widely known as the “information society”), and geography is becoming less of an issue. In addition, in the American context (and also in other countries)¹⁴ dissatisfied individuals, or individuals without access to local services (usually due to lack of insurance or unavailable services) are able to explore solutions to their health problems elsewhere. In this sense, globalization of health is about the process of long-distance exchange of medical services in an informed society. While citizens of developed countries are the prime drivers in this transformation, citizens in developing countries are gradually reaping the benefits of the information society in all aspect of their lives, including their health needs. This worldwide process can continue to be propelled in a bottom-up fashion by “e-patients” (who are equipped, enabled, empowered, and engaged).¹⁵ However, a top-down institutional/governmental thrust would have far-reaching impacts with respect to resource allocation, dissemination, and surmounting regulatory barriers.

Medical institutions are striving to increase their capabilities, improve quality, and to assure financial stability. Technology that can offer efficient yet improved care is the prime target of providers, as they attempt to increase their capacities to offer treatment to an optimal number of patients in order to generate much-needed revenues. To that end, many institutions address international or out-of-state audiences (just recall the advertisements in the airline magazine on your last flight). In addition, in answering regulatory pressure for meeting standards for quality and safety, these institutions must incorporate IT into their daily practices and infrastructure.

¹³ In the EU case law, neither the special nature of health services nor the way in which they are organized or financed removes them from the ambit of the fundamental principle of freedom of movement. A recipient of a health-care service may therefore freely seek and receive medical treatment from another Member State, regardless of how the service is delivered, i.e., also by telemedicine. In principle, the fact that telemedicine is a service delivered by electronic means does not constitute a reason for treating telemedicine as a special type of health service. See *Telemedicine for the Benefit of Patients, Healthcare Systems, and Society*, at 17, COM (2009) 943 final (June 2009).

¹⁴ Case C-372/04, *Watts v. Bedford Primary Care Trust*, 2006 E.C.R. I-04325.

¹⁵ See TOM FERGUSON ET AL., *E-PATIENTS—HOW THEY CAN HELP US HEAL HEALTHCARE 2* (2007), available at http://e-patients.net/e-Patients_White_Paper.pdf.

Finally, outsourcing medical services to other countries (most notably in teleradiology) allows significant cost saving.¹⁶

Insurers and health maintenance organizations (whether those in the American model or other nations' institutions, such as health trusts in the United Kingdom or health care providers in Israel) attempt to meet their legal obligations (whether contractual or as dictated by law) to cover health care, contain rising costs, and assure financial sustainability. Relying on empirical data from multiple demonstration projects, TM has much to offer for strategic restructuring of service provisions and to overcome current disparities within their services.¹⁷ Enhanced IT capabilities also allow for improved organization performance (such as data mining and utilization reports) and identifying pockets of under/over utilization and disparities in health outcomes.

National stakeholders (i.e., policy makers and regulators in the health and treasury/finance departments) need to accommodate competing interests while guaranteeing respect of budgetary constraints; they also need to be convinced that investments in health pay off. The prospects of harnessing IT/TM to improve public health are truly endless and are only recently starting to emerge in a more systematic fashion. Serving chronically ill patients via telemonitoring and helping patients manage their prescription drug regimens via reminders on their cellular phones are examples of such possibilities.¹⁸

Lastly, a growing commitment of developed nations and supranational bodies to the health of less fortunate countries has generated a steady influx of resources to build and maintain needed infrastructure, education, training, and the supply of medication.¹⁹ While some of these efforts have had tremendous impacts, overcoming local cultural, political, and social conditions has lowered overall success. IT and TM offer an important addition to the armory of international health aid efforts.

Thus, it seems clear that IT has been, and is, in the midst of revolutionizing the ways health care is provided. However, a thorny question persists: are we doing enough to expand the range of benefits available, both domestically and on a global scale?

A. The Maturing Promise of IT in Health Care Delivery: The Evolving Landscape of Telehealth

The following represents a cursory, bird's-eye view of some of the salient directions in which IT is reshaping the health-care scene. These changes touch on all aspects of health care and implicate both patients and providers. Importantly, as the industry is able to standardize communications and semantic protocols, quality and safety disquiet concerning the infrastructure is gradually becoming obsolete. For example, digital images that are produced on one system may be accurately stored, communicated, and interpreted across different hardware platforms regardless of location; intensive care patients do well on home remote monitoring.²⁰ Thus,

¹⁶ Rebecca S. Lewis, Jonathan H. Sunshine & Mythreyi Bhargavan, *Radiology Practices' Use of External Off-Hours Teleradiology Services in 2007 and Changes Since 2003*, 193 AM. J. ROENTGENOLOGY, 1333, 1339 (2009) (In 2007, forty-four percent of all radiology practices in the United States reported using teleradiology.).

¹⁷ See *infra* note 30 and accompanying text.

¹⁸ See *infra* note 30 and accompanying text.

¹⁹ See *infra* Part IV.B.

²⁰ See, e.g., Ben Townsend, Jemal Abawajy & Tai-Hoon Kim, *SMS-Based Medical Diagnostic Telemetry Data Transmission Protocol for Medical Sensors*, 11 SENSORS 4231 (2011), available at

demonstration projects abound and positive outcomes around the globe²¹ are constantly generated.²² The thematic fields of IT and TM include the following:

- Electronic medical/patient records that allow 24/7 access to and sharing of a patient's medical history, medication plan, or imaging studies.²³ Some countries' health systems have reached a near-complete transformation to digital information systems,²⁴ while others (notably the United States) are yet to follow.²⁵
- Remote patient care: TM offers new ways of counseling, treating, and managing patients with acute and chronic conditions—tele dermatology, telepsychiatry, or telesurgery,²⁶ to name just a few such examples. In addition, monitoring services include help lines, reminders, and tracking individuals with remote sensors and providing care, if needed.
- Safety and quality support systems, including medication, diagnostics, and treatment-decision support systems software.²⁷
- Health education and awareness, most notably using the Internet and lately even social networks.
- Remote data gathering (surveys, disease surveillance, research trials).
- Health e-commerce and e-prescription.
- Distant professional training of health workforce.
- Mobile health (m-health). TM and e-health are multiplying their potency with the addition of mobile capacities. As envisioned by the International Telecommunication Union (the leading United Nations agency for information and communication technology issues):

<http://www.mdpi.com/1424-8220/11/4/4231/>.

²¹ For a recent compilation of some international TM projects in different countries, see generally INT'L TELECOMM. UNION, QUESTION 14-2/2: MOBILE EHEALTH SOLUTIONS FOR DEVELOPING COUNTRIES (2010), available at http://www.itu.int/dms_pub/itu-d/opb/stg/D-STG-SG02.14.2-2010-PDF-E.pdf (reporting on projects in Algeria, Armenia, Germany, India, Italy, Japan, Nepal, Oman, Philippines, Thailand, Russia, and Uganda).

²² See *infra* notes 32–36 and accompanying text.

²³ For example, companies such as MMR Global and Gi Technologies provide such services. See MMRGLOBAL, <http://www.mmrglobal.com/about/> (last visited Feb. 16, 2012); *Gi EMR—Electronic Medical Records*, GI TECHNOLOGIES, <http://gi-technologies.com/solutions/healthcare.html> (last visited Feb. 16, 2012).

²⁴ See, e.g., *Belize Health Information Goes Digital*, 87 BULL. WORLD HEALTH ORG. 87 (2009), available at <http://www.who.int/bulletin/volumes/87/2/09-020209/en/index.html>.

²⁵ See Health Information Technology for Economic and Clinical Health (HITECH) Act, Pub. L. No. 111–5, 123 Stat. 226 (2009) (codified as amended in scattered sections of 42 U.S.C.) (providing for various initiatives within the Department of Health and Human Services to promote the use of health IT throughout the United States); *EHR Incentive Programs Overview*, CENTERS FOR MEDICARE & MEDICAID SERVICES (Dec. 5, 2011), <https://www.cms.gov/ehrincentiveprograms> (explaining incentive payment programs to encourage health-care providers to utilize electronic health records technology).

²⁶ See generally Lavoisier J. Cardozo et al., *Implementing the Chronic Disease Self Management Model in Vulnerable Patient Populations: Bridging the Chasm Through Telemedicine*, in *ADVANCES IN TELEMEDICINE: TECHNOLOGIES, ENABLING FACTORS AND SCENARIOS* 357 (Georgi Grasczew & Theo A. Roelofs eds., 2011), available at www.intechopen.com/download/pdf/pdfs_id/14287.

²⁷ See generally David W. Bates & Atul A. Gawande, *Improving Safety with Information Technology*, 348 NEW ENG. J. MED. 2526 (2003).

With mobile communication, populations can be treated in their homes and communities with access to expert care. Any health-care personnel can get access to vital information anywhere and at any time. Wireless technologies increase real time access to accurate patient data, including clinical histories, treatment, medication, tests, laboratory results, etc. and result in overall improvement of patient care and the provision of personalized health services. Mobile technologies can also improve data accuracy and significantly reduce errors during data collection and disease surveillance. Mobile clinics and mobile portable e-Health terminals can take health care to distant locations to support prompt medical assistance at remote sites or during emergency responses.²⁸

What seems rather clear from the above exposition is that one must reject the generic plea for one-size-fits-all regulation of e-health and TM, since the subject matter of regulation in this case is greatly heterogeneous, and different answers must be given to different aspects of TM. This in turn implies the need to bring forth a legal and regulatory analysis of each proposed TM area, and the attempted application of one solution to another area must be carefully reviewed.

The business model of TM varies. In some instances, the direct-to-consumer (DTC) model is dominant (such as telemonitoring or second opinion companies), while in other circumstances a business-to-business (B2B) model is employed (such as teleradiology outsourcing between institutions).²⁹ Publicly funded national/governmental programs are also increasing, and in the United States a considerable increase is expected following the 2009 Recovery Act allotment.³⁰ These different models implicate different legal issues, and thus necessitate different legal responses. For example, the regulatory point of leverage in the B2B model is the institutions involved, or conditional spending in the case of public financing, whereas in a DTC scenario, public education seems a leading path, which curtails the effectiveness of regulation.³¹

1. Demonstrated Benefits

The list of published results on TM care is far too extensive to be reviewed here.³² While I provide some examples, the reader is advised to explore medical databases (e.g., PubMed) for hundreds of such publications. Generally, clinical outcomes seem to have a positive trend,³³ yet

²⁸ Mobile Solutions for *Health: Better Access to Healthcare for All*, INT’L TELECOMM. UNION (Dec. 9, 2010), <http://www.itu.int/ITU-D/cyb/app/e-health/mhealth.html>.

²⁹ See Giles W. L. Boland, *Teleradiology Coming of Age: Winners and Losers*, 190 AM. J. ROENTGENOLOGY 1161, 1161–62 (2008); Robert Steinbrook, *The Age of Teleradiology*, 357 NEW ENG. J. MED. 5, 6 (2007).

³⁰ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 21, 25, 26, 29, and 42 U.S.C.).

³¹ For example, requiring a local physician to retain “ultimate authority” over a patient seems to negate a DTC model. See *infra* note 103 and accompanying text.

³² Here I wish to emphasize one important, must-read paper: Nigel R. Armfield et al., *Humour Sans Frontieres: The Feasibility of Providing Clown Care at a Distance*, 17 TELEMEDICINE & E-HEALTH 316 (2011).

³³ Melinda Beeuwkes Buntin et al., *The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results*, 30 HEALTH AFF. 464, 466 (2011); Ann G. Ekeland et al., *Effectiveness of Telemedicine: A Systematic Review of Reviews*, 79 INT’L J. MED. INFORMATICS 736 (2010) (The review included eighty heterogeneous systematic reviews. Twenty-one

hype around TM should be avoided,³⁴ and medical benefits need to be clearly proven.³⁵ Cost cutting has been demonstrated in several areas,³⁶ but economic benefits require further demonstration.³⁷ Some beneficial aspects of TM seem hard to refute—allowing access to rural areas where such care is absent, ancillary savings by avoiding travel time lost, and the like.³⁸ However, these secondary gains are difficult to quantify. Recently, the Alaska Federal Health Care Access Network reported that the introduction of telehealth carts in hard-to-serve areas saved \$5.5 million in patient travel costs in 2010, a sixty-percent increase from 2009.³⁹ As a whole, that there are benefits to the evolution of IT in health care is clear; however, the nature and degree of the benefits are still being explored and, as this Article suggests, can be compounded by the top-down adaptation of relevant laws. The beneficial potential of IT is much more powerful once we consider the provision of care to developing countries, and especially to rural areas in

reviews concluded that telemedicine is effective; eighteen found that evidence is promising but incomplete; and others found that evidence is limited and inconsistent. Emerging themes are particularly problematic in the nature of economic analyses of telemedicine, the benefits of telemedicine for patients, and telemedicine as complex and ongoing collaborative achievements in unpredictable processes.).

