MEDICAL TOURISM: THE NEED FOR THE U.S. TO REQUIRE JOINT COMMISSION INTERNATIONAL ACCREDITATION OF FOREIGN HOSPITALS AS A PREREQUISITE FOR DOMESTIC MARKETING

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INTRODUCTION

Medical tourism is a multi-billion-dollar industry.[1] Every year, medical tourism sends millions of prospective patients to foreign countries for

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medical procedures, with no assurance of the quality of care they will receive.[2] Procedures range from necessary, live-saving operations to elective, alternative therapies.[3] With the increased cost of medical procedures, the increased disparity of access to affordable health care, and the prospective savings of forty to eighty percent, the boom of medical tourism by Americans abroad will continue to dominate.[4] However, with this excitement of new medical options comes a new dilemma: how do we protect prospective patients traveling abroad for healthcare?

The Joint Commission International (JCI) is one possibility. The JCI (the international branch of the Joint Commission, which provides accreditation standards in the U.S.) is a non-governmental organization that accredits international hospitals, clinics, and similar facilities.[5] On the one hand, JCI-accreditation is beneficial and needed, as it allows for standardization in patient safety. On the other hand, JCI-accreditation is problematic, as it only provides a recommendation that is not legally binding and, thus, not required by hospitals. Additionally, JCI provides for accreditation for hospitals and other facilities, but does not regulate the health care providers, including the physicians.[6] This leaves major differences and ambiguity in healthcare standards. However, JCI-accreditation is still a better alternative than no accreditation at all.

Currently, no single regulation exists to monitor medical tourism.[7] Consumers are essentially at their own risk to research and identify potential destinations for their health care needs. Although the American Medical Association (AMA) and the World Medical Association (WMA)

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[1] Angeleque Parsiyar, *Medical Tourism: The Commodification of Health Care in Latin America,* 15 LAW & BUS. REV. AM. 379, 381 (2009).

[2] *See generally* Elizabeth Astrup, *Passport to Plastics: Cosmetic Surgery Tourism, Medical Malpractice, and the Automatic Establishment of Personal Jurisdiction by Way of the Joint Commission International,* 27 IND. J. GLOBAL LEGAL STUD. 347, 351 (2020).

[3] M. Neil Browne et al., *American Medical Tourism: Regulating a Cure That Can Damage Consumer Health,* 25 LOY. CONSUMER L. REV. 319, 321 (2013).

[4] *Id.* at 321-22.

[5] Parsiyar, *supra* note 1, at 388 ("While there is no international regulatory standard of care, the Joint Commission International (JCI) (the international counterpart to the Joint Commission Accreditation for Hospital Organizations—an independent entity that certifies American hospitals) sends its review board to foreign hospitals to determine whether that hospital is deserving of accreditation").

[6] *Id.* at 389 ("Currently, there is no database for complaints and there is no central or universal system of licensing for the doctors or the intermediaries who send them patients").

[7] *See* I. Glenn Cohen, *Medical Tourism, Access to Health Care, and Global Justice*, 52 VA. J. INT'L L. 1, 36 (2011).

have each developed guidelines that make it easier for consumers to identify and understand key points, these guidelines are simply guidelines and do not adequately aid in protecting consumers. The AMA and WMA need a counterpart to establish regulations based on their established guidelines.

The Federal Trade Commission (FTC) is a regulatory agency whose function includes establishing consumer protection regulations, including curbing deceptive advertisements.[8] Specifically, the Federal Trade Commission Act states that "unfair or deceptive acts in or affecting commerce" are unlawful.[9] Deceptive acts that hinder the average consumer from obtaining all the relevant facts needed to make an informed decision.[10]In other words, deceptive acts include those actions which are not disclosed or "hidden" from the consumer.

