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Trading Your Health: Assessing the Need for Domestic Regulation of Telemedicine and Ability to Conform to U.S. Trade Agreements

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TRADING YOUR HEALTH: ASSESSING THE NEED FOR DOMESTIC REGULATION OF TELEMEDICINE AND ABILITY TO CONFORM TO U.S. TRADE AGREEMENTS

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International telemedicine services have existed virtually outside the U.S. regulatory matrix for over a decade. This lack of regulation has opened the door for dangerous and possibly life-threatening situations to arise, leaving little to no available recourse for injured consumers.

Regulation is often cast as an antonym of liberalization and a dirty word under the current political and economic zeitgeist. Despite this common misconception, regulation can be imposed without threatening liberalized trade or breaching current free-trade agreements. All current trade agreements, by nature, seek to increase liberalization and globalization by reducing barriers to trade. However, lack of commitment, provisions allowing for domestic regulation of services, and specific exceptions within the agreements leave the door open for the U.S. to impose a regulatory matrix governing telemedicine without breaching the obligations of our current free-trade agreements.

Telemedicine's value cannot be denied. Nonetheless, trading healthcare services, and thereby the health and safety of Americans, cannot continue unchecked. If executed properly, regulations can both serve U.S. free-trade interests and protect patient-consumers.

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INTRODUCTION

Imagine waking at four in the morning with excruciating abdominal pain. You rush to your local hospital's emergency department, where you are quickly ordered a CAT scan. What's the next step? One of the hospital's many radiologists reads the report and discovers appendicitis, right? Wrong. In the wee hours of the morning it is quite unlikely the hospital will have a staff of radiologists lying in wait, particularly in rural areas. It is equally unlikely the hospital will call in a radiologist and pull them from their quiet slumber to diagnose your bad appendix. The much more likely scenario is that the report will be sent to a radiologist in Australia or India, who is on his regular shift, and he will interpret the scan and report his findings to the hospital. This is a form of medical outsourcing, often referred to as telemedicine.[1]

Telemedicine is becoming more prevalent as technology and domestic shortages of medical professionals increase. By and large, this transition to medical care and diagnostics over the internet rather than at the bedside has received positive reviews from the medical community. Faster diagnostics, lowers costs, and sometimes better care are all positive qualities of telemedicine. However, there are concerning drawbacks without easy solutions.

There are virtually no legal barriers to outsourcing disaggregate services. For the most part, medical outsourcing exists outside the U.S. healthcare regulatory matrix. This can raise serious issues when the care received is not up to par, or at worst, a patient is harmed as a result of an outsourced service. An additional concern is the impact cheaper and more readily available foreign services will have on the domestic market.

This fork in the road between the positive and negative aspects of telemedicine has led to two distinct factions: those calling for increased regulation of telemedicine and those calling for increased liberalization. In a world of growing globalization and free-

[1] It should be noted that telemedicine is not only provided internationally, but domestically as well. It is common practice for telemedicine to occur within a state or across state lines within the continental U.S. However, this Article will focus on the international supply of telemedicine, that is, healthcare services exported outside the U.S. to foreign service providers.

trade agreements, it is unlikely the multi-billion-dollar telemedicine industry will slow any time soon, expecting to grow to a $34 billion industry world-wide by 2020 with North America accounting for at least forty percent of the global market.[2]

It is clear however, that trading healthcare services and the health and safety of Americans, without imposing a regulatory structure that both serves U.S. free-trade interests and protects American patients, cannot continue unchecked. Liberalization is not synonymous with deregulation.

All current trade agreements, by nature, seek to increase liberalization and globalization by reducing barriers to trade. However, lack of commitment within the agreements, specific provisions allowing for domestic regulation of services, and exceptions to provisions leave the door open for the U.S. to impose a regulatory matrix governing telemedicine without breaching the obligations of our current free-trade agreements.

This Article endeavors to stimulate discussion on the need for regulation and the best ways to impose proposed regulations without fundamentally breaching our obligations to our international trading partners, rather than to be a comprehensive and definitive policy proposal.

Part I of this Article presents an overview of telemedicine. Part II illustrates the predominate issues in telemedicine and the proposed regulatory solutions. Finally, Part III describes the obligations of the applicable US free-trade agreements and proposes the viability of imposing regulations without violating these obligations.

I. TELEMEDICINE IN A NUTSHELL

Put simply, telemedicine is a form of medical outsourcing that can be defined as "the use of electronic communication and information technologies to provide or support clinical care at a

[2] Robert M. Wachter, Perspective: *The "Dis-location" of U.S. Medicine–The Implications of Medical Outsourcing*, 254 N ENG. J. MED. 661, 661-62 (2006); Carlo Combi et al., *Telemedicine for Developing Countries: A Survey and Some Design Issues*, 7 APPLIED CLINICAL INFORMATICS 1025, 1026 (2016).

distance."[3] Telemedicine has existed in various forms for at least thirty years.[4] Limited by the technology of the time, telemedicine began innocently enough as simple videoconferencing between healthcare providers.[5] Today, technology no longer poses a barrier to healthcare entering the international marketplace.[6] Emerging technology has created the opportunity for disaggregation of professional services, enabling professionals as far away as Australia to provide medical care to patients in the United States. The U.S. healthcare industry has leveraged this opportunity to offshore clinical tasks to facilitate reduced labor costs and navigate around domestic labor shortages.[7] Radiology and data storage and processing are the most highly outsourced areas, with electronic ICU monitoring and pathology following closely behind.[8]

The ever-increasing developments in technology have created a world where, in many cases, it is no longer necessary for a doctor to be in the same room, or even same hemisphere, as his patient to render effective treatment.[9] As early as 2006, hundreds of hospitals throughout the United States were outsourcing medical services to foreign countries, predominately India, Switzerland, Australia, Israel, and Brazil.[10]

This growing "dis-location" of medical services continues to have far-reaching implications on both healthcare and trade policy.[11] Often, patients are unaware the services they receive have

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[3] Matthew S. Yeo, *Distance Health Services Under the General Agreement on Trade in Services*, 35 J. HEALTH L. 83 (2002) (quoting U.S. Dep't of Commerce, U.S. Dep't of Health and Human Services, Joint Working Group on Telemedicine Rep. to Cong. at 1 (Jan. 31, 1997)).

[4] Yeo, *supra* note 3.

[5] Thomas R. McClean, *Future of Telemedicine and its Faustian Reliance on Regulatory Trade Barriers for Protection*, 16 HEALTH MATRIX 443, 454 (2006).

[6] *Id.* at 446; Jason W. Sapsin et al., *Part II: International Trade and Health: International Trade, Law, and Public Health Advocacy*, 31 J.L. MED. & ETHICS 546, 551 (2003).

[7] Nicholas P. Terry, *Under-Regulated Healthcare Phenomena in a Flat World: Medical Tourism and Outsourcing*, 29 W. NEW ENG. L. REV. 421, 444-45 (2007).

[8] *Id.* at 444.

[9] McClean, *supra* note 5, at 443; Vanessa deGier, "Medical outsourcing carries implications for health care policy and practice," (Univ. of Cal. San Francisco) (February 15, 2006) (available at https://perma.cc/W2XR-TFDX).

[10] deGier, *supra* note 9.

[11] *Id.*

been outsourced to a service provider outside the U.S.[12] Despite the healthcare system's status as one of the most highly regulated areas in the country, medical outsourcing remains largely unregulated.[13]

Undeterred by this dangerous gap in domestic regulatory protection, telemedicine, and medical outsourcing generally, continue to grow with the help of the U.S. government. Between 2010 and 2020, the telemedicine equipment market alone is expected to grow from $163.3 million to $6.28 billion.[14] Particularly through the Patient Protection and Affordable Care Act,[15] the federal government has provided grants and incentives to further utilize telemedicine.[16] The U.S. Department of Health and Human Services offers grants for licensure portability to allow states to combat licensure as a barrier to telemedicine and develop telehealth networks and telehealth resource centers to assist in the implementation of telehealth programs.[17]

A. Forms of Telemedicine

Telemedicine can generally be broken down into five[18] primary categories: (1) "Doctor to Doctor" exchanges in which a domestic physician seeks and receives assistance from a physician in another jurisdiction, such as consultations or supervision; (2) remote monitoring services in which professionals in remote locations monitor and report back on data transmitted from the domestic healthcare provider, such as electronic ICU monitoring; (3)

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[12] Terry, *supra* note 7, at 422.

[13] *Id.* at 470.

[14] 2-27E Forensic Sciences § 27E.03 at (f)(1)(i) (2017) [hereinafter Forensic Sciences].

[15] PATIENT PROTECTION AND AFFORDABLE CARE ACT; ELDER JUSTICE ACT, 111 P.L. 148, Part 1 of 3, 124 Stat. 119, 111 P.L. 148, 2010 Enacted H.R. 3590, 111 Enacted H.R. 3590.

[16] Forensic Sciences, *supra* note 14, at (f)(1)(i).