³⁴ See generally Joanne Spetz & Dennis Keane, *Information Technology Implementation in a Rural Hospital: A Cautionary Tale*, 54 J. HEALTH MGMT. 337, 337 (2009).

³⁵ See generally Heinrich J. Audebert & Lee H. Schwamm, *Telestroke: Scientific Results*, 27 CEREBROVASCULAR DISEASES 15 (2009) (However, improved clinical outcomes of stroke patients have only been investigated and shown when telemedicine was combined with the Stroke Unit concept based on specialized stroke wards and organized stroke care.); Friedrich Koehler et al., *Impact of Remote Telemedical Management on Mortality and Hospitalizations in Ambulatory Patients with Chronic Heart Failure: The Telemedical Interventional Monitoring in Heart Failure Study*, 123 CIRCULATION 1873 (2010) (finding remote telemedical management compared with usual care was not associated with a reduction in all-cause mortality); Susannah McLean et al., *Telehealthcare for Asthma*, COCHRANE DATABASE SYSTEMATIC REV. (2010), available at www.thecochranelibrary.com/details/file/858047/CD007717.html (Telehealthcare interventions are unlikely to result in clinically relevant improvements in health outcomes in those with relatively mild asthma, but they may have a role in those with more severe disease who are at high risk of hospital admission. Further trials evaluating the effectiveness and cost-effectiveness of a range of telehealthcare interventions are needed.); Fenne Verhoeven et al., *The Contribution of Teleconsultation and Videoconferencing to Diabetes Care: A Systematic Literature Review*, J. MED. INTERNET RES. e37 (2007), available at <http://www.jmir.org/2007/5/e37/> (The selected studies suggest that both teleconsultation and videoconferencing are practical, cost-effective, and reliable ways of delivering satisfactory health care service to diabetics. However, the diversity in study design and reported findings makes a strong conclusion premature.).

³⁶ Maria E. Dávalos et al., *Economic Evaluation of Telemedicine: Review of the Literature and Research Guidelines for Benefit-Cost Analysis*, 15 TELEMED. & E-HEALTH 933 (2009); Caroline L. Goldzweig et al., *Costs and Benefits of Health Information Technology: New Trends From the Literature*, 28 HEALTH AFF. 282 (2009).

³⁷ See Trine S. Bergmo, *Economic Evaluation in Telemedicine—Still Room for Improvement*, 16 J. TELEMED. & TELE CARE 229, 229–31 (2010); Walter Palmas et al., *Medicare Payments, Healthcare Service Use, and Telemedicine Implementation Costs in a Randomized Trial Comparing Telemedicine Case Management With Usual Care in Medically Underserved Participants with Diabetes Mellitus (IDEATel)*, 17 J. AM. MED. INFORMATICS ASSOC. 196 (2010) (Telemedicine case management was not associated with a reduction in Medicare claims in this medically underserved population. The cost of implementing the telemedicine intervention was high, largely representing special purpose hardware and software costs required at the time. Lower implementation costs will need to be achieved using lower cost technology in order for telemedicine case management to be more widely used.).

³⁸ Peter M. Yellowlees et al., *Telemedicine Can Make Healthcare Greener*, 16 TELEMED. & E-HEALTH 229, 229–32 (2010).

³⁹ These costs are typically borne by either individuals or federal health programs such as Medicaid. See Andrew Jensen, *Technology Makes Native Care Accessible*, ALASKA J. COM., Mar. 18, 2011, http://classic.alaskajournal.com/stories/031811/ANC_tmna.shtml.

those countries (in India for example, 0.9% of the GDP is spent on health care in rural areas where 70% of the population lives, while 4.2% is allocated to the urban sector).⁴⁰ In such circumstances, IT is the sole realistic vehicle to provide medical care or even public health education. Therefore, it seems safe to speculate that the willingness to engage in demonstration projects for those populations should not be restricted by legal barriers, and positive outcomes (compared to current deep deficiencies) are to be anticipated.

B. National and International Responses

The last decade has demonstrated (though not with the equivalent impetus in all jurisdictions) that regulators are finally realizing the need for incorporating IT and TM to improve societal health. In the American arena, just recently the pertinent parts of the American Recovery and Reinvestment Act (i.e., the Health Information Technology for Economic and Clinical Health (HITECH) Act) and the health care reform legislation have set forth the clear intention of steering a broad utilization of IT in health care and an expeditious uptake of TM. This includes mobilizing Medicare and Medicaid to explore remote monitoring and the provision of services to underserved populations and areas through telehealth initiatives.⁴¹ As previously noted, many institutions and agencies have funded IT/TM demonstration projects. On the American front, the list of federal agencies that have already invested in TM includes the Departments of Health and Human Services, Agriculture, Defense, and Education; the Centers for Medicare and Medicare Services; the Office for the Advancement of Telehealth; the National Library of Medicine; the Agency for Health Care Research and Quality; and NASA.⁴² However, these empirical projects must be accompanied by a corollary regulatory and legal scheme that would enable easier dissemination of IT and TM. Regretfully, the pace of such change is far from what is needed. The lack of prominent public international law devices reflects a constant reliance on bottom-up processes driven by market forces (mostly by enthusiastic providers and the telecommunication industry) and not a proactive regulatory effort.⁴³ This in turn means that not only do IT companies need to come up with the science and technology (research and development), they need to struggle with law and regulation that for most part has been hostile or unsympathetic. Reaping the benefits of IT clearly requires a different state of mind on the part of regulators and legislators, facilitating rather than obstructing progress in this area.

In Europe, the EU Commission published a Communication in 2009 on “Telemedicine for the benefit of patients, healthcare systems and society.” This communication puts forward a plan of action for three strategic goals: “(1) Building confidence in and acceptance of telemedicine services, (2) Bringing legal clarity, (3) Solving technical issues and facilitating market development.”⁴⁴ The Commission intends to create guidelines by 2011 for “consistent assessment of the impact of telemedicine services, including effectiveness and cost-effectiveness,” as well as provide funds for conducting trials.⁴⁵ In order to provide legal clarity in

⁴⁰ See McLean, *supra* note 3, at 612.

⁴¹ See *EHR Incentive Programs Overview*, *supra* note 25; Medicare & Medicaid Programs: Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314 (July 28, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422).

⁴² L. & HEALTH CARE PROGRAM, UNIV. OF MD. SCH. OF L., LEGAL IMPEDIMENTS TO THE DIFFUSION OF TELEMEDICINE (2010), available at http://www.rural.state.md.us/Roundtables/UMBC_White_Paper.doc.

⁴³ See Maurice Mars & Richard E. Scott, *Global E-Health Policy: A Work In Progress*, 29 HEALTH AFF. 239, 240 (2010).

⁴⁴ *Telemedicine for the Benefit of Patients, Healthcare Systems, and Society*, *supra* note 13, at 3.

⁴⁵ *Id.* at 25.

the area of telemedicine, the Commission has called on Member States to adopt national regulations addressing licensing, reimbursement, and privacy issues.⁴⁶

One related recommendation was already passed by the EU in 2008, providing “a set of guidelines for developing and deploying interoperable electronic health record systems, allowing for cross-border exchange of patient data.”⁴⁷ This recommendation was passed in connection with a European Parliament Resolution in 2007 that encouraged “Member States to actively support the introduction of eHealth and telemedicine, particularly by developing interoperable systems allowing the exchange of patient information between healthcare providers in different Member States.”⁴⁸

Continuing the aspirational nature of the EU’s official actions on telemedicine, a Communication from the European Parliament on the Europe 2020 Flagship Initiative calls for

[a]ccelerating the creation of the necessary framework conditions and demand, which will need to include . . . regulatory requirements such as measures to protect medical and personal data, reimbursement through national health insurance schemes and coordinated procurements by the public sector (networks of public authorities), ensuring interoperability and setting standards and reference specifications for new equipment and services for telemedicine and independent living⁴⁹

The Commission has thus expressed its desire to tap the benefits of telemedicine and has announced several initiatives to reach these goals: “The eHealth Lead Market Initiative will promote standardization, interoperability testing and certification of electronic health records and equipments.”⁵⁰ Additionally, the “EU [Ambient Assisted Living]-dedicated Joint Programme with Member States” seeks to improve and develop innovative information communications technology solutions to help “the most vulnerable members of society” live “a more independent and dignified life.”⁵¹ To this end, the Commission has announced two key actions: to work with Member States “to equip Europeans with secure online access to their medical health data by 2015 and to achieve by 2020 widespread deployment of telemedicine services”;⁵² and to reach the definition of “a minimum common set of patient data for interoperability of patient records to be accessed or exchanged electronically across Member States by 2012.”⁵³ An additional action mentioned is to “[f]oster EU-wide standards, interoperability testing and certification of eHealth systems by 2015 through stakeholder dialogue.”⁵⁴

⁴⁶ *Id.*

⁴⁷ *Commission Recommendation on Cross-border Interoperability of Electronic Health Record Systems*, at 4, COM (2008) 3282 final (July 2, 2008).

⁴⁸ *Id.* at 2.

⁴⁹ *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Europe 2020 Flagship Initiative Innovation Union*, at 41, COM (2010) 546 final (Oct. 6, 2010).

⁵⁰ *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions: A Digital Agenda for Europe*, at 29, COM (2010) 245 (May 19, 2010).

⁵¹ *Id.* at 29–30.

⁵² *Id.* at 30.

⁵³ *Id.*

⁵⁴ *Id.*

Thus, the approach of both the United States and the European Union is to attempt to regulate IT and TM insofar as they relate to their own citizens. In other words, it is an internal perspective. Far less attention is given in these places to the powers of IT/TM to improve the health of other citizens on a global scale. Clearly, both the United States and member states in the European Union are heavily invested in promotion of health in developing countries, and IT may greatly influence the health benefits of allocated resources and provide a higher return on investment.

On the international front, as early as 1998 the Valetta Declaration stated a firm support of TM projects in developing countries.⁵⁵ In 1998, responding to the growing number of regional and national initiatives in telemedicine, the G-8 countries agreed on active cooperation, to become known as G-8 GHAP SP-4.⁵⁶ The World Health Assembly adopted, in 2005, a resolution that established an eHealth strategy for the World Health Organization (WHO).⁵⁷ To implement its formal program on eHealth, the WHO created the Global Observatory for eHealth. The role of the Global Observatory for eHealth is to provide evidence-based guidance to countries and institutions involved in health-care programs about the broad range of eHealth activities that are being implemented throughout the world.⁵⁸ An atlas of eHealth profiles of 119 countries was assembled in 2009, allowing a state-by-state comparison in respect to existing frameworks needed to advance TM: policy; legal and ethical; eHealth expenditures and the funding sources; capacity building; and eHealth application (TM, mHealth and eLearning). However, these decade-long activities are yet to materialize in a more concrete and robust way.

III. CURRENT LEGAL BARRIERS

The promise of high-tech, high-quality medicine that enables enhanced access and availability with decreased costs and time is contingent not only on the computing and communication sciences, but also on clearing the legal field. Indeed, legal aspects are the most powerful inhibitory factor to the progress of telemedicine.⁵⁹ This statement reflects the situation in respect to developed countries, whereas in developing countries, major efforts are necessary to create and maintain basic infrastructure to promote workforce and economic development, IT literacy and its adoption, and social stability. Thus, some would argue that legal qualms are the luxury of only the rich. Happily, the next generation of IT, relying on mobile communication (m-health) may alleviate some of these infrastructure deficiencies.⁶⁰ With this caveat in mind, in

⁵⁵ INT'L TELECOMM. UNION, SECOND WORLD TELECOMMUNICATIONS DEVELOPMENT CONFERENCE, VALLETTA DECLARATION (1998), available at <http://www.itu.int/newsarchive/press/WTDC98/Declaration.html> (“[The International Telecommunication Union] should be urged to promote the development, expansion and operation of telecommunication networks and services, particularly in developing countries, taking into account the activities of other relevant bodies, by reinforcing capabilities for the implementation of new services and technologies including the Internet, mobile and other wireless technologies, human resources development and management, planning, management, resource mobilization and research and development.”).