The FTC must regulate the way in which medical tourism is advertised. Specifically, the FTC must create regulations that require *all pertinent* information to be disclosed, including the positives, benefits and risks, to prospective consumers. Pertinent information should include: cost, success rates, hospital or medical clinic accreditation information, procedure risks, and post-care. Further, the FTC must restrict medical tourism to JCI-accredited facilities through strict regulation of U.S.-based advertising. These regulations can be accomplished because the FTC has the legal authority to make such a regulation, JCI-accredited organizations have a higher quality of care, and JCI-accredited organizations are more trusted by leading local and international health organizations.

This note will examine the reasons why U.S.-based advertising must work hand-in-hand with the FTC to ensure that prospective consumers of medical tourism are informed before embarking on their journey. Specifically, this note does not advocate for a total ban on medical tourism, but rather advocates for regulations to ensure patient safety. Indeed, medical tourism is needed to ensure equal access to healthcare and to allow for patient autonomy. Section II explores the background of medical tourism, including the advantages, and the role of the Joint Commission International ("JCI"). Section III analyzes the value of JCI-accreditation by examining various studies conducted on the benefit of JCI accreditation. These studies show that JCI accreditation positively correlates with key performance indicators. This section also discusses the various shortcomings of JCI accreditation, but overall concludes that JCI

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[8] Browne, *supra* note 3, at 348.
[9] 15 U.S.C. § 45(a)(1).
[10] *See* Browne, *supra* note 3, at 348-349.

accreditation is a *better* alternative than the absence of any protection. Section IV provides the legal framework that makes regulating medical tourism possible. Mainly, this section recognizes that while the FTC has not regulated medical tourism in the past, the FTC has the legal authority to do so based on previous regulations in analogous fields. Section V discusses how the U.S. utilizes international regulatory bodies. Section VI discusses the trustworthiness of the JCI. Lastly, Section VII concludes that the FTC must limit medical tourism to only accredited international facilities.

I. BACKGROUND

"I've not yet had a patient with zero options, but this is as close as I've had."[11]

That was the shock expressed by an infectious disease doctor when learning of the horror Ms. Capone experienced. She thought she was making a "smart call" by traveling to Mexico for bariatric surgery, since the surgery in Tijuana would only cost $4,000, compared to $17,500 in Arkansas.[12] Upon returning to Arkansas, Ms. Capone developed a rare and potentially deadly strain of bacteria resistant to virtually all antibiotics. Yet, she wasn't alone. She was one of at least a dozen U.S. residents who returned from surgeries in Tijuana with this deadly bacterium, with eight of the infections occurring at a single hospital.[13]

In the United States, medicine is one of the most heavily regulated fields. Every patient interaction, every healthcare decision, and every stitch must comply with some regulation. However, medical tourism invariably escapes this regulation, allowing prospective patients to travel elsewhere at their own risk.[14] Many factors have contributed to the dramatic rise of the industry, including, but not limited to, cost savings, availability of treatments, and cultural preferences.

Patients who cannot afford or are ineligible for procedures in their home country travel internationally to level the playing field—to have

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[11] Lena H. Sun, *They Went to Mexico for Surgery. They CameBback with a Deadly Superbug,* WASH. POST, (Jan. 23, 2019, 6:00 AM). https://www.washingtonpost.com/national/health-science/they-went-to-mexico-for-surgery-they-came-back-with-a-deadly-superbug/2019/01/23/ac0ca280-1dcb-11e9-9145-3f74070bbdb9_story.html.

[12] *Id.*

[13] *Id.*

[14] *See* Parsiyar, *supra* note 1, at 391 ("The level of standardization that exists in the United States does not exist in the rest of the world, and there is currently not a sufficient system in place to guide people through determining where good medical care exists").

access to affordable healthcare.[15] Additionally, other patients may travel internationally to undergo procedures labeled as "unapproved" or "experimental" in their home countries.[16] Patients may also feel inclined to travel internationally for cultural comfort, preferring providers who share the same cultural beliefs and language.