[17] *Id.*

[18] Other forms of medical outsourcing (but not telemedicine) are pharmaceutical arbitrage, in which patients seek prescription drugs outside the U.S., and medical tourism, in which patients travel outside the U.S. to receive medical procedures. Though possible the most controversial, and arguably most dangerous forms of medical outsourcing, both lie outside the scope of this article. For more information *see* Terry, *supra* note 7, at 422-38, 446-51.

remote diagnostic services in which patient data is transmitted to professionals in remote locations, interpreted, and transmitted back to the domestic provider with diagnostic findings, such as teleradiology and pathology; (4) remote direct patient care in which the remote provider actually performs clinical evaluation and treatment on the patient, such as using robotic surgical devices to perform surgery remotely; and (5) remote data processing and storage in which patient data is transmitted to a foreign service provider and is processed and stored, such as medical records storage and medical transcription.[19]

Additionally, telemedicine utilizes two distinct models: the Nighthawk Model and the Indian Model.[20] The Nighthawk Model is relatively rare. Under this model, U.S. entities establish arms of their companies overseas and transport U.S.–trained physicians to the remote location to provide services to domestic physicians remotely.[21] Conversely, under the Indian Model, the service providers are incorporated in a foreign country and hire their own staff from that location.[22] Both models seek to utilize the differences in time zones between their location and the U.S., allowing staff in these international areas to provide services to U.S. providers during nightshift hours.[23]

i. Teleradiology and Telehealth

Teleradiology, perhaps the most well-known form of telemedicine, has technically existed since 1929 when a dentist transmitted dental x-rays to a distant location via telegraph.[24] Today, teleradiology serves as "a means of electronically transmitting radiographic patient images…and consultative text from one location to another," allowing a radiologist to remotely review and diagnose radiological images anywhere in the world.[25]

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[19] Yeo, *supra* note 3.

[20] McClean, *supra* note 5, at 448-49.

[21] *Id.* at 449.

[22] *Id.* at 449-50.

[23] *Id.* at 448-50.

[24] Nishigandha Burute & Bhavin Jankharia, *Teleradiology: The Indian Perspective*, 19.1 THE INDIAN J. OF RADIOLOGY & IMAGING 16-18 (2009).

[25] Vivek Nayar, *Teleradiology: Images of an Improved Standard of Medical*

The Centers for Medicare and Medicaid Services require that remotely-interpreted radiographic images must subsequently be reinterpreted by U.S. radiologists. Ergo, the overseas radiologist should only provide a preliminary report, while the U.S. radiologist should, and is required to, submit a final report.[26] However, this procedure is not always followed leading to the dangerous phenomenon known as "ghost reporting,"[27] which is likely illegal by U.S. standards, but perfectly legal from India's perspective.[28]

Regulatory entities have been slow to support teleradiology, primarily over concerns of the confidential nature of patient data, ramifications of misdiagnoses, and issues surrounding liability and legal recourse.[29]

More recently, insurance companies have instituted "tele doctor" programs where subscribers can speak to nurses and physicians over the internet to send images and describe symptoms. For certain ailments, the healthcare provider will examine, diagnose, and prescribe treatments, including prescription drugs, without having ever been in the same room with the patient.

ii. Electronic ICU and Telemonitoring

Electronic ICU monitoring allows nurses and physicians in any part of the world to remotely monitor patients and their physiological data live.[30] In some instances, providers can even enter orders remotely through connections to the local hospital's computer system.[31] Due to ICU's increasing demand and intensivist shortages, remote ICU monitoring has become common-place and is likely to grow.[32]

Care?, 35 RUTGERS COMPUTER & TECH. L.J. 104, 106 (2008).

[26] Terry, *supra* note 7, at 459.

[27] Put simply, "ghost reporting" describes the process when a radiologist (for our purposes, a U.S. radiologist) signs the radiological report performed by another radiologist (for our purposes, a foreign telemedicine provider) or imputes the report to his own diagnosis and treatment of a patient, without actually completing a "final primary report" of the image. Terry, *supra* note 7, at 445-46.

[28] Burute, *supra* note 24.

[29] Nayar, *supra* note 25, at 104.

[30] Wachter, *supra* note 2, at 663.

[31] *Id.*

[32] Terry, *supra* note 7, at 444-45; Leo Anthony Celi et al., *The eICU: It's Not*

This practice has extended beyond the ICU to include telemonitoring of patients receiving both home health and hospice care. This "remote patient monitoring" system allows patients to answer "questions designed for their condition and then send the information via phone or Wi-Fi to a nurse who reviews it and then follows up with the patient and doctor" in conjunction with remote monitoring of the patient's vital signs.[33]

As of 2017, the majority of states have expanded Medicaid insurance reimbursement laws to require payment of telemedicine services, some including remote patient monitoring.[34] The Center for Medicare and Medicaid Services has recently announced changes to Medicare reimbursement schedules for telemedicine, taking effect January 1, 2018, that also include incentives for utilizing this type of technology for patient services.[35] Private insurance reimbursement of telemedicine, particularly remote monitoring, varies by state. However, the majority of states have instituted parity laws that require insurers to reimburse telemedicine services at the same rate as face-to-face healthcare services.

iii. Data Processing and Storage

Outsourcing of information technology was the first wave of outsourcing in the healthcare system and has continued to grow by leaps and bounds.[36] The healthcare industry relies on data at its core, including patient data, medical transcription, and claims processing and billing.[37] The need for efficient and cost-effective processing and storage of these vast amounts of data has led to outsourcing of these services. Outsourcing of medical data and transcription to foreign time zones allows for round-the-clock

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Just Telemedicine, 29 CRITICAL CARE MED. N183, N183-N184 (2001).

[33] Interview with Kristin Reid, RN, BSN, CHPN (December 6, 2017).

[34] *See, e.g.,* Miss. Code Ann. § 83-9-353; *Telehealth, Medicaid, and State Policy*, Center for Connected Health Policy, https://perma.cc/7J36-QQ2K.

[35] 42 C.F.R. § 414 (2017). *See also* Jodi G. Daniel & Maya Uppaluru, *New Reimbursement for Remote Patient Monitoring and Telemedicine*, C & M HEALTH L. BLOG, (Nov. 3, 2017), https://perma.cc/5X9R-FND6. It should be noted that some restrictions on Medicare reimbursement still exist. However, they are rapidly diminishing.

[36] Terry, *supra* note 7, at 439-40.

[37] Yeo, *supra* note 3.

productivity and decreased labor costs.[38]

Information technology is not a common skill in the healthcare industry. This shortage of qualified professionals, administrative complexity, and skyrocketing healthcare costs opened the door for countries like India to step in and pick up the slack.[39] For example, data entry costs in the U.S. are over double the cost in India resulting in over half of the U.S. transcription services being outsourced to other countries by 2007.[40]

B. Why Telemedicine Developed

Outsourcing of healthcare services saves money and allows professionals overseas to provide services when professionals in the U.S. are not awake, or at least don't want to be.[41] Put simply, telemedicine capitalizes on time differences.[42] Advances in technology opened the door for foreign competitors to step in and take advantage of domestic shortages of qualified professionals and the need for cost efficiencies.

i. Technological Advances

We live in a digital world and healthcare is not exempt. When we picture healthcare, we are more than likely to imagine direct patient care: doctors and nurses examining patients, rendering treatment, and prescribing medications. In today's world, however, healthcare is data: patient history and health records, lab results, diagnostic imaging data, physician examination reports, nurse's notes, and a multitude of test results.

The entrance into the digital age allowed the flow of this data to revolutionize healthcare and give rise to telemedicine. The emergence of the internet and vast expansion of telecommunication

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[38] Terry, *supra* note 7, at 440.
[39] *Id.* at 441.
[40] *Id.* at 441.
[41] McClean, *supra* note 5, at 450.
[42] Wachter, *supra* note 2, at 662.

"catalyzed the development of telemedicine applications and increased awareness of its commercial potential."[43] The first international operation occurred in 2001 when surgeons in New York City removed the gall bladder of a woman in France through the use of a remotely controlled surgical robot.[44] One of the surgeons who performed the operation touted, "the barriers of space and distance have collapsed . . . any surgeon could feasibly take part in any operation anywhere in the world."[45] Today, the internet facilitates nearly all facets of healthcare.

In the years following the internet boom, there has been ever-growing decline in the cost of data transmission, increased awareness and ease of use of technology, increased reliability of technological systems, and most critically for telemedicine, increased ability to separate services from the production process. By separating the evaluation or test from interpretation process and digitally shipping the data overseas, the often most expensive and complex portion of the service can be performed at lower cost and increased efficiency without the patient and the technician even residing in the same country.[46]

ii. Physician Shortages and Supply-Side Surplus

Telemedicine, and teleradiology in particular, came into existence out of a disparity between the demand for and availability of some health services.[47] Specifically, the demand for radiologic services could not be fulfilled due to the lack of qualified, available, and rested physicians in the overnight hours.[48] Hospitals are increasingly having difficulty obtaining qualified radiologists on the third shift leading to possible accreditation issues as they are required to provide services delivered quickly and accurately.[49] As a

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[43] Yeo, *supra* note 3.

[44] *Id.*

[45] *Id.* (quoting Rebecca Harrison, "Surgeons in U.S. Operate on Woman in France," TORONTO STAR, Sept. 20, 2001, at A03).

[46] Wachter, *supra* note 2, at 663.

[47] Burute, *supra* note 24.

[48] *Id.*; McClean, *supra* note 5, at 499.

[49] McClean, *supra* note 5, at 499.

result, hundreds of U.S. hospitals outsourced imagery by 2007.[50] Likewise, outsourced services like electronic ICU are often marketed as a response and solution to the shortage of qualified critical care physicians.[51] By outsourcing services to countries like Australia and India, U.S. hospitals are able to provide efficient and cost effective care to their patients.[52]

Several issues have led to this domestic shortage, "creating a supply-side surplus in some less-industrialized countries."[53] Immigration issues pose one of the most severe barriers to foreign educated physicians.[54] The J-1 Visa Program[55] has helped somewhat, but with the ever-increasing restrictions being placed on immigration through the current U.S. administration, the U.S. has been unable to fulfill its need for qualified foreign doctors and nurses.[56] Hospitals and other healthcare providers have chosen to "end-run this barrier" by simply outsourcing services overseas to countries with a surplus, as there are minimal barriers to sending disaggregate services overseas.[57]

iii. Cost Benefits

The U.S. healthcare industry is in a constant battle between ensuring quality and reducing costs. As a result, outsourcing services helps to strike a balance by providing arguably comparable quality at severely decreased costs.[58] According to the World Bank, the costs of healthcare in the U.S. are "significantly higher . . . than

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[50] Terry, *supra* note 7, at 445.