⁵⁶ See generally André Lacroix et al., *International Concerted Action on Collaboration in Telemedicine: Recommendations of the G-8 Global Healthcare Applications Subproject-4*, 8 TELEMED. & E-HEALTH 149 (2002).

⁵⁷ WORLD HEALTH ORG. GLOBAL OBSERVATORY FOR EHEALTH, GLOBAL EHEALTH SURVEY 31 (2005), available at http://www.who.int/entity/kms/initiatives/Global_eHealth_survey_FINAL.doc.

⁵⁸ *Id.* at 3.

⁵⁹ Gil Siegal, *Telemedicine: Licensing and Other Legal Issues*, 44 OTOL. CLINICS N. AM. 1375 (2011).

⁶⁰ While IT availability is restricted in most developing countries, cellular services are readily available. Several high-tech companies are working on more widespread adoption of software solutions to

order to successfully cross the legal battleground that will facilitate the dissemination of IT-driven health care, key issues must be resolved, including licensure, liability, insurance coverage, and data protection. The following section summarizes the prominent developments with respect to these areas of the law in the United States and the European Union. Solutions presented here are geared toward the notion that leaving things “as they are” is unacceptable, as the interests of patients (e.g., right to access), providers (e.g., to offer better or more efficient care), and the health system at large (e.g., to contain the rising costs or decreased availability) to date are not adequately served.⁶¹ While the intracontinental approach predominates current legal discussion, this section alludes to possible needed resolutions in order to enable global dissemination in the meaning of augmenting access to care in developed as well as developing countries. A more detailed exposition is offered in Part IV.

A. Licensure

In most jurisdictions, practicing medicine without a valid license is a criminal offense.⁶² In the United States, licensure has been, and remains, a state’s prerogative, resulting in the need to obtain a license for every state in which one wishes to practice.⁶³ The licensure requirement is founded on the need to protect the public from the practice of medicine by unqualified providers, as well as to restrict unwanted competition. Moreover, some states and countries forbid the practice of medicine in another jurisdiction without a proper license in that second state, and local disciplinary measures (including revocation of license) may ensue. This restrictive policy for practicing medicine across state lines has been subject to growing criticism.⁶⁴ First, notwithstanding state sovereignty, it is hard to defend a locally based licensure process to protect the “public safety.” Local requirements for a North Carolina license should be sufficient for practicing medicine in Virginia, as citizens in both states should similarly enjoy the practice of medicine by qualified professionals who are practicing according to commonly accepted professional standards and enjoy access to the same global medical knowledge. To use the language of an international document, “[r]estrictions and standards must not be more burdensome than necessary to ensure the quality of the service.”⁶⁵

Second, medical malpractice jurisprudence throughout the United States has repeatedly endorsed a national standard for determining if a provider rendered “reasonable care.”⁶⁶ Such

turn each mobile phone into a portal of information (i.e., a smartphone), allowing access to the Internet, social networks and other modes of communication.

⁶¹ Venable, *supra* note 1, at 1183.

⁶² See e.g., CAL. BUS. & PROF. CODE § 2052 (West Supp. 2012); Hageseth v. Superior Court of San Mateo Cnty., 59 Cal. Rptr. 3d 385 (Cal. Ct. App. 2007). See also J. Scott Andresen, Comment, *Is Utilization Review the Practice of Medicine? Implications for Managed Care Administrators*, 19 J. LEGAL MED. 431, 439, 452 (1998) (listing the medical practice acts of all fifty states and Washington, D.C.).

⁶³ See *Physician Licensure: An Update of Trends*, AM. MED. ASS’N, available at <http://www.ama-assn.org/ama/pub/about-ama/our-people/member-groups-sections/young-physicians-section/advocacy-resources/physician-licensure-an-update-trends.shtml> (last visited Feb. 13, 2012). For a compilation of states’ regulation and licensure requirements in respect to TM, see *Physician Licensure*, ROBERT J. WATERS CENTER FOR TELEHEALTH & E-HEALTH L., <http://ctel.org/expertise/physican-licensure/> (last visited Feb. 25, 2012).

⁶⁴ See, e.g., Sarah E. Born, *Telemedicine in Massachusetts: A Better Way to Regulate*, 42 NEW ENG. L. REV. 195, 198–99 (2007).

⁶⁵ General Agreement on Trade in Services, art. VI(2(b)), Jan. 1 1995, 1869 U.N.T.S. 183.

⁶⁶ See, e.g., Logan v. Greenwich Hosp. Ass’n, 465 A.2d 294, 301 (Conn. 1983) (rejecting locality rule and adopting national standard of care); Young v. Univ. of Miss. Med. Ctr., 914 So. 2d 1272, 1276 (Miss. Ct. App. 2005) (stating that Mississippi applies a national standard of care).

recognition means that citizens living in remote areas are entitled to the same level of care rendered in sophisticated urban settings. Therefore, in effect, a national standard of practice has been deployed. It seems a very small leap to accept that safety and qualifications requirements can and should be harmonized, allowing easier access to health care. Currently, “protecting the public” is artificially recruited to support a parochial states’ sovereignty argument, supposedly designed to guarantee and protect the interests of the local medical community.⁶⁷ On both accounts (i.e., state sovereignty and a national standard of care on malpractice), the establishment of the National Practitioner Data Bank and its incorporation in the daily practices of staff recruitment and privileges was a significant step in the harmonization direction.⁶⁸

The need to eliminate or diminish such unwarranted restriction on cross-state practice has been reflected (while obviously stated in a far less blunt tone) in the Federation of State Medical Boards Special Committee on License Portability recommending that state medical boards develop and use an expedited licensure by endorsement process to facilitate multi-state practice.⁶⁹ Unfortunately, after almost two decades of attempts to resolve the licensure barrier, we must admit that not enough has been accomplished—most states’ licensure statutes still require full, unrestricted licensure to practice medicine across state lines. Thus, while I add my voice to the critics of the current licensure segregation, my ambition here is relatively modest: to illuminate the current regulation’s negative impact with respect to TM’s licensure requirements. Indeed, IT and border-free TM support a strong dissenting view negating this parochial, protectionist segregation and a call for a more uniform licensure process based on accepted requirements that are already in place. Moreover, some scholars have argued that states’ current legal barriers to TM licensure are unconstitutional.⁷⁰

1. Licensure Options

Assuming the patient and the physician are not located in the same state or country, the question arises: under which jurisdiction is the telemedical event taking place? While technically there are at least three options—i.e., the location of the patient, the place of the provider, or in the abstract cyberspace—legislators and policy makers opted for the first of these. Seemingly unable to relinquish traditional concepts, a physician is considered by too many jurisdictions as practicing medicine in the state where the *patient* is located (termed the originating site), which is the fundamental contributor to the licensure barrier, as the provision of medical care by TM is still caught by the originating site’s licensure state law requirements. Requiring practitioners to acquire state-by-state licensure is very cumbersome in the United States. Considering the global scope of IT-driven health care (some 190 countries), it becomes apparent that licensure creates an irresolvable hurdle if we insist on viewing TM as being rendered in the originating site.

⁶⁷ Regarding the events that led to the closure of Mydoc.com, see McLean, *supra* note 3, at 621–22 (Mydoc.com provided a platform for patients to purchase health-care services from an Indiana-based group. Alas, by attracting a significant number of patients from Illinois—17,000 over two years—some Illinois physicians filed complaints for cross-border practice of medicine. Eventually, an Illinois court ordered Roche, the company supporting the website, to close Mydoc.).

⁶⁸ See U.S. Dep’t of Health & Human Servs., THE DATABANK, <http://www.npdb-hipdb.hrsa.gov/> (last visited Feb. 15, 2012).

⁶⁹ FED’N OF STATE MED. BDS., REPORT OF THE SPECIAL COMMITTEE ON LICENSE PORTABILITY (2002), available at http://www.fsmb.org/pdf/2002_grpol_License_Portability.pdf.

⁷⁰ Gupta & Sao, *supra* note 1, at 1.

However, in the United States, a trend towards accepting the borderless nature of TM has seemed to unfold. To date, approximately ten states⁷¹ have adopted some version of a limited or special-purpose licensure, allowing practitioners to obtain a limited license for the delivery of specific health services under particular circumstances, which can be regarded as suitable for the TM care. Practitioners are required to maintain a full and unrestricted license in at least one state, while practicing TM in others. For example, Montana created a telemedicine license that authorizes an out-of-state physician to practice telemedicine only with respect to the specialty in which the physician is board-certified.⁷² Notably, a telemedicine license authorizes an out-of-state physician to practice *only* telemedicine.

Another option for the U.S. situation that may assist fruitful dissemination of TM is a national system that would issue a TM license based on national standards.⁷³ This national system could be constructed in a way that does not necessarily preempt states' sovereignty and thus avoids unnecessary opposition. Uniform legislation in health care has been successful in the past, such as the Uniform Anatomical Gift Act of 1968, which was adopted and implemented in every state.⁷⁴ Nevertheless, some national involvement is warranted (e.g., data collection and setting standards for education, qualifications, training, and disciplinary measures). Some steps in this direction on other fronts of health care are aligned with such a national undertaking, such as the establishment of the National Practitioner Data Bank,⁷⁵ the acceptability of the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations, or JCAHO) as a national standard for medicine and practices, and the expanding reach of the Food and Drug Administration over health issues.

In particular, in 2001, the Joint Commission introduced standards for institutional credentialing of TM providers. Under these standards, a physician credentialed in any Joint Commission facility would be permitted to provide TM services in another Joint Commission facility.⁷⁶ A stronger version would attempt a federal licensure system that would preempt state

⁷¹ These states include Alabama, California, Minnesota, Montana, Nevada, New Mexico, Ohio, Oregon, Tennessee, and Texas. See CENTER FOR TELEMED. L., TELEMEDICINE LICENSURE REPORT 11 (2003), <ftp://ftp.hrsa.gov/telehealth/licensure.pdf>.

⁷² Mont. Code Ann. § 37-3-343 (2011).

⁷³ Gupta & Sao, *supra* note 1, at 61. See also *United States v. Lopez*, 514 U.S. 549, 567 (1995) (acknowledging Congress's power to regulate those activities that have a substantial relationship to interstate commerce); *Pharm. Mfrs. Ass'n v. FDA*, 484 F. Supp. 1179, 1187–88 (D. Del. 1980), *aff'd* 634 F.2d 106 (3d Cir. 1980) (allowing federal regulation to interfere with states' rights to regulate the practice of medicine where there is a legitimate interest).

⁷⁴ *Legislative*, ASS'N ORGAN PROCUREMENT ORGS., <http://www.aopo.org/legislative-a33> (last visited Feb. 26, 2012).

⁷⁵ Health Care Quality Improvement Act of 1986, 42 U.S.C. § 11101 (2006). See also U.S. Dept. of Health & Human Servs., *About Legislation and Regulation*, THE DATABANK, <http://www.npdb-hipdb.hrsa.gov/legislation.html> (last visited Feb. 15, 2012).

⁷⁶ The Joint Commission rules allowed the facility where the patient was being treated to credential the distant treating physician in two ways: (1) the treating facility could fully credential the physician based on their own facility's standards; or (2) the treating facility could accept the credentials of the treating physician based on the fact that the remote institution was Joint Commission-certified. However, in 2009, CMS stated that only option one remains valid. In 2011, CMS agreed to a compromise position, whereby hospitals must still grant privileges to remote physicians, but they may rely on the certifications of outside organizations in doing so. See *Medicare and Medicaid Programs: Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging*, 76 Fed. Reg. 25,550 (May 5, 2011) (to be codified at 42 C.F.R. pts. 482, 485).

licensure laws, issuing one license that would be valid throughout the United States.⁷⁷ A more ambitious attempt to establish an international licensure system (similar to the Vienna Convention on road traffic)⁷⁸ might seem farfetched at this time but can be contemplated, as discussed in Part IV. For example, international agreements such as GATS permit member states to “recognize the education obtained, requirements met, or licenses or certifications granted in a particular country.”⁷⁹

Another less ambitious and less productive option is by endorsement, whereby state boards can award licenses to professionals in other states with equal standards. To have one’s license endorsed by another state, a professional must apply for a “license by endorsement” from each state in which he or she seeks to practice. However, since states may require additional qualifications or documentation before endorsing a license issued by another state, endorsement can be time-consuming and expensive for a multi-state practitioner in the field of TM. To address part of this difficulty, a licensure system based on reciprocity requires the authorities (rather than individual practitioners) of each state to reach agreements to recognize licenses issued by other states (bilateral or multilateral) without further review of individual credentials. A license valid in one state would allow the practice of medicine in all other states with which such agreements exist; but notification or registration might still be needed. Such a requirement may be waived by mutual recognition, in which a state’s licensing authority legally accepts the licensure of another state without further action. The nurse licensure compact, legally accepted in twenty-four states,

⁷⁷ U.S. DEP’T OF COMMERCE, TELEMEDICINE REPORT TO CONGRESS (1997) *available at* <http://www.ntia.doc.gov/legacy/reports/telemed/legal.htm>.