A. Medical Tourism from a Bird's Eye View

The exact number of patients traveling abroad for treatment is unknown, but the overall trend continues to climb upwards.[17] In 2007, approximately 750,000 American patients traveled abroad for medical treatment.[18] In 2017, that estimate roughly doubled, with more than 1.4 million American patients traveling abroad for medical treatment.[19] The trajectory is expected to continue to rise, with cost being a major contributing factor. Specifically, more Americans have become medical tourists to combat the expensive nature of U.S. healthcare, with treatments being available at 30-65% of the cost of care in the U.S.[20]

According to *Patients Beyond Borders*, the most current average range of savings, using U.S. costs as a benchmark, include: 20-30% in Brazil, 45-65% in Costa Rica, 65-90% in India, 45-60% in Mexico, 50-75% in Thailand, and 50-65% in Turkey.[21] The savings are even more profound when examined on a procedure-to-procedure basis. By one estimate, a heart bypass surgery has a U.S. retail cost of $210,842, compared with $10,000, $12,000, and $20,000 in India, Thailand, and Singapore, respectively.[22] While these estimates may provide a broad overview of the types of savings

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[15] Tamara L. Hill, Comment, *The Spread of Antibiotic-Resistant Bacteria through Medical Tourism and Transmission Prevention Under the International Health Regulations,* 12 CHI. J. INT'L L. 273, 279 (2011).

[16] *Id.*

[17] *Id.*

[18] *Id.* at 279-30.

[19] James E. Dalen & Joseph S. Alpert, *Medical Tourists: Incoming and Outgoing,* 132 AM. J. OF MED. 9, 9 (2019).

[20] *Id.*

[21] Patients Beyond Borders, https://www.patientsbeyondborders.com/media (last visited Nov. 5, 2022).

[22] I. Glenn Cohen, *Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument,* 95 IOWA L. REV. 1467, 1473 (2010) (stating that these estimates are based on a 2007 report from the National Center for Policy Analysis; though current estimates are not provided, it may be reasonably inferred that since medical tourism has dramatically increased since the date of the report in 2007, the prices of common procedures most likely have not significantly changed).

possible, consider the following case study of U.S. medical tourists, as described in a recent New York Times article.

Ms. Jackson laid curled up, unable to move due to the excruciating and debilitating pain.[23] This, however, was not a one-off occurrence. Instead, it was the sixth consecutive week that Ms. Jackson was unable to work.[24] As her symptoms worsened and her options dimmed, Ms. Jackson began exploring options for medical tourism. She needed a hysterectomy to "free [herself] from pain" caused by endometriosis.[25] "As if the surgery isn't bad enough, I need to find $20,000 bucks to pay for it," she said.[26] Faced with uncertainty, Ms. Jackson started to plan a trip to Mexicali, Mexico, where the same procedure was available for $4,000, one-fifth the cost of the same procedure she was offered in New Jersey.[27] Ms. Jackson was not alone.

The same was equally true for dental treatment. For example, take the case of Mr. Somerville, who traveled to Los Algodones, Mexico to get his crowns replaced, a procedure that cost him $7,000, compared to $25,000 in Florida.[28]

Cost aside, medical tourism raises issues concerning quality, standards, and acceptability of care. Overshadowed by the surge of the industry, adverse side effects may arise, and at times, be more dangerous. Risks include susceptibility to antibiotic-resistant bacteria, infectious diseases, lower quality of care, lack of a continuum of care, and language barriers. Given the risks, the AMA established guidelines to best combat the risks and called for more public awareness. The guidelines include:

(1) Medical care outside of the U.S. must be voluntary;[29]

(2) Financial incentives to travel outside the U.S. for medical care should not inappropriately limit the diagnostic and therapeutic

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[23] Ceylan Yeginsu, *Why Medical Tourism is Drawing Patients, Even in a Pandemic,* N.Y. TIMES, https://www.nytimes.com/2021/01/19/travel/medical-tourism-coronavirus-pandemic.html (Jan. 19, 2021).