[51] Wachter, *supra* note 2, at 663.

[52] Burute, *supra* note 24.

[53] Terry, *supra* note 7, at 458.

[54] *Id.* at 421, 458.

[55] The Rural Initiative - J-1 Visa Waiver (Dec. 17, 2002), 45 C.F.R. Part 50. *See also* Foreign Physicians: Preliminary Findings on the Use of J-1 Visa Waivers to Practice in Underserved Areas: Hearing Before the Subcomm. on Immigration, Border Security and Claims of the H. Comm. on the Judiciary, 109th Cong. (2006) (statement of Leslie G. Aronovitz, Dir., Health Care Issues, U.S. Gen. Accounting Off.), available at https://perma.cc/L9EM-GQP2.

[56] Terry, *supra* note 7, at 458-59.

[57] *Id.*

[58] deGier, *supra* note 9.

in a number of other countries."[59] Despite the enormous costs of healthcare, the U.S. falls below the median[60] on service utilization.[61] In addition, the costs associated with entering the telemedicine marketplace are markedly low as a result of today's technology; the hardware is cheap by healthcare standards, leaving software, contract negotiation costs, and opportunity costs as the only real capitalization requirements.[62]

One of the guiding principles of telemedicine costs is simple supply and demand: if supply of available providers increase, costs decrease.[63] In the U.S. the "skyrocketing" costs of healthcare are viewed as an overwhelming drain on the economy.[64] The Indian model of telemedicine allows U.S. providers to skim from the lower-wage and larger pool of providers overseas.[65] For example, an Indian radiologist would receive approximately $60,000 per year, whereas an American radiologist with comparable specialization and years of experience would be paid approximately $350,000 per year for providing the same services.[66] Many argue medical outsourcing could "potentially stabilize the cost of health care because of improvements in access to care, creation of economies-of-scale, reduction of medical errors, and improved competition amongst providers."[67]

iv. Increasing Quality of Care Abroad

Many advocates for telemedicine argue outsourcing

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[59] Aaditya Mattoo & Randeep Rathindran, *Does Health Insurance Impede Trade in Health Care Services?* (World Bank, Policy Research, Working Paper No. 3667, 2005) (stating that the World Bank uses 2002 hospital reimbursement data from Centers for Medicare and Medicaid Services (CMS) and data from select foreign hospitals, e.g., the Apollo Hospital in Delhi).

[60] Organisation for Economic Co-Operation Development.

[61] Terry, *supra* note 7, at 455 (citing Michael F. Cannon & Michael D. Tanner, HEALTHY COMPETITION: WHAT'S HOLDING BACK HEALTH CARE AND HOW TO FREE IT 18-25 (2005)).

[62] McClean, *supra* note 5, at 447-48.

[63] McClean, *supra* note 5, at 451-52.

[64] Wachter, *supra* note 2, at 661.

[65] McClean, *supra* note 5, at 483, 502.

[66] Burute, *supra* note 24.

[67] McClean, *supra* note 5, at 450-51.

healthcare services can provide patients numerous benefits including service providers who speak numerous languages and centers of specialized care known as "centers of excellence" or "focus factories."[68] Domestically, telemedicine has provided rural providers and their patients access to the level of care they would otherwise be unable to obtain.[69] However, discrepancies among the quality of care have remained a concern among critics.

In recent years, developing countries have increased education and training to compete with the western world, and increasingly produce medical professionals that meet North American and European standards.[70] As a result, U.S. medical schools and hospitals accept a large number of foreign students, interns, fellows, and residents into their programs.[71] Many of them practice in the U.S. before returning to their respective home countries to practice.[72]

Likewise, hospitals in developing countries have upped the ante as well.[73] The Joint Commission International, an arm of the same Joint Commission that oversees accreditation of American hospitals, has accredited hundreds of organizations around the world, including hospitals in India.[74]

Though some foreign service providers in developing countries increasingly have the professionals, technology, and facilities to offer care comparable to our own, not all service providers in countries utilized for telemedicine services are up to par with our standards, and U.S. healthcare remains superior.[75]

C. Who We Outsource To

The U.S. healthcare system outsources services to numerous countries around the world. For the purposes of this Article the

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[68] *Id.* at 452-53; Wachter, *supra* note 2, at 662.

[69] Wachter, *supra* note 2, at 663.

[70] Nathan Cortez, *Patients Without Borders: The Emerging Global Market for Patients and the Evolution of Modern Health Care*, 83 IND. L.J. 71, 82-83 (2008).

[71] *Id.*

[72] *Id.* at 83.

[73] *Id.*

[74] Joint Commission International, *JCI-Accredited Organizations*, https://perma.cc/BYX3-E9GQ.

[75] Cortez, *supra* note 70, at 82-84.

predominate providers are India, Australia, Brazil, Israel, and Switzerland, the most utilized of which is India. The first use of teleradiology occurred in India in 1996 and the first teleradiology company was started in India in 2002.[76] As early as 2003, when telemedicine was in its infancy, India had already captured 2% of the U.S. healthcare market, with the U.S. paying $340 million to India for outsourced medical transcription and billing services alone.[77]

In India today, healthcare is one of its largest sectors both in employment and revenue, expected to reach $280 billion by 2020.[78] Specifically, India's health information technology market was valued at $1 billion in 2016 and is expected to increase by 150% by 2020.[79] The main telemedicine services in India focus on cardiology, radiology, ophthalmology, and nephrology.[80]

Due to India's large number of English speakers, proficiency in technology, and strong engineering and technical infrastructure, India stands to gain more of the U.S. telemedicine market than any other country worldwide.[81] India is unlikely to take any interest in the nighthawk model discussed above and will continue to gain a larger market share as their business model is the most cost-effective.[82]

The Indian business model has significant advantages over competing telemedicine exporting countries, like Australia and Switzerland.[83] Indian service providers not only make less money, but also work under cheaper, less ideal conditions.[84] In addition to

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[76] Burute, *supra* note 24.

[77] McClean, *supra* note 5, at 443.

[78] India Brand Equity Foundation, Sectoral Report: Healthcare Industry in India, https://perma.cc/2JYK-HNK9.

[79] Foreign Direct Investment is outside the scope of this article, but it is worth mentioning that India attracted FDI worth US$ 4.34 billion between April 2000 and March 2017 to illustrate the ever-increasing foreign investment leading to the growth of India as the dominate telemedicine provider. *See id.*

[80] Combi, *supra* note 2, at 1032.

[81] McClean, *supra* note 5, at 502.

[82] *Id.*

[83] Burute, *supra* note 24.

[84] McClean, *supra* note 5, at 507-08.

cheap labor,[85] India offers lower costs of services,[86] an ideal time difference with the U.S.,[87] and skilled support staff[88].

II. ISSUES IN TELEMEDICINE AND POSSIBLE SOLUTIONS

It would be difficult to argue that telemedicine could not, and does not, provide extensive benefits and opportunities to the U.S. healthcare market. However, these benefits may be outweighed by the possible harms that could occur if we lose sight of quality of care, patient confidentiality, and patient security.[89] Given these obvious concerns, coupled with differing cultural and political attitudes towards medicine and ethical issues surrounding extraterritorial medical care, it is shocking that telemedicine exists primarily unregulated.[90]

A. Ensuring Quality

Put most simply, "to the extent that some care will be provided by anonymous people in cyberspace rather than by local doctors, distinguishing competent providers from hucksters will become even more difficult."[91] Quality in itself is exceedingly difficult to measure and ample care is required to measure differences in quality across various countries.[92] Quality cannot be confined to simply the "absence of error," nor can quality be affected by the negative stereotype of medical care in less-developed countries.[93]

Despite the increasing standards in countries like India, we

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[85] An Indian Radiologist is paid approximately $60,000 per year as opposed to $350,000 per year earned by a comparable American radiologist. Burute, *supra* note 24.

[86] An MRI in India costs approximately $150, the professional's fee component ranging approximately from $15 to $20. *Id.*

[87] Simply, when it is nighttime in the U.S., it is daytime in India.

[88] India possesses a large number of trained information technology professionals, engineers, and "business processing outsourcing manpower." Burute, *supra* note 24.

[89] deGier, *supra* note 9.

[90] Yeo, *supra* note 3.

[91] Wachter, *supra* note 2, at 663.

[92] Cortez, *supra* note 70, at 102-03.

[93] Terry, *supra* note 7, at 463.

still simply do not know how the quality of care received from foreign countries stacks up in comparison to the U.S. Around the world, most hospitals are not required to report procedural outcomes, and even if they were, there is no system in place for reporting or measuring outcomes internationally.[94]

Increasingly, governments are allowing the private sector to take over the country's healthcare system, opening the door to reduced "public accountability in the design, funding, and delivery of public services."[95] Simply by utilizing software assistance in the transmission of data, diagnostics, and treatment, the door has been opened for latent errors into the practice of medicine.[96] Basically, in using telemedicine, physicians, and unfortunately their patients, are subjected to unknown risk.

Even in India, where the majority of teleradiology occurs, there is a shortage of U.S. board certified radiologists, resulting from a desire to remain in the U.S. upon certification, as a result of wage discrepancies.[97] In 2004, the American College of Radiology Task Force reported that it was "very concerned about the implications of overseas radiology and its potential effect on patient care in the United States."[98] The Task Force also stressed the need for providers performing services outside the U.S. to be "licensed to practice medicine in the state where the imaging examination is originally obtained as well as possess any medical or other licensure required within the jurisdiction of the interpretation site," have appropriate liability insurance in the state where the examination was obtained, be credentialed in the U.S. facility where the image was obtained, "be responsible for the quality of the images being interpreted," and "willingly agree to submit to the jurisdiction of and be completely accountable to all applicable state and federal laws in the United States."[99]

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[94] Cortez, *supra* note 70, at 102-03.