⁷⁸ The United Nations Convention on Road Traffic, art. 41, Nov. 8, 1968, 1042 U.N.T.S. 17 provides that:

1. Contracting Parties shall recognize:
 - (a) Any domestic permit drawn up in their national language or in one of their national languages, or, if not drawn up in such a language, accompanied by a certified translation;
 - (b) Any domestic permit conforming to the provisions of Annex 6 to this Convention; and
 - (c) Any international permit conforming to the provisions of Annex 7 to this Convention

as valid for driving in their territories a vehicle coming within the categories covered by the permit, provided that the permit is still valid and that it was issued by another Contracting Party or sub-division thereof or by an association duly empowered thereto by such other Contracting Party.

...

3. Contracting Parties undertake to adopt such measures as may be necessary to ensure that the domestic and international driving permits referred to in subparagraphs 1(a), (b) and (c) of this Article are not issued in their territories without a reasonable guarantee of the driver’s aptitude and physical fitness.

...

5. An international permit shall not be issued only to the holder of a domestic permit for the issue of which the minimum condition laid down in this Convention have been fulfilled. It shall not be valid after the expiry of the corresponding domestic permit

For our purposes, the mutual recognition of domestic licenses and the need to reasonably guarantee a licensee’s aptitude and fitness are demonstrative.

⁷⁹ General Agreement on Trade in Services, art. VII(1), Apr. 15, 1994, 1869 U.N.T.S. 183.

is based on this model, and one is left to wonder why it has not been adopted in other areas of licensing health-care professionals.⁸⁰

Measures presented thus far relate to regulating the practice of TM within the United States, where there has been a trend toward national standardization. How should these solutions apply in a global context? Even though good medicine can be practiced in places all over the world, multinational conflicts regarding licensing requirements may appear to prevent access by patients to providers in foreign locales, primarily relying on the “patient’s safety” argument. Therefore, severing the Gordian knot should be considered, both for the United States and on a global scale. The most sensible and productive solution to TM licensure would be “electronic patient transfer,”⁸¹ viewing TM as being rendered at the location of the physician, the distant site.⁸² After twenty years of TM and the dramatic increase in medical tourism, such understanding should not be hard to accept. Since a patient may travel to any state or country to be treated⁸³ at his sole discretion (as evident by the thriving medical tourism phenomenon), patients should be allowed to “travel” electronically, i.e., to engage in what can be termed “electronic medical tourism.” It allows the needed access to care, with ancillary benefits such as saving money, travel time, and the environment by avoiding physical travel and its associated by-products. Accepting electronic medical tourism thereby creates a legal way to allow TM activities according to the location of the treating professional. Arguably, this is especially compelling if we are concerned with the underinsured or uninsured segment of society, for whom IT-driven health care could be the single viable option for medical care they want and/or need.

The most recent relevant decision of the European Court of Justice stated the following:

[I]t is to be emphasized that, in the absence of harmonization at EU level, it is for the legislation of each Member State to determine, in particular, the conditions for the grant of social security benefits covering treatment such as that concerned by the first head of claim. The fact remains, nevertheless, that when exercising that power the Member States must comply with EU law, in particular, with the provisions on freedom to provide services (see, to that effect, *Commission of the European Communities v Spain* (C-211/08) [2010] 3 C.M.L.R. 48 at [53] and the case law cited). According to settled case law, medical services supplied for consideration fall within the scope of those provisions, there being no need to distinguish between care provided in a hospital environment and care provided outside such an environment (see, in particular, *Leichtle v Bundesanstalt für Arbeit* (C-8/02) [2004] E.C.R. I- 2641; [2006] 3 C.M.L.R. 4 at [28]; *Watts* [2006] 3 C.M.L.R. 5 at [86];). It has also repeatedly been held that the freedom to

⁸⁰ Siegal, *supra* note 59, at 1378. For the complete list of those twenty-four states, see *Nurse Licensure Compact* NAT’L COUNCIL ST. BDS. NURSING, <https://www.ncsbn.org/nlc.htm> (last visited Feb. 15, 2012).

⁸¹ Arnold Milstein & Mark Smith, *America’s New Refugees—Seeking Affordable Surgery Offshore*, 355 NEW ENG. J. MED. 1637, 1639 (2006); Levi Burkett, *Medical Tourism, Concerns, Benefits, and the American Legal Perspective*, 28 J. LEG. MED. 223, 243 (2007).

⁸² A similar view was adopted by the G-8: “The major barrier of healthcare to professionals licensing should be resolved by deciding that the telemedicine activity is occurring at the site of the consultant. The patient should agree that he will follow the legal rules at the site of the consultant as done currently when the patient travels physically to that site.” RECOMMENDATION 4 ON MEDICO-LEGAL ASPECTS, INTERNATIONAL CONCERTED ACTION ON COLLABORATION IN TELEMEDICINE: FINAL REPORT AND RECOMMENDATIONS OF THE G-8 GLOBAL HEALTHCARE APPLICATIONS PROJECT 4, *available at* <http://mi.med.u-tokai.ac.jp/g7sp4/final.htm> (last visited Feb. 16, 2012).

⁸³ See Milstein & Smith, *supra* note 81, at 1637–40; I. Glenn Cohen, *Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument*, 95 IOWA L. REV. 1467 (2010).

provide services includes the freedom for the recipients of services, including persons in need of medical treatment, to go to another Member State in order to receive those services there without being hampered by restrictions (see, in particular, to that effect, Watts [2006] 3 C.M.L.R. 5 at [87], and Commission v Spain [2010] 3 C.M.L.R. 48 at [49]).⁸⁴

Indeed, the Joint Committee (revising its credential policy), opted that practitioners who render care using live/interactive systems are subject to credentialing and privileging at the distant site (where the consultant is located) when they are providing direct care to the patient. At first, the Centers for Medicare and Medicaid Services (CMS) had required a change of this groundbreaking resolution, requiring institutions to establish independently the credentials of remote TM practitioners. However, responding to pleas from the telemedicine industry and other stakeholders, the final rule on this contention published in May 2011, re-adoption of the Joint Committee's stance.⁸⁵

Some have attempted to circumvent current licensure hurdles by regarding all TM interactions as "recommendations/consultation." Apart from being dishonest about the true nature of the evolving capacities of TM, this classification has several disadvantages. First, it probably would not stand legal scrutiny in most states' courts. It would also require a local referring physician who keeps full authority and legal responsibility over the patient (e.g., Hawaii, Colorado, and California allow significant consulting exceptions⁸⁶). Therefore it would restrict patients' autonomy in interacting with physicians at their convenience and choice without relying on other local providers. Consequently, it would prevent a productive, cost-effective business model on the part of providers and investors alike, seeking to enjoy the full array of TM's potential. The end result is an inhibitory effect on the uptake of TM, as a more restrictive arena chills the incentive to fully engage in TM.

In the European Union, several court decisions have reiterated the need to remove barriers that might diminish free trade. The Commission recognizes:

Typical examples of the legal obstacles that wider deployment of telemedicine is facing are the need for physicians to be registered in all EU countries where they are providing services via telemedicine (e.g. interpretation of radiographs received via teleradiology), or the legal requirement for all medical acts to be carried out in the physical and simultaneous presence of the health professional and patient.⁸⁷

Accreditation and authorization schemes for health professionals are listed as one of the greatest sources of concern regarding telemedicine in the European Union.⁸⁸

⁸⁴ Case C-512/08, *Comm'n v. France*, (2010) (some citations omitted), available at <http://curia.europa.eu/juris/document/document.jsf?jsessionid=9ea7d2dc30ddd139ca233e734c28bda0eccd712d1f6f.e34KaxiLc3qMb40Rch0SaxqTbhb0?text=&docid=81397&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=6248>.

⁸⁵ Medicare & Medicaid Programs: Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging, 76 Fed. Reg. 25,550 (May 5, 2011) (to be codified at 42 C.F.R. pts. 482, 485).

⁸⁶ See *Physician Licensure: An Update of Trends*, *supra* note 63.

⁸⁷ *Telemedicine for the Benefit of Patients, Healthcare Systems and Society*, at 17, SEC (2009) 943 final (June 2009).

⁸⁸ *Id.*

From the standpoint of Community law, telemedicine is both a health service and an information society service within the meaning of Article 49 of the EC Treaty. The European Court of Justice stated that neither the special nature of health services, nor the way in which they are organized or financed removes them from the ambit of the fundamental principle of freedom of movement. A recipient of a healthcare service may therefore freely seek and receive medical treatment from another Member State, regardless of how the service is delivered, i.e. also by telemedicine. In principle, the fact that telemedicine is a service delivered by electronic means does not constitute a reason for treating telemedicine as a special type of health service.

Another key driver for the clarity of legislation is to ensure that telemedicine does not in any way reduce the quality of the services provided to the public. At EU level, a range of actions have already been taken. Specific aspects of the provision of health services are governed by the existing secondary legislation, which builds on the basic principle enshrined in Article 49 of the EC Treaty and the above-mentioned ECJ case law.⁸⁹

Assuming we have resolved licensure issues, or that TM is practiced within a state's borders (in which case no additional licensure for TM is needed), other legal issues emerge on which I regretfully can only make several short notes.⁹⁰ For example, providers' authentication remains a challenge.⁹¹ Space limits a thorough discussion of this point, but suffice it to assert that TM should not be restricted on these grounds, as authentication requirements are shared by all IT-based modern enterprises (such as banking, credit, and e-learning), and have been reasonably resolved. Therefore, TM should not be treated differently and available cyber-tech solutions should be employed. Practically, responsibility for assuring and protecting authentication of providers in a TM interaction is and should be the responsibility of the institution that provides the medical service, and appropriate regulations should be instituted and monitored (e.g., passwords, event log/access archive, log-in log, etc.). In contrast, authentication of nonaffiliated Internet providers in cyberspace becomes much more problematic. Attempts to regulate this "wild medical cyberspace" have proven futile in most cases (e.g., pharmaceuticals and DTC genetic tests),⁹² and it seems that in these circumstances, responsibility should be shifted to consumers, expecting them to utilize only credible sources. Consumers should be steadily informed about the hazards of receiving medical care or consultation from non-affiliated practitioners. In addition, a regularly updated listing of illegitimate websites and other electronic sources of unauthorized TM should be made available (for example, automatically annotating a Google search), similar to travel warnings published by the U.S. State Department.⁹³

⁸⁹ *Id.*

⁹⁰ See generally Jeffrey L. Rensberger, *Choice of Law, Medical Malpractice and Telemedicine: The Present Diagnosis with a Prescription for the Future*, 55 U. MIAMI L. REV. 31 (2000).

⁹¹ Riccardo Bellazzi et al., *Web-Based Telemedicine Systems for Home-Care: Technical Issues and Experiences*, 64 COMPUTER METHODS & PROGRAMS IN BIOMEDICINE, 175, 179 (2001); V. Perminov et al., *Preventing Unauthorized Access to User Accounts in a Telemedicine Consultation System*, 54 J. COMM. TECH. & ELECTRONICS 1319, 1319 (2009).

⁹² Dov Wisebrod, *Controlling the Uncontrollable: Regulating the Internet*, 4 MEDIA & COMM. L. REP. 331, 332 (1995) available at <http://www.wisebrod.com/docs/dw-inet.htm> ("King Canute had as much success having the tides to retreat as a national government will have regulating cyberspace.").

⁹³ See U.S. Bureau of Consular Affairs, *Current Travel Warnings*, U.S. DEP'T OF STATE, http://travel.state.gov/travel/cis_pa_tw/tw/tw_1764.html (last visited Feb. 5, 2012).