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] Am. Med. Assoc., *New AMA Guidelines on Medical Tourism*, http://www.medretreat.com/templates/UserFiles/Documents/Whitepapers/AMAGuidelines.pdf (last visited Nov. 11, 2022) [hereinafter AMA Guidelines].

> alternatives that are offered to patients, or restrict treatment or referral options;[30]
>
> (3) Patients should only be referred for medical care to institutions that have been accredited by recognized international accrediting bodies (e.g., the Joint Commission International or the International Society for Quality in Health Care);[31]
>
> (4) Access to physician licensing and outcome data, as well as facility accreditation and outcomes data, should be arranged for patients seeking medical care outside the U.S.[32]

Though not an exclusive exhaustive list, the guidelines provide and emphasize patient safety, all while noting the importance and need for medical tourism.

Despite the risks associated with medical tourism, this industry is needed because its benefits maintain and provide individuals with essential medical care. Organizations and agencies such as the JCI and the FTC are crucial for maximizing and ensuring patient safety.

B. The Joint Commission International

Patient safety is the foremost factor in regulating medical tourism. Currently, no authoritative accreditation body for international healthcare exists.[33] In the U.S., the Joint Commission provides certification and licensing of hospitals and sets standards that hold the medical staff to a higher level of responsibility.[34] Although Joint Commission accreditation is not required for licensing in the United States, Joint Commission accreditation indicates that the hospital "meets at least minimum acceptable standards of care as recognized by the federal government and most states."[35] The certification process improves the quality of patient care by reducing variation, providing a framework for disease management, and promoting a "culture of excellence."[36]

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[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] Hill, *supra* note 15, at 281.

[34] Browne, *supra* note 3, at 333 ("Today, the Joint Commission accredits eighty-eight percent of the nation's hospitals.").

[35] *Id.*

[36] *Benefits of Joint Commission International*, WOLTERS KLUWER, https://www.wolterskluwer.com/en/expert-insights/benefits-of-joint-commission-accreditation (Apr. 14, 2017).

Internationally, the JCI operates in the same manner as the Joint Commission in the U.S. The JCI is a non-profit international organization that accredits and certifies healthcare organizations and programs across the globe.[37] JCI standards extend beyond hospitals, including ambulatory care centers, clinics, home care, laboratories, and medical transport organizations.[38] The JCI maintains its best practices and upkeep of international standards through its Standards Advisory Panel, which consists of physicians, nurses, and public policy experts from Latin America, Asia, the Middle East, Europe, and the United States.[39] As in the U.S., JCI accreditation "generally signals that a facility meets the minimum standards of competence and quality."[40]

In order to achieve JCI accreditation status, "the hospital must achieve the requisite score on JCI's six patient goals and its more than 100 standards."[41] JCI accreditation lasts three years, at which point the organization is again fully evaluated.[42] Currently, there are more than 250 JCI-accredited hospitals outside the U.S., in countries like India, Thailand, Singapore, China, and Saudi Arabia, with many more accredited clinics, ambulatory centers, and home care centers.[43]

The benefits of JCI-accreditation are two-fold. First, JCI standards for quality and care are comparable with their U.S. counterparts. JCI developed the International Patient Safety Goals as a means of "helping accredited organizations address specific areas of concern on some of the most problematic areas of patient safety."[44] The JCI describes its International Patient Safety Goals as: identifying patients correctly; improving effective communication; improving the safety of high-alert medications; ensuring safe surgery; reducing the risk of healthcare-associated infections; and reducing the risk of patient harm resulting from falls.[45]

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[37] THE JOINT COMM'N INT'L, https://www.jointcommissioninternational.org/about-jci/who-we-are/ (last visited Oct. 23, 2022).

[38] *Id.*

[39] *Id.*

[40] Browne, *supra* note 3, at 338.

[41] Cohen, *supra* note 22, at 1485.