[95] Sapsin *supra* note 6, at 551 (quoting World Trade Organization, Assessment of Trade in Services, Geneva: World Trade Organization at 1 (2001)).

[96] McClean, *supra* note 5, at 455.

[97] Burute, *supra* note 24.

[98] Am. Coll. of Radiology, Revised Statements on the Interpretation of Radiology Images Outside the United States (May 2006).

[99] *Id.*

B. Liability

Calculating liability exposure in telemedicine is an especially complex undertaking. Though some courts have held the local arm of the provider liable, e.g. the hospital that outsourced the patient's MRI to India for interpretation, patients will face significant obstacles in attempting to establish liability against the offshore provider.[100]

If the patient seeks redress in the foreign country where the service was provided, the task that awaits the patient is daunting. Attempting to navigate unfamiliar legal, regulatory, and financial systems that are significantly less comprehensive and mature than the U.S. system is not an easy task.[101] Even if the patient is able to establish liability under a foreign jurisdiction, actually obtaining redress is unlikely. In India, for instance, there are very few resources dedicated to malpractice suits and many "insurance companies do not recognize Indian medical qualifications."[102] It could easily be argued that, in fact, one of the reasons healthcare costs are significantly lower in India is the significantly lower amount of malpractice recovery and lower malpractice insurance costs.[103]

Likewise, attempting to bring suit against a foreign provider within the patient's jurisdiction would be a comparably daunting task. In order to proceed in a medical negligence lawsuit, the patient will first and foremost have to establish the physician owed him a duty of care. Upon establishing such duty, the patient would then be required to show the physician breached that duty. Telemedicine has made it exceedingly difficult to establish duty by removing the physical proximity and hands-on care present in the traditional doctor-patient relationship.[104] The act of a third party performing diagnostics, and even procedures on patients, has created "the opportunity for the courts to recast the physician/provider-patient relationship and the duties that flow from it more flexibly."[105]

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[100] Terry, *supra* note 7, at 465.
[101] *Id.* at 464; Cortez, *supra* note 70, at 91, 101.
[102] Cortez, *supra* note 70, at 91.
[103] Terry, *supra* note 7, at 464-65.
[104] Nayar, *supra* note 25, at 123.
[105] *Id.* at 119-20 (quoting Patricia C. Kuszler, *Telemedicine and Integrated*

As far as liability is concerned, the current state of liability of third party telemedicine providers remains a legal uncertainty at best.[106] Despite the existence of state regulatory statutes[107] that apply to anyone who does business within the state, the ability to enforce such statutes is tenuous.[108] Further regulation and policy are required to protect patients and their legal rights.[109]

i. Independent Contractors

Many foreign telemedicine providers may be able to escape liability through artfully negotiating service contracts as independent contractors, and to a lesser extent, subcontractors. Yes, the domestic provider could be held liable for the acts of the contracted providers, yet this is often a difficult task made even more arduous when the contracting party operates in another hemisphere.

Generally, courts are only willing to hold vicarious liability in circumstances where there exists an employer-employee relationship and that employee commits a tortious act within the scope of that employment. Hospitals may be held liable for the acts of their employed physicians; however, many telemedicine relationships do not fit the mold of employer-employee.[110]

Additionally, courts may hold providers vicariously liable for the actions of their contractors through ostensible or apparent agency.[111] Again, foreign telemedicine providers can circumvent liability because the patient would be required to prove: (1) he had a reasonable belief the contractor was an agent of the domestic provider, (2) the domestic provider "somehow acted to lead the plaintiff to believe the physician was its agent or at least have failed to give the plaintiff a contrary impression," and (3) the domestic pro-

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Health Care Delivery: Compounding Malpractice Liability, 25 AM. J.L. & MED. 297, 308 (1999)).

[106] Nayar, *supra* note 25, at 123.

[107] *See* Cal. Civ. Code § 1798.82(a) (West 2006).

[108] Terry, *supra* note 7, at 461.

[109] Nayar, *supra* note 25, at 105.

[110] Phillip Mirrer-Singer, *Medical Malpractice Overseas*, 70 L. & CONTEMP. PROBS. 211, 219 (2006).

[111] *Id.*

vider's "act or failure to act must have been the reason for the [patient's] mistaken impression" that the foreign provider was an agent.[112]

ii. Jurisdictional Issues

Even on the off-chance a patient can surmount the hurdle of establishing liability against a foreign telemedicine provider, an even greater obstacle of establishing jurisdiction awaits. Dr. Robert Wachter said it best: "having service providers operating under different laws and, potentially, value systems can create opportunities for new kinds of mischief."[113] Jurisdiction is not at issue for telemedicine providers practicing the Nighthawk Model. However, telemedicine providers operating under the Indian Model are not located in the U.S., nor do they have a principal place of business in the U.S. to establish domicile or have sufficient ties to the forum state to establish personal jurisdiction.

Unfortunately, even state long-arm statutes, which serve as a method of exercising jurisdiction over defendants who "transact business in the state or who regularly solicit business in the state while committing a tort," are insufficient.[114] Courts have often held that the "transacting" and "soliciting" provisions fail to give rise to jurisdiction.[115] This observation is particularly true in the case of out-of-state physicians,[116] whether those physicians directly treat the patient or operate through referral from an in-state physician.[117]

In order to have a functional system to facilitate telemedicine litigation, there must be "rules of jurisdiction and commerce . . . recognized by parties on both sides of the ocean."[118] Foreign telemedicine providers should be required to submit to U.S. jurisdiction as a condition of access to the domestic market.

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[112] *Id.* at 219-20.

[113] Wachter, *supra* note 2, at 663.

[114] Singer, *supra* note 109, at 213.

[115] *Id.*

[116] See Ingraham v. Carroll, 687 N.E.2d 1293, 1295–96 (N.Y. 1997). *See also*, Nicholas v. Ashraf, 655 F. Supp. 1418, 1419 (W.D. Pa. 1987).

[117] Singer, *supra* note 109, at 213.

[118] McClean, *supra* note 5, at 477.

The jurisdictional issue snowballs: Indian telemedicine providers consider themselves outside the limits of U.S. jurisdiction, faced with little to no exposure to liability, thus able to avoid malpractice insurance requirements.[119] This perception further encourages "telemedical providers to take risks that the nighthawk providers could never take."[120]

iii. Malpractice

The unique patient-doctor relationship generated by telemedicine creates novel complications and tests the traditional laws surrounding medical malpractice.[121] This new wrench in the system is coupled with an already complex medical malpractice framework that relies on differing state laws and fact-specific analyses.[122] Though domestic providers that utilize telemedicine are held by the courts to the same standard of care as any other physician,[123] there is no international standard of care that governs telemedicine services, nor has any U.S. court established the standard of care for foreign telemedicine providers.[124] In fact, the American Telemedicine Association specifically lists the prevention of "clinical practice rules that impose higher standards for telehealth-provided services than in-person care" as one of its guiding principles for federal policy.[125]

The concern is simple: that our developing telemedicine partners do not and will not give U.S. patients adequate malpractice protections, even those with adequate healthcare systems.[126] Not only is it necessary that a standard, preferably an international

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[119] I. Glenn Cohen, Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument, 95 IOWA L. REV. 1467, 1517-18 (2010).

[120] McClean, *supra* note 5, at 451.

[121] *Id.* at 454-55; Forensic Sciences, *supra* note 14, at (f)(1)(i).

[122] Forensic Sciences, *supra* note 14, at (f)(1)(vii)(B).

[123] See, e.g. Planned Parenthood of the Heartland, Inc. v. Iowa Bd. of Med., 865 N.W.2d 252, 257 (Iowa 2015).

[124] Gil Siegal, *Enabling Globalization of Health Care in the Information Technology Era: Telemedicine and the Medical World Wide Web*, 17 VA. J.L. & TECH. 1, 21-22 (2012).

[125] American Telemedicine Association, TRANSFORMING HEALTHCARE FOR PATIENTS: 2017 POLICY PRIORITIES, available at https://perma.cc/FS44-XQM9.

[126] Cortez, *supra* note 70, at 74.

standard, be developed, but that foreign telemedicine providers submit to the standard prior to receiving access to U.S. patients.

As the system currently stands, telemedicine providers utilizing the Indian Model are unlikely to be subject to malpractice liability.[127] In contrast, U.S. physicians are required by most states to obtain malpractice insurance "as a condition[128] of licensure."[129] Foreign telemedicine providers cannot be allowed to continue to provide services to U.S. patients without a requirement to hold adequate malpractice coverage and a system in place to manage international malpractice claims.

C. Disruption of the Domestic System

Under our current political and economic zeitgeist, the battle of nationalism versus globalization is constantly subjected to the ever-lingering weight of foreign competition. Telemedicine is primed to become a real threat to the role of community hospitals and local providers.[130] As a result of the United States' ever-growing cost of healthcare and inefficiencies, domestic providers are not armed to combat the ease of access and low wage labor pool of telemedicine.[131]

Further liberalization could possibly have a negative impact on health systems, due to the "shifts in health care spending to high-tech care; exacerbation of the 'brain drain' phenomenon; creation of two-tiered health systems; or weakening of national regulatory systems ensuring quality and universal coverage."[132]

D. Data Security

The backbone of telemedicine is comprised of a constant and borderless stream of data. This transmission of vast amounts

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[127] McClean, *supra* note 5, at 450-51.

[128] Pursuant to the McCarran-Ferguson Act, the individual states have the right to govern and impose the insurance requirements for medical providers. 15 U.S.C.S. § 1011.

[129] McClean, *supra* note 5, at 461.

[130] *Id.* at 455-56.

[131] *Id.* at 456.