A final related question refers to choice of venue and of law. Assume a multi-state or multi-nationality TM interaction: which court should have jurisdiction, and what legal norms should be used?⁹⁴ Since TM will undeniably create legal disputes such as claims of malpractice or breach of privacy/confidentiality, this issue must be proactively determined. A thorough exposition of choice-of-law rules, especially as they pertain the cyber-law, is beyond the scope of this paper, as it requires a case-by-case determination and can be found elsewhere.⁹⁵ However, most uncertainties can be resolved by adopting the electronic medical tourism concept.⁹⁶ Alternatively (or in addition), binding arbitration can provide clearer *ex-ante* solutions. Arbitration is commonly utilized in multinational commercial interactions, thanks to the successful United Nations Convention on Recognition and Enforcement of Foreign Arbitral Awards of 1958, also known as the New York Convention.⁹⁷ As discussed in the following section, other legal regimes should be advanced to enable a clear legal territory for patients/consumers, providers, TM companies, and national authorities. The growing trend of electronic health care must be met by an equivocal legal progress. As stated earlier, a legal nexus based on physical locality seems at odds with the true nature of cyberspace, and (self-imposed) forbearance should be the norm in assertion of local law as opposed to an accepted global regime.

B. Liabilities – Medical Malpractice and Informed Consent

This section briefly surveys legal topics that have emerged in health law jurisprudence, viewing them through the prism of using IT to create a patient–provider relationship (PPR). These liabilities stem from traditional tort doctrines such as negligence, providing plenty of case law and statutes from which to draw.⁹⁸ At the outset it should be noted that in health systems around the world, most notably in the United States, rising costs of legal liabilities due to medical malpractice litigation have resulted in an insurance coverage crisis,⁹⁹ costly defensive medicine,¹⁰⁰ and an insufficient impact on patients’ safety.¹⁰¹ I will not attempt to predict the

⁹⁴ For a general discussion on global choice-of-law issues in a digital context, see Anupam Chander, *Trade 2.0*, 34 YALE J. INT’L L. 281, 310–325 (2009); Blum, *supra* note 2; Paul Schiff Berman, *The Globalization of Jurisdiction*, 151 U. PA. L. REV. 311 (2002). Regarding TM, see generally B.M. Dickens & R.J. Cook, *Legal and Ethical Issues in Telemedicine and Robotics*, 94 INT’L J. GYNECOLOGY OBSTETRICS 73 (2006).

⁹⁵ RALPH D. CLIFFORD, *COMPUTER AND CYBER LAW: CASES AND MATERIALS* (1999); Cohen, *supra* note 83 at 1494–1504.

⁹⁶ See *supra* note 83 and accompanying text.

⁹⁷ Zawadski, *supra* note 1, at 166.

⁹⁸ See generally Blum, *supra* note 1; Arthur R. Derse & Tracy E. Miller, *Net Effect: Professional and Ethical Challenges of Medicine Online*, 17 CAMBRIDGE Q. HEALTHCARE ETHICS 453 (2008).

⁹⁹ The term “crisis” has been widely used to refer to repeated, unusually large increases in professional liability insurance premiums and shrinking options for coverage in many markets across the country. See generally Daniel P. Kessler, William M. Sage & David J. Becker, *Impact of Malpractice Reforms on the Supply of Physician Services*, 293 JAMA 2618, 2618 (2005); Michelle M. Mello, David M. Studdert & Troyen A. Brennan, *The New Medical Malpractice Crisis*, 348 NEW ENG. J. MED. 2281 (2003); William M. Sage, *The Forgotten Third: Liability Insurance and the Medical Malpractice Crisis*, 23 HEALTH AFF. 10 (2004); Kenneth E. Thorpe, *The Medical Malpractice ‘Crisis’: Recent Trends and the Impact of State Tort Reforms*, HEALTH AFF., (Jan. 21, 2004), <http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.20v1/DC1>.

¹⁰⁰ See, e.g., Daniel Kessler & Mark McClellan, *Do Doctors Practice Defensive Medicine?*, 111 Q. J. ECON. 353 (1996); Daniel Kessler & Mark McClellan, *How Liability Law Affects Medical Productivity*, 21 J. HEALTH ECON. 931 (2002); David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609, 2617 (2005); Ken L. Bassett et al., *Defensive Medicine During Hospital Obstetrical Care: A Byproduct of the Technological Age*, 51 SOC. SCI. & MED. 523 (2000).

impact of TM on this landscape, though some questions deserve due attention. What constitutes malpractice in TM? Should TM malpractice cases be treated differently by the courts? Are TM practices covered by current malpractice insurance policies, and would TM lead to another increase in legal/administrative costs? Empirically, after some ten years of expanding practice (especially in teleradiology), no extraordinary legal activity has been documented in the IT/TM area. Nevertheless, expanding or transforming medical services to the digital market is bound to evoke a medical malpractice “knee-jerk reaction” (mostly on the part of providers or insurers) and hence a need to comprehensively address liability issues. Liability issues from a global perspective seem no different, though I argue later that in exchange for improved dissemination of IT and TM—and concomitant improved access to health care—some adjustments or even concessions can be acceptable in order to reduce decision makers’ angst and reluctance to fully engage in TM for reasons of uncertain liability or perceived exposure. The following analysis presupposes that the current “silo mentality” still prevails—no harmonization or global agreements have been achieved, thus creating only local standards and remedies for liability. This is by no means the proper aspiration but rather a realistic depiction. The concluding sections will offer some general comments on one alternative, based on a global compact with agreed-upon standards of legal review and remedies/compensation.

For analysis of liabilities, recall that TM interactions are conducted in different models, which can impact liability.¹⁰² Some involve direct provider-to-patient interaction such as in DTC enterprises, or in telemonitoring or telepsychiatry. Others stipulate the presence of another provider at the originating site (the consulting, provider-to-provider (P2P) model), customarily practiced in teleconsultation or telesurgery. The latter model tends to shift ultimate authority (and thus responsibility) to the provider at the originating site. Yet another model is devoid of patient presence altogether (e.g., teleradiology). Such different models of TM interactions have important legal implications, for example on creating a binding PPR. Thus, what seems clear is that one should reject the notion that “telemedicine is telemedicine is telemedicine” and rather identify within each TM interaction the relevant components that can impact legal responsibilities and liabilities.

1. Medical Malpractice

To invoke malpractice, a plaintiff must establish that the provider has breached the duty of care owed to his patient (based on legally binding PPR) by performing below the standard of care (SOC) expected from a reasonable professional under the same circumstances, a breach that directly brought about his injuries (causation).¹⁰³ Clearly, delineating the SOC in TM in all countries is still in its infancy. To date and to the best of my knowledge, no court ruling has grappled with TM’s SOC (clearly it is only a matter of time); thus we must assume that traditional malpractice precedents will serve TM cases, until new case law emerges. This in turn dictates complying with reasonable care with respect to the medical interaction. For providers, factors include medical history-taking; employing appropriate diagnostics; reaching a diagnosis based on adequate differential diagnosis; choosing and providing the accurate treatment in a reasonable manner; appropriate follow up; and timely intervention if the need arises. For institutions, institutional practices are implicated, such as establishing and enforcing appropriate recruiting and privileges policies; assuring that only competent practitioners are providing care;

¹⁰¹ Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 TEX. L. REV. 1595, 1604–05 (2002).

¹⁰² Siegal, *supra* note 59.

¹⁰³ Edward B. Hirshfeld, *Practice Parameters and the Malpractice Liability of Physicians*, 263 JAMA 1556 (1990).

and making sure that the infrastructure is adequate.¹⁰⁴ As I have indicated, the fact that many American courts have declared a de facto national SOC¹⁰⁵ seems to help the establishment of general SOC for the TM industry. These standards in turn can provide greater predictability of what is expected from providers with respect to equipment, training, and performance without leaving it to the discretion of arbitrators, judges, or juries. Thus, professionals should actively seek to establish the SOC in their respective specialties within the TM domain by producing comprehensive SOC and guidelines. Examples of TM standards promoted by professional associations in the United States include the American Telemedicine Association's standards for telemedicine operations;¹⁰⁶ standards for videoconferencing telemental health provision, also by the American Telemedicine Association;¹⁰⁷ the American Academy of Dermatology's minimal pixel resolution and connection speed standards;¹⁰⁸ and the American College of Radiology's standards for teleradiology.¹⁰⁹ In Europe, several national standards have also emerged, especially in teleradiology.¹¹⁰

One can easily identify a prominent American involvement in the setting of standards, and this should be of no surprise when one recalls the prominent role of the United States in advancing medical technology and health care. The challenge of creating internationally accepted standards is at first sight daunting. However, one should remain optimistic for the following reasons. First, North American generated guidelines already serve many other nations' medical/professional associations, and common ground can be reached if the stakes (becoming part of a global TM market) are high enough. Examples include the Digital Imaging and Communications in Medicine (DICOM) standard, which was developed by the Medical Imaging & Technology Alliance, a division of the National Electronic Manufacturers Association¹¹¹ or the growing credibility and the much sought-after Joint Commission International (JCI) standardized approval. Second, as discussed below, the leverage power of America's massive investments in foreign aid should suffice in bringing all parties to the table. Finally, the responsibility for creating international standards does not fall to the United States or American organizations alone, and many countries and organizations around the world are competent to help draft adequate standards.

Until an international initiative is successfully instated, the question of whose SOC should be used to determine negligence must be addressed. The previous debate concerning the

¹⁰⁴ See, e.g., *McClellan v. Health Maint. Org. of Penn.*, 604 A.2d 1053 (Pa. Super. Ct. 1992).

¹⁰⁵ See *supra* Part III.A.

¹⁰⁶ AM. TELEMED. ASS'N, CORE STANDARDS FOR TELEMEDICINE OPERATIONS (2007), available at http://www.americantelemed.org/files/public/standards/CoreStandards_withCOVER.pdf.

¹⁰⁷ AM. TELEMED. ASS'N, PRACTICE GUIDELINES FOR VIDEOCONFERENCEING-BASED TELEMENTAL HEALTH (2009), available at <http://www.americantelemed.org/files/public/standards/PracticeGuidelinesforVideoconferencing-Based%20TelementalHealth.pdf>.

¹⁰⁸ See AM. ACAD. OF DERMATOLOGY & AAD ASS'N, POSITION STATEMENT ON TELEMEDICINE (2004), available at <http://www.aad.org/forms/policies/Uploads/PS/PS-Telemedicine%206-15-07.pdf>.

¹⁰⁹ AM. COLL. OF RADIOLOGY, ACR TECHNICAL STANDARD FOR ELECTRONIC PRACTICE OF MEDICAL IMAGING (2007), available at http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/med_phys/electronic_practice.aspx.

¹¹⁰ In the United Kingdom, see generally ROYAL COLL. OF RADIOLOGISTS, STANDARDS FOR THE PROVISION OF TELERADIOLOGY WITHIN THE UNITED KINGDOM (2010), available at [http://www.rcr.ac.uk/docs/radiology/pdf/BFCR\(10\)7_Stand_telerad.pdf](http://www.rcr.ac.uk/docs/radiology/pdf/BFCR(10)7_Stand_telerad.pdf). In Turkey, see TURKISH SOC'Y OF RADIOLOGY, STANDARD ON TECHNOLOGY, available at http://www.turkrad.org.tr/pdf/Teleradiology_English.pdf.

¹¹¹ See generally NAT'L ELEC. MFR. ASS'N, DIGITAL IMAGING & COMMUNICATION IN MEDICINE (DICOM) (2004), available at http://medical.nema.org/dicom/2004/04_01PU.PDF.

licensure barrier strongly reflects the question of the appropriate SOC to be used in malpractice cases. A genuine legal debate in respect to the SOC for TM will arise only if the provider attempts to refute a plaintiff's allegation of not meeting a higher SOC by reverting to a lower standard practiced in the locality of the provider. In all other cases, the SOC for TM will not generate a need to choose between the two. In this case, coherency mandates that accepting the rule of locality in respect to licensure should be decisive in establishing the chosen SOC. Within the United States, the locality standard has lost favor to a national one. The same legal evolution should transpire in international forums. Following the WTO example in respect to *goods*, where the Technical Barriers to Trade Agreement obliges countries to "accept[] as equivalent technical regulations of other Members . . . provided . . . these regulations adequately fulfill the objectives of their own regulations,"¹¹² a similar effort geared at IT health care *services* must be undertaken. Thus, if an international TM license option should prevail, and once prior agreement on web-based standards of care can be developed, most providers are likely to accept and abide by these terms which will reflect a global SOC. Furthermore, providers' acquiescence to such a standard should be part of the review procedure and be part of the informed consent process prior to providing telemedical care. Finally, what constitutes a compensable injury varies from one jurisdiction to another. For example, caps on noneconomic damages or dignitary damages are dealt with differently within the United States and in other countries, and the choice-of-law debate previously addressed will have important implications in this regard as well. In Part IV, I briefly describe how this component is tackled by pre-treatment agreements on the governing legal regime and its rules for compensable injuries.