[132] Sapsin, *supra* note 6, at 553.

of private patient data has created concerns in the area of cross-border data security. The fears regarding confidentiality and security were brought to life as early as 2003, when two separate medical transcription and data processing contractors in India and Pakistan attempted to blackmail the U.S. providers, threatening to release confidential patient data if they were not paid.[133] Fortunately, both attempts were thwarted, but served to illustrate that the threat of a telemedicine data breach was real.[134]

The data transmitted includes not only patient personal information and medical records, but confidential emails and doctor-patient communications. In a world where hacker conglomerates such as WikiLeaks regularly make national news and security breaches of major corporations seem endless, more must be done in terms of regulation to protect patient privacy.[135]

The processing and storage of patient data is highly regulated in the U.S. In addition to state and federal regulations, licensure laws, and Medicare rules, The Joint Commission and AMA Code of Medical Ethics places increased responsibilities on healthcare providers.[136] Failure to comply with these rules may result in penalties and even malpractice.[137] However, it remains unclear just how effective these "domestic-facing" regulations are at protecting patient data that is off-shored.[138]

Additionally, the U.S. approach to data protection has been deemed insufficient as compared to others like the EU countries and Canada.[139] The U.S. approach, similar to both Japan and Australia, is primarily market-driven and self-regulatory, whereas the EU and Canadian regulatory systems employ a much more interventionist approach.[140] As a result, the EU found the U.S. system

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[133] Terry, *supra* note 7, at 442-43.

[134] *Id.*

[135] *See* Dan Munro, *Data Breaches in Healthcare Totaled Over 112 Million Records In 2015*, FORBES (Dec. 31, 2015, 9:11PM), https://perma.cc/A6BW-EHLG.

[136] *Id.* at 441-42.

[137] *Id.*

[138] *Id.* at 442.

[139] Nany J. King & Kishani Kalupahana, *Choosing Between Liberalization and Regulatory Autonomy under GATS: Implications of U.S.-Gambling for Trade in Cross Border E-Services*, 40 VAND. J. TRANSNAT'L L. 1189, 1265 (2007); Siegal, *supra* note 124, at 27.

[140] King, *supra* note 136, at 1265.

lacking by comparison to its own Data Protection Directive,[141] which allows the EU to extend its reach extraterritorially to govern offshore healthcare data processing.[142] Following a five-year negotiation to allow transfer of its patient data into the U.S., the Safe Harbor Principles[143] that developed lead to only certified companies in the U.S. being granted "the presumption of providing sufficient data protection as far as EU law is concerned."[144]

Absolute data security is impossible. However, considering that a significant portion of western industrialized countries find U.S. patient data security protection to be lacking, the current state of regulation should not be accepted as sufficient to protect America's own citizens.[145]

i. HIPAA

HIPAA privacy rules apply to U.S. providers who partake in telemedicine; however, it remains unclear whether and to what extent HIPAA rules govern and could be enforced against the foreign arm of U.S. data extension.[146] Some foreign telemedicine providers have become HIPAA compliant and use their certification as a marketing strategy. However, compliance is expensive, and these companies would only be held liable for HIPAA violations if they have entered into agreement as a "covered entity" thereby extending the HIPAA compliance requirements of the U.S. provider to the foreign entity.[147] As a result, little incentive to maintain compliance exists.[148]

Though contract provisions can serve to heighten compliance and increase protections, the truth is that there is little to no

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[141] 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.

[142] Siegal, *supra* note 124, at 27.

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

[144] Siegal, *supra* note 124, at 27.

[145] *Id.*

[146] Terry, *supra* note 7, at 443.

[147] *Id.*; McClean, *supra* note 5, at 460.

[148] McClean, *supra* note 5, at 460.

oversight of the sufficiency of U.S. telemedicine contracts.[149] In 2004, in response to formal questioning of the adequacy of offshored patient data protections by Congressman Edward Markey, the Secretary of Health and Human Services ("HHS") "admitted that his department failed to document the 'nature or content' of the contracts between covered entities and their business associates, or directly regulate offshore business associates."[150]

ii. Personal Data Offshoring Protection Act

In 2004, Congressman Markey introduced the Personal Data Offshoring Protection Act[151] in response to both the data breaches in India and Pakistan and HHS's admitted failure to properly ensure the security of patient data.[152] The bill served to protect patients by "prohibit[ing] the transfer of personal information to any person outside the United States, without notice and consent, and for other purposes."[153] In short the act would have required patients to provide consent for their data to be offshored to countries without adequate privacy protection, disallowed entities from refusing to provide service as a result of a patient's exercise of the right to consent, and called for the Federal Trade Commission to oversee certification of countries with adequate privacy protection.[154] Additionally, the bill would have provided for civil remedies upon failure to comply with the contents of the act.[155]

Unfortunately, the bill did not become law.[156] A similar

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[149] Terry, *supra* note 7, at 443-44.

[150] Nicolas P. Terry, *To HIPAA, a Son: Assessing the Technical, Conceptual, and Legal Frameworks for Patient Safety Information*, 12 WIDENER L. REV. 137, 165 (2006) (citing Letter from Tommy G. Thompson, Sec'y, U.S. Dep't of Health & Human Servs., to Edward J. Markey, Congressman, U.S. H. of Reps. 2 (June 14, 2004)).

[151] H.R.4366 — 108th Congress (2003-2004).

[152] Terry, *supra* note 7, at 461.

[153] H.R.4366 — 108th Congress (2003-2004).

[154] *Id.*

[155] *Id.*

[156] *Id.*

piece of legislation[157] did pass in California but was vetoed by Governor Arnold Schwarzenegger.[158]

E. Additional Regulatory Solutions

At this point, it should be clear that regulations protecting patients from fraud, malpractice, exploitation, and misuse of personal data must be in place.[159] Because there are no longer any realistic monetary or physical barriers to the outsourcing of healthcare, coupled with the insufficiencies of current U.S. trade in services agreements, domestic regulations are the only force available to protect patients.[160]

Domestically, trade barriers in the form of licensure and insurance regulation are executed primarily at the state level.[161] However, at this point, the protective measures that exist are primarily governed by nongovernmental organizations and commercial entities.[162] Regulation should be put in place by state and national government regulators that have the authority to impose sanctions, civil liabilities, and criminal charges in situations requiring this level of penalty.[163]

Imposing regulations over telemedicine, or any e-service provider, would be simple administratively.[164] Regulations should require foreign service providers to register within the states in which they provide services, submit to U.S. jurisdiction, and appoint a domestic agent for receipt of service of process (rather than being required to have a domestic address or place of business within the state).[165] This type of regulation could provide the opportunity to induce jurisdiction, and with it, the ability to impose

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[157] S. 1492, 2003-2004 Sess. § 56.32(b) (Cal. 2004).

[158] Terry, *supra* note 7, at 461 (citing John M. Hubbell & Mark Martin, "Governor Vetoes Bills on Offshoring Jobs: Legislation Bans Foie Gras Starting in 2012", S.F. Chron., Sept. 30, 2004, at B1, available at 2004 WLNR 7621668 (Westlaw).

[159] Siegal, *supra* note 124, at 24.

[160] McClean, *supra* note 5, at 456.

[161] *Id.* at 462.

[162] Siegal, *supra* note 124, at 24.

[163] *Id.*

[164] King, *supra* note 136, at 1263.

[165] *Id.*

both civil and criminal liability and enforcement actions.[166]

The only real danger in imposing domestic regulations governing telemedicine is the possibility of imposing an unauthorized restrictive barrier to trade, as complying with requirements in all localities where the foreign provider does business may be costly and laborious.[167] However, the less than stellar regulatory framework imposed under the current U.S. trade agreements leaves room for many forms of regulation and will be discussed further in Part III.

i. Licensing Requirement

Regulations requiring foreign service providers to obtain in-state or dual licenses to perform telemedicine services within the U.S. would possibly be the most effective protective regulation but would also have the greatest likelihood of imposing an unreasonable barrier to trade.

Healthcare licensing serves two main protective purposes: to protect patients from unqualified providers and to protect local providers from competition.[168] Licensing requirements are set by the individual states through policing power allowing the states to "regulate activities affecting the health, safety, and welfare of their citizens."[169] Additionally, the Supreme Court has authorized the states to set their own licensing requirements to govern the "quality of medical care providers within their boundaries according to their fiscal resources and the needs of their populace."[170]

Domestically, healthcare providers cannot practice within a state without a state license.[171] Additionally, some countries and

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[166] *Id.*

[167] *Id.*

[168] Siegal, *supra* note 124, at 13.

[169] Nayar, *supra* note 25, at 118 (quoting Joanne Kumekawa, Legislative Update, U.S. Dep't of Health and Hum. Servs., Health Res. and Servs. Admin. (May 1999).

[170] McClean, *supra* note 5, at 462 (quoting Thomas R. McLean, *Crossing the Quality Chasm: Autonomous Physician Extenders Will Necessitate a Shift to Enterprise Liability Coverage for Health Care Delivery,* 12 HEALTH MATRIX 239, 252 (2002)).

[171] Siegal, *supra* note 124, at 13.

states forbid practitioners from performing services in another jurisdiction without obtaining a license in that jurisdiction.[172] Currently, several states require a physician to have a full medical license in any state in which that physician practices telemedicine (where the patient is located).[173]

At least six states have taken this requirement a step further, by requiring practitioners of telemedicine to have a "special purpose" license.[174] In Texas, this license is required for any physician who is "physically located in another jurisdiction but . . . through the use of any medium, including an electronic medium, performs an act that is part of a patient care service initiated in this state…that would affect the diagnosis or treatment of the patient."[175] In order to obtain the Texas special purpose license the practitioner must not only be actively licensed in his home state, but also pass a Texas jurisprudence exam.[176]

Failing to comply with licensure requirements can result in sanctions, fines, and even a state shut down of the provider's practice.[177] However, because not all states have considered foreign telemedicine providers fully in their licensing regulations, this protective barrier has not encompassed the entire U.S. telemedicine market. This failure exists despite the American College of Radiology calling for all teleradiology providers to obtain a dual license in both the jurisdiction where they interpret the diagnostic image and the jurisdiction where the image was obtained (generally the location of the patient).[178]

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[172] *Id.*

[173] Forensic Sciences, *supra* note 14, at (c).