As with medical tourism,¹¹³ policy making is required to address the question of whether and how to protect the wellbeing (the safety argument)¹¹⁴ and the legal rights (the legal protection argument, assuring redress in case of an adverse outcome) of electronic medical tourists who seek care elsewhere.¹¹⁵ For example, should patients be barred from visiting some places (or in our case, certain "e-locations"), based on their safety record, their informed consent standards, or their malpractice compensation options or actual payments? In respect to TM, some have argued that allowing individuals to submit to foreign law "without the notice of entry into foreign jurisdiction" by a click of a mouse should not be accepted.¹¹⁶

Recall that while travel warnings are prevalent, bans on travel are rare. Moreover, such concerns with respect to "entry into foreign jurisdiction" in the midst of the Internet-driven economy seem out of date and can be easily rectified with appropriate notices, disclaimers, or warnings. And for patients using TM care within the United States, I find the safety and legal protection arguments even less persuasive, as discussed in great detail earlier.¹¹⁷ Thus, from a domestic legal point of view, the restricting (and enforcing) leverage point would target contractual claims for reimbursement for telehealth care,¹¹⁸ yet would be more problematic for international health care.

¹¹² Agreement on Technical Barriers to Trade art. 2.7, Apr. 15 1995, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 120.

¹¹³ See *supra* note 83 and accompanying text.

¹¹⁴ See *infra* Part IV.

¹¹⁵ Cohen, *supra* note 83 (discussing in great detail how many medical tourists might be exposed to a different level of care and are left without any legal redress or sufficient financial compensation for medical accidents or errors).

¹¹⁶ Chander, *supra* note 94, at 312.

¹¹⁷ See *supra* note 65 and accompanying text.

¹¹⁸ See, e.g., Telehealth Advancement Act of 2011, A.B. 415, 2011–12 Leg., Reg. Sess. (Cal. 2011) (enacted) (prohibiting in-person contact as a condition for reimbursement).

Protective measures against fraud, exploitation, and misconduct should be in place. Such measures should not be left to nongovernmental organizations, supranational bodies, or commercial entities, but rather should be carried by active involvement of national or states regulators with significant sanctions such as disciplinary measures as applicable to medical practitioners, or civil liabilities and criminal charges when appropriate. However, a multi-national concerted action to provide the legal and financial remedies that transcends political borders is needed, as addressed below in Part IV.

2. Informed Consent

Informed consent (IC) doctrine has become a foundational precept in medical ethics and health law.¹¹⁹ The underlying ethical principle is that since individuals are rational moral agents, they should be in command of decisions that relate to *their* lives and bodies.¹²⁰ The corollary obligation of the physician is to respect and facilitate patient autonomy. Consent should be given to the medical interaction (be it diagnosis, treatment, monitoring, etc.). As for TM, valid IC requires deliberation regarding the procedures, benefits, risks, and available alternatives that is part of all medical IC, with the additional information relevant to providing the service via telecommunication. These additional elements of IC in TM pertain to special risks that are generated because the procedure is done via telecommunication (such as communication failures), and informational risks that relate to privacy and confidentiality (because of transmission of medical and/or personal information via digital media to other providers and possibly storing it elsewhere).¹²¹ This latter aspect is discussed below in Part III.C.

In obtaining IC for a TM procedure, one must clarify if a particular TM interaction is materially different than its non-TM counterpart. For example, consent to a telesurgery removal of a gallbladder procedure (termed laparoscopic cholecystectomy) involves all the risks of the medical procedure with the addition of “tele-risks” (e.g., failure of communication lines or a need to convert a laparoscopic teleprocedure to an open cholecystectomy, perhaps or most probably by a different surgeon). As a result, if deemed material, the batch of information which is required to obtain valid IC must be expanded to incorporate the unique features of TM.¹²² Conversely, if the TM procedure does not carry special or significant additional risks (as is safe to speculate in respect to telepsychiatry), the IC process should be basically identical to the processes currently employed, notwithstanding informational risks (such as digital breach of confidentiality).

As with the discussion regarding licensing and medical malpractice above, in obtaining such informed consent an underlying legal question must be considered: What standard of disclosure should be used? Some countries and U.S. states have adopted the “reasonable patient” standard in determining the nature and amount of information that should be provided to patients by their doctors (i.e., “what would a reasonable patient need to know to make a decision?”). Others adhere to the “reasonable physician” standard (i.e., “what information would a reasonable

¹¹⁹ See generally JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE (2001); Gil Siegal, Richard J. Bonnie, & Paul S. Appelbaum, *Personalized Disclosure by Information-on-Demand: Attending to Patients' Needs in the Informed Consent Process*, J.L. MED. & ETHICS (forthcoming 2012).

¹²⁰ See *Canterbury v. Spence*, 464 F.2d 772, 784 (D.C. Cir. 1972) (“Respect for the patient’s right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves.”).

¹²¹ See generally Goldstein, *supra* note 1.

¹²² Siegal, *supra* note 59.

physician convey to her patient prior to treatment?”).¹²³ If a TM interaction involves countries or states with different standards of information disclosure, such a conflict might be resolved in a similar fashion as was suggested above for the licensure or SOC disagreement—assuming the electronic medical tourism concept is accepted, it seems reasonable to implement the provider’s domestic standard. However, prior notice on this matter should be the norm. Furthermore, it is strongly recommended that professional bodies such as the American Medical Association or specific associations (e.g., the American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) for head & neck surgery, the American College of Surgeons for general surgery, etc.) along with their legal advisors and patients’ advocacy groups evaluate all proposed TM interactions and clearly define the set of information required for valid IC; it should not be left to the discretion of individual practitioners or the injudiciousness of juries in court. These domestic paradigms should be further developed to become international, thereby setting the legal stage to address future disputes regarding IC.

A separate question relates to the identity of the provider responsible for obtaining consent from the patient. One can make the following observations. In California, a state that is actively engaged in promoting TM, the relevant statute required a state-licensed physician to establish legally binding patient–physician relationship.¹²⁴ Therefore, in such circumstances, prime liability rests on a physician at the originating site. If a state allows out-of-state practitioners to diagnose or treat patients, both physicians (at originating and at distant sites) need to make sure to document the receipt of valid IC, preferably by a signed form. In a direct patient-care model (which is devoid of an originating site provider), clearly the TM provider is responsible for a valid IC process. Finally, to further the goal of a global platform for providing medical care, all involved parties (especially in multinational interactions) should verify the accuracy and adequacy of the IC process and maintain access to the signed IC forms for future reference. New web-based, multi-lingual platforms¹²⁵ enable providers to obtain standardized, automatic, and computerized IC; manage legal risks; and improve patients’ education.¹²⁶

¹²³ For a tabulation of U.S. states’ informed consent laws, see Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429 (2006). In the United Kingdom, “reasonable physician” is the standard (*see Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582; Margaret Brazier & Jose Miola, *Bye-bye Bolam: A Medical Litigation Revolution*, 8 MED. L. REV. 85), while Israeli law opted for the reasonable patient standard (Patient Rights Act cl. 13b (1996) (Isr.)).

¹²⁴ “The health care practitioner who has ultimate authority over the care or primary diagnosis of the patient shall obtain verbal and written informed consent from the patient” Telemedicine Development Act of 1996, S.B. 1665 § 4(c), 1995–96 Reg. Sess. (Cal. 1996), *repealed by* Telehealth Advancement Act of 2011, A.B. 415, 2011–12 Leg., Reg. Sess. (Cal. 2011). The current language of the law states:

2290.5. (b) Prior to the delivery of health care via telehealth, the health care provider at the originating site shall verbally inform the patient that telehealth may be used and obtain verbal consent from the patient for this use. The verbal consent shall be documented in the patient’s medical record. (c) The failure of a health care provider to comply with this section shall constitute unprofessional conduct. Section 2314 shall not apply to this section.

The law does not relate to telehealth interactions without the presence of a provider at the originating site (i.e., the locality of the patient).

¹²⁵ Deborah Franklin, *Uninformed Consent: Tech Solutions for Faulty Permissions in Health Care*, SCI. AM., Mar. 15, 2011, <http://www.scientificamerican.com/article.cfm?id=uninformed-consent-mar-11> (describing, *inter alia*, informed consent programs developed by Emmi Solutions and Dialog Medical).

¹²⁶ Siegal et al., *supra* note 119.

Documentation of IC remains essential, and many information technologies are available to record and archive ICs for future contentions.

C. Data Protection and Confidentiality

The need to protect medical information and patient privacy are well-known concerns and received much attention in state statutes and in federal legislation, especially the Health Insurance Portability and Accountability Act (HIPAA).¹²⁷ The growing interest in and development of electronic health records (EHR)¹²⁸ highlights the need to assure these rights, especially if one recognizes the ease in which privacy can be breached in the digital era. Thus, a detailed assessment of where in the process of IT-driven medical care confidentiality might be undermined is needed. Transferring medical data to distant sites might transpire in several ways. In teleradiology, imaging studies are transferred, while in teleconsultation, one's entire medical record could be shared with others. Telesurgery or telepsychiatry would create a live video file that can be stored, copied, and transmitted. All these cases involve informational risks that must be contained and to which patients need to consent.¹²⁹ Some of these risks are not adequately met by current practices. For example, institutions and practitioners who outsource diagnostic services out-of-state or to foreign countries rarely share this fact with their patients.¹³⁰ As stated by Professor George Annas:

Under the terms of HIPAA, a valid authorization to release health information must contain at least the following: “a description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion”; “the name [of the person or entity] authorized to make the use or disclosure”; “the name [of the person or entity] to whom the disclosure may be made”; “a description of each purpose of the requested use or disclosure”; “an expiration date or expiration event” (“none” or “end of the research study” is sufficient for research-related use, research data bases, or research repositories); and “the signature of the individual and date.”¹³¹

While understandable from an institution's prestige perspective (i.e., the need to rely on outsourced consultation) or from a business point-of-view (i.e., the cost containment gained by outsourced medical services), this “ghost” practice raises serious concerns over patients' consent to such data transformation.¹³² It is true that under the HIPAA Privacy Rule, uses and disclosures for the purpose of “treatment” do not require any consent or authorization of the patient. This is,

¹²⁷ See 42 U.S.C. § 1320d-2 (Supp. IV 2010); see also George J. Annas, *HIPAA Regulations - A New Era of Medical-Record Privacy?*, 348 NEW ENG. J. MED. 1486, 1486 (2003); Barbara J. Williams, *Virtual Web Waves of the Future: Integrating of Healthcare Systems on the Internet*, 76 N.D. L. REV. 365 (2000).

¹²⁸ See generally U.S. Dept. of Health & Human Servs., *Health Information Security and Privacy Collaboration (HISPC)*, OFF. NAT'L COORDINATOR FOR HEALTH INFO. TECH. (Apr. 9, 2010), <http://healthit.hhs.gov/portal/server.pt?open=512&objID=1240&parentname=CommunityPage&parentid=2&mode=2>; James G. Hodge et al., *Legal Issues Concerning Electronic Health Information: Privacy, Quality, and Liability*, 282 JAMA 1466 (1999).

¹²⁹ Recently, international standards have been developed by the International Organization for Standardization (ISO). See INT'L ORG. FOR STANDARDIZATION [ISO], *Health Informatics—Security Requirements for Archiving of Electronic Health Records—Principles*, ISO/TS 21547:2010 (2010); ISO, *Health Informatics—Security Requirements for Archiving of Electronic Health Records—Guidelines*, ISO/TR 21548:2010 (2010).

¹³⁰ Zawadski, *supra* note 1, at 153. See generally McLean, *supra* note 1.

¹³¹ Annas, *supra* note 127, at 1488.