[174] *Id.*

[175] *Id.*; Tex. Occ. Code Ann. § 151.056(a).

[176] Forensic Sciences, *supra* note 14, at (c).

[177] *See* Jones v. N.D. State Bd. of Med. Examiners-Investigative Panel, 691 N.W.2d 251 (N.D. 2005); *See also* Ann Carrns, Illinois Orders Indiana Web Site to Stop Offering Medical Service, WALL ST. J., Oct. 30, 2002, at D4.

[178] Terry, *supra* note 7, at 459; Am. Coll. of Radiology, Revised Statement on the Interpretation of Radiology Images Outside the United States (May 2006).

III. ABILITY TO REGULATE UNDER CURRENT TRADE AGREEMENTS

In the growing battle between nationalism and globalization, supporters of liberalized trade in health services hinge on the positive aspects of healthcare liberalization as the backbone of the argument against regulation. In essence, further liberalization requires dismantling rather than imposing non-tariff barriers.[179] However, this point is moot as even the WTO admits, in referring the General Agreement on Trade in Services ("GATS"),[180] liberalization is not synonymous with deregulation.[181]

In truth, the current U.S. trade agreements have little impact on the regulatory structure of healthcare services in the U.S., especially in comparison to other governed areas like finance and environmental law.[182] Most U.S. multilateral and bilateral trade agreements are comprised mostly of what not to do in the way of imposing regulations, rather than what member nations should or must do.[183] From a trade liberalization perspective, regulations of national health and safety could be considered barriers to trade. However, the current U.S. trade agreements applicable to telemedicine include vast amounts of uncertainty, loopholes, and exceptions that allow for domestic regulation of telemedicine services.

Rather than simply acknowledging that regulation is possible, regulation must be demanded. In any trade service, regulations should be in place prior to market opening. Put aptly, "the single most important international trade objective for the United States healthcare industry should be to get its own house in order with respect to cross-border provision of health services."[184]

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[179] Sapsin, *supra* note 6, at 551.

[180] Final Act Embodying the Results of the Uruguay Round of the Multilateral Trade Negotiations, Dec. 15, 1993, Annex 1B, GENERAL AGREEMENT ON TRADE IN SERVICES (GATS) - RESULTS OF THE URUGUAY ROUND Vol. 31 (1993) [hereinafter "GATS"].

[181] Raymond J. Ahearn & Ian F. Fergusson, WORLD TRADE ORGANIZATION (WTO): ISSUES IN THE DEBATE ON CONTINUED U.S. PARTICIPATION, Congressional Research Service (June 16, 2010).

[182] Terry, *supra* note 7, at 467.

[183] Antonia Eliason, Lecture on the General Agreement on Trade in Services, University of Mississippi School of Law (Nov. 2, 2017).

[184] Yeo, *supra* note 3.

A. The GATS

The World Trade Organization is the single international organization governing global trade through agreements negotiated between its 164[185] member countries.[186] The WTO agreements establish rules and guidelines for trade between the member countries which, if breached, are subject to the WTO's dispute settlement body.[187] In general, all WTO agreements seek to liberalize trade.[188] The GATS developed from the WTO's "Uruguay Round" of international trade negotiations.[189]

The GATS seeks to address and avoid protectionist policies and actions in trade in services by eliminating or reducing barriers to trade in services.[190] Since the GATS came into being in 1995, e-commerce, and thereby electronically traded cross-border services, has grown by leaps and bounds.[191] It is unlikely that Members could have contemplated the telemedicine market as it exists today.[192]

The agreement applies to "all measures of WTO Members affecting trade in services."[193] This applies to any measures taken by the government or authorities to impose laws, regulations, or procedures that would place a restriction on service providers or the supply of service.[194] These prohibited measures can be quantitative or qualitative, and discriminatory or nondiscriminatory.[195] The GATS, however, does not "require any service to be deregulated [and] [c]ommitments to liberalize do not affect governments'

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[185] World Trade Organization, *Members and Observers*, https://perma.cc/W9ZM-W7FL.

[186] World Trade Organization, *What is the WTO?*, https://perma.cc/YV26-58UQ.

[187] World Trade Organization, *What we do*, https://perma.cc/UFD8-V9DF.

[188] World Trade Organization, *What we stand for*, https://perma.cc/NF76-WGZG.

[189] World Trade Organization, *Services Trade*, https://perma.cc/5YZ5-NVPS.

[190] King, *supra* note 136, at 1201-02.

[191] *Id.* at 1257.

[192] "Members" means members of the World Trade Organization who are parties to the World Trade Organization agreements. A complete list of Members is available at https://perma.cc/W9ZM-W7FL.

[193] King, *supra* note 136, at 1210.

[194] *Id.* at 1213.

[195] *Id.* at 1221, 1289.

right to set levels of quality, safety, or price, or to introduce regulations to pursue any other policy objective they see fit."[196]

Except a few universally-binding obligations, discussed *infra*, the GATS obligations only apply to the extent each Member country has committed within the modes of service and service sectors of the GATS. The GATS is separated into four modes: (1) Cross-border Supply, where a service is traded across the border from one member to another; (2) Consumption Abroad, where an individual (or their property) receive a service in a foreign country; (3) Commercial Presence, where an entity sets up shop in a foreign country; and (4) Presence of Natural Persons, where an individual provides services in a foreign country.[197] For the purposes of this Article, telemedicine falls primarily under Mode 1.[198]

The GATS is further broken down into sectors and subsectors.[199] Telemedicine falls under the "Health Related and Social Services" sector with the exception of some data processing aspects that may fall under the "Telecommunications" sector. With that sector, healthcare services are further broken down into two subsectors: "Hospital Services" and "Other Human Health Services."[200]

Within each sector and subsectors, Members are required to make specific commitments and provide additional limitations, if any, to those commitments. Under each schedule of commitments, each member country can specify its level of commitment: "none," meaning it is fully committed to imposing no limitations on market access or national treatment; "unbound," meaning it makes zero commitments to market access or national treatment and is free to impose regulations that limit market access or impose national treatment; or "limitations," meaning it commits to market access or national treatment, but with listed limitations or conditions.[201]

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[196] World Trade Organization, "Services: rules for growth and investment," available at https://perma.cc/2FXZ-CU34.

[197] GATS, *supra* note 178, at Art. 1, ¶ 2.

[198] Other forms of medical outsourcing like medical tourism and pharmaceutical arbitrage encompass Mode 2, and less frequently, Mode 3.

[199] General Agreement on Trade in Services, United States of America, Schedule of Specific Commitments (Apr. 15, 1994).

[200] *Id.*

[201] World Trade Organization, *Services: rules for growth and investment*,

Market Access, National Treatment, and the specific U.S. commitments in the Health sector will be discussed *infra* Part III(A)(ii) and Part III(A)(iii)(3).

i. Universally-Binding Obligations

There are few universally-binding obligations under that GATS.[202] The exceptions are Most Favored Nation and Transparency, which apply to all member countries regardless of specific commitments.[203] In contrast, commitments to National Treatment and Market Access are not imposed on member countries unless they are specifically committed to within the sectors and subsectors.

1. Article II: Most-Favored-Nation

The "Most-Favored-Nation Clause" ("MFN") can be described simply as a "favor one, favor all" requirement.[204] Basically, the best terms you offer to one nation must be offered to all other Members.[205] MFN prohibits any member country from discriminating based on nationality between "like"[206] services and suppliers of other member countries.[207] The clause encompasses both de jure and de facto discrimination; therefore, MFN prohibits facially neutral policies or regulations that ultimately result in discrimination in practice.[208]

MFN applies to all Members universally, regardless of specific commitments under the GATS. However, the GATS includes a provision allowing Members to reserve exemptions to MFN.[209]

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https://perma.cc/2FXZ-CU34.

[202] King, *supra* note 136, at 1203.

[203] *Id.*

[204] McClean, *supra* note 5, at 481.

[205] *Id.*

[206] "GATS provides no definition of "like" services or service . . . the determination of 'likeness' is left to be decided through the process of scheduling commitments, and ultimately through dispute settlement in the event of disagreement" King, *supra* note 136, at 1225.

[207] *Id.* at 1212.

[208] *Id.* at 1211; McClean, *supra* note 5, at 481-82.

[209] King, *supra* note 136, at 1211.