¹³² *Id.* at 1487.

however, replaced by the Notice of Privacy Practices given to the patient by the provider at the time at their first visit.¹³³ So, Annas's observation should not apply here. Despite the legal standard under HIPAA, a physician should obtain authorization from the patient before any such disclosure—this was accepted practice before HIPAA came along, and HIPAA should not have the effect of lowering the standard on this account. Involving consultants in medical care requires providers to be transparent about the latter's identity and qualifications, and to provide patients with binding assurance as to the state of record keeping, confidentiality, and the possibility for future access to their files, also known as "fair information practices." Clearly, patients must be given the opportunity to decline such transfers. Whenever applicable, institutions should attempt to "anonymize" transferred medical records (for example, by using one-way codes), as the identity of the patient is not material to diagnosing a pathology slide or reading an MRI. In this case, most legal concerns are alleviated, as de-identified medical information (in which identifiers such as names, address, birth or hospital discharge dates, telephone or fax numbers, email addresses, social security numbers, medical record or health plan account numbers, or Internet Protocol (IP) address numbers were removed) is not subject to the stringent regulation mentioned.

With respect to sharing medical information over state borders, the United States did not have an easy task dealing with the European Union. The European Union has found U.S. privacy legislation insufficient in comparison to its own Data Protection Directive¹³⁴ and has entered into a five-year negotiation with the U.S. Department of Commerce to allow transfer of data from the European Union to American companies. These negotiations matured in the Safe Harbor Principles,¹³⁵ which grant certified companies the presumption of providing sufficient data protection as far as EU law is concerned.¹³⁶ The requisites include notice, choice, onward transfer, security, data integrity, access, and enforcement.¹³⁷ Pertinent to this discussion, the choice principle mandates an opt-out approach to collection of "general" personally identifiable information. Information identified as "sensitive" requires an opt-in choice, with the clear intent of ensuring that individuals explicitly grant data collection under well-understood conditions. Sensitive information is defined as including medical or health conditions. However, the opt-in is not necessary when the processing is: "(1) in the vital interests of the data subject or another person; [or] . . . (3) required to provide medical care or diagnosis."¹³⁸ The security principle states that any organization seeking refuge under the safe harbor "must take reasonable precautions to protect personal information from loss, misuse and unauthorized access, disclosure, alteration and destruction."¹³⁹ Qualifying protection to be "reasonable" has been a constant compromise in the IT world, where absolute protection is impossible. After a decade, empirical review of some 1,200 commercial entities currently included in the list of companies asserting safe harbor eligibility has revealed that meeting the seven principles or any enforcement by the EU or

¹³³ 45 C.F.R. § 164.520 (2010).

¹³⁴ Directive 95/46/EC, of the European Parliament and of the Council of 24 Oct. 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, O.J. (L 281) 31.

¹³⁵ Issuance of Safe Harbor Privacy Principles and Transmission to European Commission, 65 Fed. Reg. 45,666 (July 24, 2000).

¹³⁶ U.S. Dep't of Commerce, *Safe Harbor List*, EXPORT.GOV, <https://safeharbor.export.gov/list.aspx> (last visited Feb. 12, 2012).

¹³⁷ Anna E. Shimanek, *Do You Want Milk with Those Cookies: Complying with the Safe Harbor Privacy Principles*, 26 IOWA J. CORP. L. 456, 473 (2000–2001).

¹³⁸ Christopher Wolf & Timothy P. Tobin, *Privacy Laws*, PROSKAUER ON INT'L LITIG. & ARB., http://www.proskauerguide.com/law_topics/28/I (last visited Feb. 26, 2012).

¹³⁹ U.S. Dep't of Commerce, *U.S.-EU Safe Harbor Overview*, EXPORT.GOV (Apr. 11, 2011), http://export.gov/safeharbor/eu/eg_main_018476.asp.

American authorities is highly questionable.¹⁴⁰ Regrettably, no data exists in respect to medical institutions. However, the qualified requirements in respect to medical data transfer seem to offer a somewhat sanguine prognosis for reaching common ground in respect to harmonizing medical data transfer.

D. Coverage

Tied to the above issues of licensure, liabilities, and data protection lies the concern regarding the availability of recovery for injured patients. To be clear, by “injured patient” I refer to physical injuries resulting from substandard care as well as dignitary injuries resulting from breach of privacy protection. Such recovery is essential to patients, to their families, and to society at large (if the latter, through its civil mechanisms, is called upon to redress such injuries), and recovery for TM related injuries is no different. However, the complexities of global health care delivery make assuring compensation a tricky task, as it requires assuring existing coverage of providers, determining compensable events, adjusting compensation to various countries and hence different financial needs, and finally assuring fast collection of adjudicated compensation. Insofar as insurance coverage for practitioners is involved, most policies exclude unlicensed activity. Therefore, practitioners must ascertain their coverage status (including the need to resolve the licensure hurdle) prior to engaging in TM activity (with the exception of infrequent, not-for-profit teleconsultation).¹⁴¹ In 2007, the American Telemedicine Association endorsed a special insurance policy (TelMed™, offered by The Campania Group) that aims at clearing the obfuscation on the part of providers and guaranteeing full malpractice coverage for TM activities.¹⁴² Other dedicated insurance products are available, and thus coverage issues should not halt TM's proliferation, as long as the policies clearly and unambiguously provide coverage for the exact and specific TM activity being practiced and the injuries implicated. As stated earlier, reaching global agreement on the elements of coverage, establishing claims, and recovering damages should be part of a global compact on TM. Looking at the tremendous diversity of national laws and civil procedures, finding private-law common ground seems unrealistic, and alternatives to tort law should be sought. As discussed in the following part, I find that the most attractive option is an insurance model. The ingredients of such a compact must confront hard questions such as eligible causes for compensation (e.g., accepting or rejecting dignitary damages or a cap on non-economic damages), the standard for compensation, statutes of limitations, and verifying the existence of sustainable insurance schemes. However, the alternative (i.e., adapting the current state-of-affairs) is far more demanding and the current slow pace of progress of the TM industry needs to be avoided.

IV. MOBILIZING IT-DRIVEN HEALTH CARE – SOME SUGGESTIONS FOR FUTURE DIRECTIONS

Harnessing IT to promote globalization of health care requires a substantial legal and regulatory effort. In this section I delineate several areas in which I anticipate that successful

¹⁴⁰ See Daniel R. Leathers, *Giving Bite to the EU-US Data Privacy Safe Harbor: Model Solutions for Effective Enforcement*, 41 CASE W. RES. J. INT'L L. 193, 198–208 (2009); CHRIS CONNOLLY, *US SAFE HARBOR—FACT OR FICTION?* (2008), available at http://www.galexia.com/public/research/assets/safe_harbor_fact_or_fiction_2008.

¹⁴¹ Siegal, *supra* note 59.

¹⁴² See Cohen, *supra* note 83, at 1536; see also *ATA Telemedicine Buyer's Guide*, AM. TELEMED. ASS'N, <http://media.americantelemed.org/news/buyersguide.htm> (last visited Feb. 26, 2012); TELMED INSURANCE, <http://www.telmedinsurance.com/> (last visited Feb. 15, 2012).

engagement may assist in a more robust exploitation of IT/TM to promote the goal of a globalized TM regime. The basic premises I rely on have been set forth in previous sections and their aggregated form lays out a modest proposal for future progress. First, individuals may travel to other states or countries where medical care is readily available to them. However, a great number of patients that could benefit from medical tourism will not or cannot travel for their health care needs. For the sake of clarity, I refrain from dealing with the issue of patients attempting to gain access to medical procedures deemed illegal in their home countries, much less procedures that are in fact illegal in the host country.

Second, medical facilities, current practices, and workforce qualifications can be reliably subjected to external, independent, and effective standardized review. Providers and institutions in turn will willingly submit to such review if it is conceived as a prerequisite to partake in the global market of electronic medical tourism. Third, the need to protect patients is a constant concern. Arguing for patient protection has two major facets: protecting their health during and following TM care (the quality/safety argument) and protecting their legal rights when injury has occurred and redress is sought (the legal protection argument). The quality/safety argument has been pivotal in fueling a negative attitude toward traditional medical tourism in general and toward TM in particular. However, the quality/safety argument is neither proven, well founded, nor insurmountable.¹⁴³ Finally, redress for avoidable injuries or mishaps is required to prevent a situation where injured patients face substantial loss or devastating outcomes, or where these losses are externalized to the home country's social security system.

A. Medical WWW – Approved/Eligible Providers

A collective process of international/supranational official recognition based on established accreditation process (e.g., a JCI-like accreditation procedure) should enable the creation of a “medical world-wide web” (M-WWW), in which national bodies, institutions and providers all subscribe to standardized infrastructure and equipment and accepted standards of practice, data management, and privacy. The formation of this trusted web should be concerted, bringing in the private sector as well as governments. The private–public partnership is indispensable. The former constituent is essential to infuse the enthusiasm and efficiency of entrepreneurship. The latter is critical in harnessing state powers to allow cross-border health care, to enable the resolutions of current legal obstacles, and to assure that patients and public interests are adequately promoted, including the need to promote access to health care via such globalization to underserved populations.

Importantly, supranational health organizations and players have an important leadership role, as stated by Borris & Anderson:

Even the often-maligned WHO and the World Health Assembly (WHA) occupy a relatively impressive position of normative power and institutional authority among actors in the global arena. WHO's record in influencing international and national policy and practice compares very favorably with that of a wide array of human rights and development bodies charged with promoting social justice under the UN system. Its clear health mission and the capacities of its staff amplify the normative power of its recommendations and pronouncements. Few organizations have scientific

¹⁴³ See Cohen, *supra* note 83, at 1471–73.

credibility to match the WHO imprimatur in matters of health, a power more often evident in lesser developed than rich countries.¹⁴⁴

A successful and trusted establishment of the M-WWW would depend primarily on addressing the following: instituting appropriate privileges/credentials to verify professional competence; introducing safeguards to prevent unauthorized access, use, and fraud (passwords, logs, etc.); and implementing sanctions in case of a breach (including revocation of institutional certification, agreed-upon penalties, complaint mechanisms to an institution's home national authorities). Responsibility for compliance and performance should rest on providing institutions. They must assure that only licensed and qualified providers are practicing TM and guarantee their authentication. Institutions must meet standards of care and protect patients' confidentiality and privacy according to predetermined criteria.¹⁴⁵

Furthermore, participating parties should establish “contact points” in participating countries and states to provide interested patients and contact points in other countries and states with information concerning the recognition of professional qualifications and relevant practices of those professions, and, where appropriate, the pertinent rules of health law and medical ethics.¹⁴⁶ In this regard, some countries and some U.S. states have adopted the “reasonable patient” standard in determining the nature and amount of information that should be provided to patients by their doctors, while others adhere to the “reasonable physician” standard.¹⁴⁷ If a TM interaction involves countries or states with different standards of informational disclosure, prior notice on this matter should be available to patients. Notably, electronic medical tourism allows states and countries to maintain their sovereign legal regimes, as patients accept the *lex domicilii* of the provider.

Responsibility for consuming health care from non-accredited providers should be shifted to consumers, expecting them to utilize only credible sources. Indeed, health consumers should be well informed about the hazards of receiving medical care or consultation from non-affiliated practitioners. Such requirement necessitates the creation of an updated listing of flawed sources/sites (“medical travel warnings”) by the M-WWW governance. One such example is the work carried by the Health On the Net Foundation (HON),¹⁴⁸ which promotes and guides the deployment of useful and reliable online health information and its appropriate and efficient use. Dealing with patients who have been injured using non M-WWW members deserves serious deliberation, especially if they are left without means to regain their social functions or are forced to absorb the costs of their injuries. Holding patients responsible for their lack of responsibility in consuming non-accredited care seems objectionable¹⁴⁹ (although American patients injured using

¹⁴⁴ Scott Burris & Evan D. Anderson, *A Framework Convention on Global Health: Social Justice Lite or a Light on Social Justice?*, 38 J.L. MED. & ETHICS 580, 586 (2010).

¹⁴⁵ See *supra* Part III.C.

¹⁴⁶ Miek Peeters, *Free Movement of Medical Doctors: The New Directive 2005/36/EC on the Recognition of Professional Qualifications*, 12 EUR. J. HEALTH L. 373, 385 (2005).

¹⁴⁷ See *supra* note 121 and accompanying text.