Because these exemptions modify their obligations under MFN and contradict the purpose of a universally-binding obligation, the exceptions are time-constrained and must eventually be removed subject to negotiation.[210] However, like nearly all WTO negotiations, these removal negotiations are slow and limited in success; thus, many of the exemptions remain in place.[211]

2. Article III: Transparency

Like MFN, Transparency requirements apply regardless of specific commitments. In short, if a Member establishes any new measures of general application that effect trade in services, they are required to publish the basic information related to that measure.[212]

Additionally, if any Member creates or alters any regulation, law, or administrative guideline that would affect trade in sectors covered under their specific commitments, the Member must notify the Council for Trade in Services and answer questions posed by other Members about the new or altered regulations.[213]

ii. Commitment-Specific Obligations

1. Article XVI: Market Access

The Market Access ("MA") requirement of the GATS imposes perhaps the greatest restriction and most rigid barrier against regulation.[214] MA requires Members to allow other Members to enter their market and prohibits restrictions that impose a barrier to those foreign services and suppliers.[215]

MA applies to both quantitative and "quantitative-type" restrictions on foreign suppliers.[216] The GATS denotes six specific limitations prohibited under Article XVI: (1) the number of service

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[210] *Id.*
[211] *Id.* at 1211-12.
[212] *Id.* at 1212.
[213] *Id.*
[214] McClean, *supra* note 5, at 484-85.
[215] King, *supra* note 136, at 1220.
[216] *Id.*

suppliers through quotas, monopolies, exclusive service providers, or economic needs tests; (2) the total value of service transactions or assets, based on numerical quotas or economic needs test; (3) the number of service operations or quantity of service output, based on quotas or economic needs test; (4) the total number of persons employed or that a service supplier may employ, through quotas or economic needs test; (5) the participation of foreign capital based on a maximum percentage on amount of foreign shareholding or total amount of foreign investment; and (6) measures that require or prohibit specific types of legal entities or joint ventures through which a provider provides a service.[217]

The above list is exhaustive; therefore, if the measure is not deemed to fall within the confines of one of the listed prohibited measures, it is allowed regardless of suppressive effect.[218] However, because MA also prohibits nondiscriminatory trade barriers, any prohibited limitation imposed may be precluded even if the limitation restricts domestic providers and foreign providers equally.[219]

However, MA obligations only apply to the "extent promised in the Member's schedule."[220] A full commitment to MA prohibits Members from instituting regulations that impose the restrictions listed above, and requires Members to award treatment "no less favorable than that provided for under the terms, limitations and conditions, agreed and specified" in the Member's schedule of commitments.[221] A Member may circumvent MA by simply designating itself as "unbound" for each mode of supply within each sector and subsector, or may designate specific limitations to its granting of MA.[222]

2. Article XVII: National Treatment

National Treatment ("NT") requires Members to treat other Member's service suppliers "no less favorably than they treat their

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[217] GATS, *supra* note 177, at Art. XVI, ¶ 2(a)-(f).
[218] King, *supra* note 136, at 1221-22.
[219] *Id.* at 1221.
[220] *Id.* at 1214.
[221] *Id.* at 1220-21.
[222] *Id.* at 1221.

own 'like' services and service suppliers."[223] In short, Members may not impose regulatory treatment on foreign service suppliers that is different from those imposed on domestic providers.[224]

NT applies to measures that discriminate against foreign service suppliers by affording them "less favorable treatment" than that afforded to a Member's domestic providers.[225] "Less favorable treatment" comprises any treatment that modifies competition at a detriment to foreign suppliers, even if the measures are identical to those imposed on domestic providers.[226] So, like MFN, NT applies to both de jure and de facto discriminatory measures.[227] Additionally, NT applies to discriminatory qualitative measures that "discriminate against foreign services or suppliers on the basis of the origin of the service or the nationality of the service supplier."[228]

However, like MA, NT only applies to the extent Members have made specific commitments within their schedule. Likewise, Members may evade NT obligations by designating themselves as "unbound" or list specific limitations to NT.[229]

iii. Obligations Specific to Regulation and How to Comply

Application of the specific obligations and elements of GATS to regulation is difficult. The determination of whether or not a specific regulation is allowed or precluded requires establishing whether it is prohibited under Articles II, XVI, and XVII, or specifically allowed under Articles VI and XIV.

In general, regulations must find the sweet spot that complies with GATS balance of undermining exercise of national sovereignty through obligations and respecting sovereignty through flexibility. The way in which a government measure is defined within GATS is often determinative of whether the measure will be considered a violation. For instance, quantitative discrimina-

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[223] *Id.* at 1222; GATS, *supra* note 177, at Art. XVII, ¶ 1.
[224] McClean, *supra* note 5, at 481.
[225] King, *supra* note 136, at 1214.
[226] *Id.* at 1223; GATS, *supra* note 177, at Art. XVII.
[227] King, *supra* note 136, at 1223.
[228] *Id.* at 1220.
[229] *Id.* at 1223-24.

tory measures that fall under Articles XVI and XVII must be eliminated (unless unbound or lists limitations in that sector), whereas qualitative nondiscriminatory measures are generally allowed under Article VI.[230]

So, when does a Member have authority to impose restrictive measures under GATS? The level to which Members may regulate trade is highly dependent on sector specific commitments. Luckily for the future of U.S. telemedicine regulation, the U.S. has made extremely limited commitments in the Healthcare sector. Additionally, even if a Member makes specific commitments under Articles XVI and XVII, all hope is not lost. Members retain the right to exercise "necessary disciplines" governing licensure and certification requirements, technical standards, and public policy objectives as long as they do not breach general obligations or specific commitments and are not "more burdensome than necessary to ensure the quality of the service."[231] Articles VI and XIV provide additional flexibility to uphold domestic policy objectives through regulation.

1. Article VI: Domestic Regulation

Despite containing both substantive and procedural obligations, Article VI is seen as a preservation of regulatory sovereignty.[232] In its decision in U.S.–Gambling,[233] the WTO Panel determined that, despite requirements to oblige with specific commitments, Members "maintain the sovereign right to regulate within the parameters of Article VI."[234] Additionally, the Panel deemed Article XVI to be mutually exclusive from chapters 4 and 5 of Article VI.[235] Therefore, any measure determined to comply with Article VI is presumed compliant with any commitments

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[230] *Id.* at 1193-94.

[231] GATS, *supra* note 177 at Art. VI, paragraph 4(b); McClean, *supra* note 5 at 482.

[232] King, *supra* note 136 at 1213.

[233] Appellate Body Report, United States - Measures Affecting the Cross-Border Supply of Gambling and Betting Services, WT/DS285/AB/R (Apr. 7, 2005) (adopted Apr. 20, 2005 [hereinafter U.S. Gambling].

[234] King, *supra* note 136 at 1239 (quoting Gambling *supra* note 231 at 6.316).

[235] King, *supra* note 136 at 1237; U.S. Gambling *supra* note 231 at 6.305.

made in the Member's schedule. However, Article VI, chapters 4 and 5 still limit regulation through requirements that measures not be "more burdensome than necessary to achieve legitimate objective."[236]

a. Article VI: 1-3

Paragraphs 1 and 3 of Article VI impose procedural restrictions requiring transparency and due process in imposing regulations.[237] These procedural requirements are construed broadly and are generally determined based on the level of specific commitments made by Members.[238]

Paragraph 2 additionally requires Members to "provide judicial review of administrative decisions affecting trade in services," but this requirement only applies "to the extent such procedures are consistent with a member's constitutional structure and legal system."[239]

To comply with paragraphs 1-3,[240] the measures generally only need to have been "administered in a reasonable, objective, and impartial procedure."[241]

b. Article VI: 4

Paragraph 4 of Article VI is perhaps the most important, excepting specific commitments, in governing the application of domestic regulatory measures. Paragraph 4 suggests that measures governing licensing requirements, technical standards, and qualification requirements and procedures "do not constitute unnecessary barriers to trade."[242] Specifically, requirements should be "(a) based on objective and transparent criteria, such as competence and the ability to supply the service; (b) not more burdensome than

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[236] King, *supra* note 136 at 1213.

[237] *Id.* at 1216.

[238] *Id.*

[239] *Id.*

[240] Additional tests apply for compliance; however, they are limited in applicability by specific commitments.

[241] King, *supra* note 136, at 1214.

[242] GATS, *supra* note 177, at Art. VI, ¶ 4.

necessary to ensure the quality of the service; (c) in the case of licensing procedures, not in themselves a restriction on the supply of the service."[243]

These suggestions apply to all Members regardless of specific commitments. However, they are construed quite broadly and regulations need only be "related to the broad objective of ensuring the quality of the service" and be the least trade restrictive.[244]

To draft regulations consistent with paragraph 4, regulations must be based on transparent and objective criteria, comply with Article III transparency requirements, articulate a legitimate policy objective, and be proportional and not more burdensome than necessary to achieve that policy objective.[245]

In addition to the broad and slightly ambiguous rules under paragraph 4, there is an additional and exceedingly important caveat: the qualifications of paragraph 4 are not active obligations. Paragraph 4 specifically requires the Council for Trade Services to create disciplines that require regulation to comply with the qualifications set out in paragraph 4. However, no disciplines have been adopted except in the Accountancy services sector.[246]

Without specific disciplines, paragraph 4 provides very little in the way of structural framework to determine whether a domestic regulation is in compliance with GATS. However, to combat this obvious regulatory black hole, Article VI, paragraph 5 serves as the interim rule governing domestic regulation until disciplines can be erected under paragraph 4.[247]

c. Article VI: 5

Pending development of disciplines under paragraph 4, par-

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[243] GATS, *supra* note 177, at Art. VI, ¶ 4(a)-(c).

[244] King, *supra* note 136, at 1271 (quoting Council for Trade in Servs., Note by the Secretariat: Art. VI:4 of the GATS: Disciplines on Domestic Regulation Applicable to All Services, 26, S/C/W/96 (Mar. 1, 1999)).

[245] King, *supra* note 136, at 1214.

[246] Negotiations are still ongoing. Updates on the progress of negotiations may be found on the WTO website.

[247] King, *supra* note 136, at 1217.

agraph 5 provides temporary imposition of the guidelines suggested in paragraph 4.[248] However, paragraph 4, and thus paragraph 5, are generally presumed to apply only to the extent that they "nullify or impair" specific commitments and universal obligations of GATS.[249] In addition, Members are not required to alter rules or policies that were in affect or could have reasonably been expected to come in to affect when commitments were made.[250]

Essentially, in order for domestic regulations to overcome the overly broad requirements of paragraph 5, they simply must not compromise specific commitments made in the Member's schedule and must comply with the equally broad disciplines outline in paragraph 4. However, even if the regulation fails the aforementioned test, it may be allowed to stand so long as it was in affect by the Member or reasonably contemplated of the Member at the time of commitment.[251]

2. Article XIV: Exceptions

Article XIV exceptions[252] serve as an affirmative defense to any challenge to a domestic regulation and preserves the right of Members to impose regulation to achieve policy interests and protect security interests.[253] The exceptions allow certain regulation even if they conflict or directly oppose other GATS obligations, including commitments.