¹⁴⁸ “Created in 1995, HON is a non-profit, non-governmental organization, accredited to the Economic and Social Council of the United Nations. . . . [T]he HONcode of conduct offers a multi-stakeholder consensus on standards to protect citizens from misleading health information.” HEALTH ON NET FOUND., <http://www.hon.ch/> (last visited Feb. 15, 2012).

¹⁴⁹ For example, Germany has instituted fines against patients who fail to meet advocated screening tests. See generally Gil Siegal & Neomi Siegal, *Leadership and the Road to Personal Responsibility to Healthy Behavior—Between Autonomy and Paternalistic Interventions*, in ACCOUNTABILITY AND RESPONSIBILITY IN HEALTH CARE: ISSUES IN ADDRESSING AN EMERGING GLOBAL CHALLENGE (Bruce Rosen, Stephen Shortell & Avi Israeli eds., 2012).

“regular” medical tourism are frequently left to bear the results of their choices, while in countries with national health systems, the cost are still externalized). Creative means to address such eventualities, as well as means to dissuade patients from using non-approved providers should be discussed.

B. Financing

Identifying needed funds to promote a more extensive dissemination and utilization of IT and TM, including infrastructure, standardization, workforce training, and ancillary costs is a task that I shall not attempt here. That having been said, the thriving medical tourism industry is a vivid testament to the ability to generate sufficient economic incentives for parties involved in cross-border medicine, and the more efficient IT/TM holds a similar chance of success. Indeed, globalization of health care in the form of medical tourism has shown remarkable acceleration; hundreds of thousands of Americans seek medical care in other countries, at a projected estimated cost of \$200 billion by 2020.¹⁵⁰ However, as opposed to the individually driven medical tourism movement, utilizing IT capabilities should become a prime target for national players, including governments, when addressing their citizens’ needs, and when reviewing their foreign health aid investments.

In this respect, another important source of funding should be added to the discussion—funds dedicated by nations to foreign aid. In 1974, the UN passed a resolution calling for a New International Economic Order (NIEO), upon which member countries would dedicate 0.7% of their annual GNP to global aid. While this pledge has never been fully implemented, and the political stalemate in the UN and its severely biased forum raises serious concern on the expected misguided decisions,¹⁵¹ deploying IT/TM could serve as an easier test-case for global aid, because many parties stand to benefit (that is, the investment is not an act of mere charity but is instead cross-subsidiary). The nature of the IT industry seems to facilitate more control over resources, to be handled primarily by developed countries, thereby diminishing unwanted waste and even corruption.

The following depicts the American experience, but it is true for other developed countries and supranational institutions like the EU. Despite the economic crisis, the United States continues to play a leading role in foreign aid.¹⁵² President Obama recently submitted his fiscal-year 2013 budget request to Congress, which included an estimated \$8.5 billion for the Global Health Initiative (GHI).¹⁵³ The GHI is an “umbrella” fund that directs money to various health organizations throughout the world. President Obama announced the fund in 2009 and

¹⁵⁰ See McLean, *supra* note 3, at 599.

¹⁵¹ For example, more than thirty percent of the 2011 budget for the United Nations Relief and Works Agency (UNRWA) came from American donations (*Financial Updates*, UNITED NATIONS RELIEF & WORKS AGENCY (Jan. 30, 2012), <http://www.unrwa.org/etemplate.php?id=246>), yet many of its employees in the Gaza Strip are members of the extreme military group of Hamas, a terrorist organization with an unquestionably anti-Western record). See also Barry Rubin, *Hamas Bombmakers and Fighters Need Not Quit Their UN Day Jobs*, THE CUTTING EDGE (May 26, 2008), <http://www.thecuttingedge.com/index.php?article=525>.

¹⁵² DEP’T OF STATE, EXECUTIVE BUDGET SUMMARY – FUNCTION 150 AND OTHER INTERNATIONAL PROGRAMS, FY 2012 (2011), available at <http://www.state.gov/documents/organization/156214.pdf>.

¹⁵³ HENRY J. KAISER FAMILY FOUND., U.S. FUNDING FOR THE GLOBAL HEALTH INITIATIVE (GHI): THE PRESIDENT’S FY 2013 BUDGET REQUEST 1 (2012), available at <http://www.kff.org/globalhealth/upload/8160-02.pdf>.

pledged sixty-three billion dollars over the next six years toward programs that combat HIV/AIDS, malaria, tuberculosis, infant mortality, and other health problems.¹⁵⁴

Adding new expenses in today's economy is politically problematic. But diverting existing expenses to other causes can be more palatable, especially if geared toward multiple beneficiaries. On the one hand, demonstration projects that facilitate better health care in developing countries can create important or even crucial health outcomes for disadvantaged populations in both developed and developing countries. On the other hand, investments in infrastructure and education can create collateral benefits for donating countries as well, where the emerging technological know-how can boost economic growth within donating countries, and can simultaneously serve their internal medical markets (for example, in rural areas). In other words, a dedicated portion should be earmarked for reinvestment in providers and manufacturers operating within donating countries to create substantial incentives to participate in these projects (including tax incentives) and as a consequence boost the capabilities in developed countries as well. Indeed, the expected spillover to the domestic arena in developed countries would have a beneficial effect, allowing all stakeholders to benefit. In addition, by infusing resources committed to high-tech medicine, developing countries may do better in keeping their qualified workforce, as the current departure of health professionals tends to create severe disadvantageous results for poorer countries.¹⁵⁵

C. Redress

Patients interested in receiving cross-border TM will be prompted to learn about the legal remedies available to them in case of an injury. Two main options can be pursued. The first involves the continuous reliance on the tort system either in the jurisdiction of the provider or the patient. As a result, a host of problems previously presented emerges (choice of law, appropriate forum, setting the applicable standard, and determining compensable injuries, to name a few).¹⁵⁶ As scholars have noted, the availability of adequate compensation is doubtful (in terms of the likelihood of success, the amount awarded, and the prospects of enforcing a judgment) in certain TM sites, and the jurisdiction of the patient's country over the event is doubtful.¹⁵⁷ Thus, alternative approaches that seek to provide compensation without involving the problematic tort avenue should be considered.

Substitutes that should be explored include a no-fault administrative compensation scheme (where redress is provided for injuries without the need to prove provider's negligence), or a mandated insurance-coverage program. In the former alternative, such as current no-fault programs in Nordic countries such as Sweden, Norway, and Denmark, as well as in New Zealand, compensation for injuries attributed to avoidable events is granted by government-operated bodies.¹⁵⁸ I find this option unsuitable for the current global TM market for the following reasons.

¹⁵⁴ *Id.*

¹⁵⁵ See Fitzhugh Mullen, *The Metrics of the Physician Brain Drain*, 353 NEW ENG. J. MED. 1810 (2005); C.R. Hooper, *Adding Insult to Injury: The Healthcare Brain Drain*, 34 J. MED. ETHICS 684, 686 (2008); J. Snyder, *Is Health Worker Migration a Case of Poaching?*, 9 AM. J. BIOETHICS 3, 3 (2009); J. Dwyer, *What's Wrong with the Global Migration of Health Care Professionals?*, 37 HASTINGS CENTER REP. 36 (2007).

¹⁵⁶ See *supra* Part III.A.

¹⁵⁷ See Cohen, *supra* note 83, at 1494.

¹⁵⁸ See Rolf Gunnar Jørstad, *The Norwegian System of Compensation to Patients*, 21 MED. & L. 681, 683 (2002); David M. Studdert & Troyen A. Brennan, *No-Fault Compensation for Medical Injuries: The*

First, it would be extremely difficult to establish multiple schemes for every country, adjusting to its nuanced political and legal institutions. The pace of progress can never be synchronized globally, leading to piecemeal progress and an extended period of legal uncertainty for patients attempting to choose between international providers. Second, the nascent phase of TM requires much expertise, and it is highly unlikely that a diffuse system that is based in every country and operates independently can shorten the learning curve and operate smoothly and rapidly in order to assure compensation, as opposed to a centralized attempt. However, I would advise against embarking on an attempt to establish a central, supranational authority for the obvious managerial and access difficulties it represents.

The other option for remedies for TM-based injuries is mandatory insurance with differential pricing, both in insurance acquisition (i.e., the premium) and in respect to compensation. In other words, patients contemplating the use of TM interactions would be well advised to obtain “TM medical accident insurance.” This is neither impossible nor impractical—in the medical tourism case, the American insurance industry has already responded to the need for coverage with a more limited version. AOS Assurance Company Limited is offering “Patient Medical Malpractice Insurance” that insures against “the risk of suffering Medical Malpractice abroad.”¹⁵⁹ I will not attempt to address the details of such insurance but only delineate its general nature. Similar to personal injury coverage (which does not require the proof of negligence), patients will be entitled to compensation if specified adverse events transpire. Payments are subject to local insurance laws in the originating site of care (i.e., the location where the patient is). The concept of “glocal” (the hybrid of global and local) works very nicely for TM, as the premium as well as the compensation for damages will reflect local (in respect to the originating or patient’s site) values in a transparent, up-front fashion, while allowing individuals to enjoy the benefits of global medicine in a manner in which the risk of non-compensable injuries is contained. Local mandatory insurance has an important role in such a system, as it is best situated to assess local (country-specific) costs of harm. Given local standards, insurance premiums are expected to be lower in poor countries (allowing access to persons other than the affluent), as well as compensation (which will keep the general premiums at a reasonable rate). Such stratification has been suggested in dealing with global health and intellectual property rights in pharmaceutical products and can be modified to an international IT/TM scheme.¹⁶⁰ In dealing with services as opposed to goods, differential pricing omits the need to deal with preventing leakage from low to high cost markets. The ability of poor patients to buy such insurance is obviously questionable, and more thought should be given to ways to provide them compensation (for example, a dedicated fund based on a fixed percentage of M-WWW providers’ revenues).

The drawback of an insurance model must be acknowledged—providers will be enjoying liability-free practice, thus creating the need to replace the tort system’s primary role in deterring negligent conduct.¹⁶¹ Several tools can be used to create positive as well as negative incentives to enhance accountability and safety. For example, market forces and tools can be put to work, such as leveraging the commercial value of reputation. Or insurance companies could post the number

Prospect for Error Prevention, 286 JAMA 217, 219 (2001); Allen B. Kachalia et al., *Beyond Negligence: Avoidability and Medical Injury Compensation*, 66 SOC. SCI. & MED. 387, 388–92 (2008).

¹⁵⁹ Cohen, *supra* note 83, at 1536.

¹⁶⁰ Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. MED. & ETHICS 184, 185 (2009).

¹⁶¹ MAXWELL J. MEHLMAN & DALE A. NANCE, *MEDICAL INJUSTICE: THE CASE AGAINST HEALTH COURTS* (2007); Daniel P. Kessler, *The Effect of the U.S. Malpractice System: A Review of the Empirical Literature* 19–20 (2007) (unpublished manuscript), available at <http://www.pointoflaw.com/pdfs/kessler-malpractice-jced1.pdf>.

of patients who were injured in a particular TM interaction by a particular provider, and premiums within states can differ accordingly. Ultimately, insurance companies could refuse to cover particular TM interaction by a particular provider if the latter's records fall below industry standards. Compensating patients should be closely linked to reporting requirements to providers' national authorities and/or to a central M-WWW database to allow for disciplinary and market-based measures both locally and internationally.

V. CONCLUSION

This Article aimed at reviewing the existing impediments to a more robust exploitation of IT to promote the globalization of health care—more care where it is needed. In addressing current barriers, the need to develop a cross-border approach (as a natural outgrowth of the border-free nature of IT) seems evident, both for the internal markets in developed countries as well as internationally. To that end, I have proposed a dedicated effort to establish a formal M-WWW. The following elements need to be resolved in order to ensure a thriving international M-WWW that would benefit all stakeholders and allow the materialization of the benefits of globalization: sufficient funding for demonstration projects and subsequent translation to large-scale sustainable programs; a strong commitment to quality by appropriate training of the workforce and establishing guidelines, protocols, and accepted accreditation processes with adequate sanctions; transparent and trusted information on care availability and patients' rights; and finally, assuring remedies for those injured. Identified legal obstacles such as licensure, liabilities, and privacy must be overcome in a manner that enables sensible solutions with appropriate adaptation from traditional health-care law and ethics. The materialization of such a scheme is contingent on a bifurcated maneuver—the bottom-up drive of the industry and providers as well as medical tourists/patients, and the top-down efforts of governments and supranational organizations. Such engaged partnership would enable reaping the benefits of IT in modern health care for the global citizenry.