Article XIV specifically provides an exception for services that are provided in the "exercise of governmental authority."[254]

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[248] GATS, *supra* note 177, at Art. VI, ¶ 5(a).

[249] *Id.*; King, *supra* note 136, at 1217.

[250] King, *supra* note 136, at 1217.

[251] *Id.* at 1214.

[252] The Article XIV exceptions are equivalent to the General Agreement on Tariffs and Trade (GATT), Article XX General Exceptions. Many provisions of the GATS are modeled after its GATT predecessor. *See* Final Texts of the GATT Uruguay Round Agreements Including the Agreement Establishing the World Trade Organization, Apr. 15, 1994, AGREEMENT ESTABLISHING THE WORLD TRADE ORGANIZATION-RESULTS OF THE URUGUAY ROUND VOL. 1 (1994), 33 I.L.M. 1125 (1994).

[253] King, *supra* note 136, at 1219-20.

[254] McClean, *supra* note 5, at 479.

Unfortunately, this particular provision fails significantly as applied to telemedicine regulation as most healthcare is privately, rather than governmentally funded.

However, other specific regulations desperately needed to govern issues in telemedicine are also included in Article XIV: regulations that protect human health, public morals, and privacy of personal data processing; measures preventing fraud; regulations to secure compliance with existing laws; and rules governing contract default.[255]

For U.S. telemedicine regulation to comply with the exceptions, the measure must: (1) be necessary to achieve one the objectives listed above, and (2) not be applied in an arbitrary manner, create unjustifiable discrimination between Members, or serve as a "disguised" trade barrier.[256] To comply with part (1), certain factors must be measured including whether the measure applies to an overriding national interest, the extent the measure accomplishes that goal, and the trade impact considering readily available less-restrictive alternatives.[257]

3. Lack of Commitment in Healthcare Sector

Apart from the universally-binding obligations of MFN and Transparency, U.S. domestic regulation of telemedicine faces very little restriction due to its lack of specific commitment in the healthcare sector. To date, the U.S. has designated itself "unbound" under Mode 1 in both MA and NT. This allows the U.S. to basically circumvent the requirements of MA, NT, and Article VI obligations, as these requirements apply generally only to the extent a Member has made specific commitments to a particular sector in its schedule.

However, under Article XIX, Member countries are required to complete successive negotiations to further liberalize trade. Therefore, it is likely only a matter of time before the U.S is required to further reduce barriers to trade, thereby, restricting its

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[255] GATS, *supra* note 177, at Art. XIV; King, *supra* note 136, at 1214.
[256] King, *supra* note 136, at 1214, 1219.
[257] *Id.* at 1214.

ability to establish telemedicine regulation[258].

In order to maintain this freedom to regulate, the U.S. should make every attempt to remain "unbound" in Mode 1 of the healthcare sector or if commitment becomes necessary, specify additional conditions and limitations on foreign suppliers in the schedule. The conditions and limitations must be specified explicitly and "with absolute clarity."[259] Otherwise, the U.S. will be considered to have made full commitments to MA and NT.[260]

B. U.S.–Australia FTA

i. Obligations Comparable to GATS

The U.S.–Australia FTA[261] ("AUSFTA") is very similar to GATS in its application to telemedicine regulation, but much simpler to interpret. Unlike GATS, AUSFTA does not condition obligations in the Cross-Border Trade in Services chapter (Chapter 10) on commitment in specific sectors or modes of service. Instead, the obligations of Chapter 10 apply to all trade in services except financial services, government procurement, air services, subsidies, and services provided in the exercise of government authority.[262] Specific limitations and conditions to the obligations are set out by both parties in Annex 1-3 of the agreement and organized by specific sector[263]

Like GATS, AUSFTA imposes obligations for MFN, MA, NT, and Transparency and imposes specific obligations for domestic regulation. Additionally, AUSFTA includes specific allowances protecting the sovereignty of the individual country to impose regulation.

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[258] It should be noted that some suggested regulations governing telemedicine likely will fail under a GATS analysis including imposing visa requirements on telemedicine providers utilizing the Indian Model, as this would impose an untenable barrier to trade. *See* McClean, *supra* note 5, at 458-59.

[259] King, *supra* note 136, at 1204.

[260] *Id.* at 1203-04.

[261] United States-Australia Free Trade Agreement, U.S.-Austl., May 18, 2004, 43 I.L.M. 1248 [hereinafter "AUSFTA"], available at https://perma.cc/USH3-38BF.

[262] AUSFTA, *supra* note 255, at Art. 10.1.4.

[263] AUSFTA, *supra* note 255, at Annex 1-3.

Under MFN and NT, the AUSFTA simply incorporates the "treatment no less favorable" language of GATS.[264] For MFN, this requires the U.S. to give equal or greater treatment to Australian service suppliers than it does to a non-Party service supplier, that is any service supplier that does not originate in Australia.[265] For NT, this simply means the U.S. cannot grant domestic suppliers treatment that is more favorable than it accords Australian service suppliers.[266]

Under MA, AUSFTA prohibits regulations that impose the exact limitations listed in Article XVI of GATS[267], with the exception financial investment.[268] Likewise, AUSFTA imposes nearly identical transparency requirements to GATS Article III.[269]

Article 10.7 of AUSFTA, incorporates the notification requirements and suggested disciplines outlined in Article VI, chapter 4 of GATS, additionally requiring further negotiation and amendment should results WTO chapter 4 negotiations come into effect.[270] Likewise, AUSFTA Chapter 22 incorporates Article XIV of GATS in its entirety.[271]

ii. AUSFTA Specific Provisions

Unlike GATS, AUSFTA includes provisions that mitigate some of the issues in telemedicine, including licensing and certification standards. Annex 10-A of AUSFTA specifically encourages the development of mutually acceptable standards for licensing and certification service suppliers as determined by a Working Group on Professional Services.[272] These standards apply to education, examination, experience, conduct and ethics, professional development and re-certification, scope of practice, local knowledge,

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[264] AUSFTA, *supra* note 255, at Art. 10.2-10.3.
[265] AUSFTA, *supra* note 255, at Art. 10.3.
[266] AUSFTA, *supra* note 255, at Art. 10.2.
[267] *See* Part II(A)(ii)(1) *supra.*
[268] AUSFTA, *supra* note 255, at Art. 10.4.
[269] *See* Part II(A)(i)(2) *supra.*
[270] AUSFTA, *supra* note 255, at Art. 10.7, *See* Part II(A)(iii)(1)(b) *supra.*
[271] AUSFTA, *supra* note 255, at Chapter 22; GATS, *supra* note 177, at Art. XIV.
[272] AUSFTA, *supra* note 255, at Annex 10-A.

and consumer protection.[273]

Under Annex II of AUSFTA, the U.S. outlines specific limitations to obligations. However, the only limitations the U.S. imposed relevant to telemedicine regulations are (1) the right to adopt and maintain measures that are not inconsistent with Article XIV of GATS as it pertains to MA, and (2) the right to adopt and maintain measures with respect to the provision of law enforcement that maintain social welfare and health.[274]

iii. Application of Regulation Under AUSFTA

The AUSFTA accomplished more in the way of preserving the right to regulate telemedicine. Specifically, as Annex 10-A specifically addresses the need to establish acceptable licensing and certification standards.[275] Because AUSFTA essentially incorporates GATS Articles II, III, XVI, XVII, VI Chapter 4, and XIV, the analysis for imposing regulation governing telemedicine under the AUSFTA would be nearly identical to that of the GATS discussed *supra* Part III(A). Additionally, because Australia is a WTO Member, thus a party to GATS, any obligation under GATS applies to the U.S.–Australia telemedicine trade relationship.

C. Other Telemedicine Trading Partners

The U.S. has an active Free Trade Area Agreement with Israel.[276] However, that agreement does not apply to trade in services, and thereby, telemedicine. The U.S. and Israel have created a Declaration on Trade in Services; however, because the declaration is not a legally binding agreement, it bears no significance in determining the application of regulations to U.S.–Israel telemedicine services. In contrast, there are currently no free-trade agreements between the U.S. and India, Switzerland, or Brazil.

However, as with Australia, all four countries are WTO

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[273] *Id.*

[274] AUSFTA, *supra* note 255, at Annex II.

[275] AUSFTA, *supra* note 255, at Annex 10-A.

[276] Israel-United States: Free Trade Area Agreement, Apr. 22, 1985, U.S.-Isr., 24 I.L.M. 653.

Members. Thus, any obligation under GATS applies to the U.S. telemedicine trade relationship with all four countries. As a result, the analysis for imposing regulation governing telemedicine trade relationship would be nearly identical to that of the GATS discussed *supra* Part III(A).

CONCLUSION

It is clear that regulatory measures are not only necessary but should be demanded to protect the safety and security of U.S. patients receiving healthcare services via telemedicine. Healthcare is one of the most highly regulated areas in the U.S.; however, this strict regulation does not translate overseas or into the virtual world of telemedicine. "There is nothing sacred about the Internet that should or will preclude governments from . . . attempting to regulate the on-line supply of medical . . . services to their citizens."[277] Additionally, there is no insurmountable barrier to imposing the suggested protective measures within current U.S. trade agreements.

The only true barrier is lack of understanding and fear of regulating trade. Both can be combatted by simply acknowledging that regulation is not the enemy of liberalization–a fact that is not only acknowledged by U.S. multilateral and bilateral trade agreements but encompassed in their respective flexibility within obligations and preservation of domestic sovereignty in imposing protective measures.

[277] King, *supra* note 136, at 1268.