[42] *Id.*

[43] *Id.*

[44] THE JOINT COMM'N INT'L, INTERNATIONAL *Patient Safety Goals*, https://www.jointcommissioninternational.org/standards/international-patient-safety-goals/ (last visited Nov. 12, 2022).

[45] *Id.*

Similarly, in the U.S., the Joint Commission publishes the National Patient Safety Goals, which include identifying patients correctly, improving staff communication, using medicines safely, preventing infections, and identifying patient safety risks.[46] The JCI and the Joint Commission base their accreditation standards on closely resembling safety goals, further signifying the hope that the care one receives internationally will closely resemble the "American model" of healthcare.

The second benefit of JCI-accreditation is that JCI-accreditation is advocated by the AMA. Specifically, the AMA advocates that "patients should only be referred for medical care to institutions that have been accredited by recognized international accrediting bodies (e.g., the Joint Commission International or the International Society for Quality in Health Care)."[47] Yet, through its guidelines, the AMA does not have any regulatory power to regulate medical tourism. A regulatory authority is needed, such as the FTC.

II. VALUE OF JCI-ACCREDITATION

All medical treatments and interventions carry the risk of complications. Yet, medical tourism invariably increases the likelihood of contracting a serious, medical complication. Data on clinical outcomes associated with medical travel is rather limited. On the one hand, patients may travel abroad and receive professional, timely, affordable, and high-quality health care.[48] On the other hand, patients may receive the exact opposite. Evidence suggests that "poorer outcomes are attributable to substandard surgical care," infections arising from "inadequate infection control measures in surgical settings, deep vein thrombosis," and "inadequate post operative care following departure from the treating facility."[49] Given the potentiality for serious complications, oversight and regulations, such as JCI accreditation, must be adopted. Though not perfect, JCI-accreditation would help reduce the risk of serious complications by standardizing healthcare delivery.

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[46] THE JOINT COMM'N, *Hospital National Safety Goals* (2022), https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/2022/simple_2022-hap-npsg-goals-101921.pdf.

[47] New AMA Guidelines on Medical Tourism, *supra* note 20.

[48] Leigh G. Turner, *Quality in Health Care and Globalization of Health Services: Accreditation and Regulatory Oversight of Medical Tourism Companies,* 23 INT'L J. FOR QUALITY IN HEALTH CARE 1, 2 (2010).

[49] *Id.*

Destination hospitals often boast their JCI accreditation to attract patients from around the world. JCI-accreditation is preferred since it effectively suggests that the hospital has earned the same rigorous accreditation as hospitals in the U.S. aim for and, therefore, just as reliable.[50] Further, to maintain accreditation, hospitals must consent to rigorous evaluation by the JCI review board every three years.[51]

Accreditation has often been viewed as an accurate marker of quality, and several international healthcare organizations have "discussed the effectiveness of using accreditation as a tool to enhance organizational and clinical performance."[52] However, the literature remains scarce.[53] In a literature review assessing seventy-six studies concerning the relationship between accreditation status and quality of care, the most studied scheme of accreditation was the JCI approach.[54] Of the studies examining hospital accreditation's impact on patient outcomes, the results showed a clear positive trend between accreditation and clinical outcomes.[55]

One of these studies examined the impact of JCI-accreditation on infectious control performance in a Dubai Hospital. The study examined the following four variables, before and after JCI-accreditation to evaluate their impact: ventilator assisted pneumonia (VAP), central line associated bloodstream infection (CLABSI), catheter associated urinary tract infection (CAUTI), and surgical site infection (SSI).[56] For VAP, pre-accreditation showed "no significant month-to-month decline."[57] However, after accreditation, the rate of VAP dropped significantly by 1.7% per month.[58] For CLABSI, pre-accreditation showed a significant month-to-month decline, but post-accreditation, the rate of CLABSI dropped significantly *immediately* after accreditation.[59] Similarly, for CAUTI, pre-accreditation showed a significant month-to-month decrease, yet after accreditation, a

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[50] Levi Burkett, *Medical Tourism: Concerns, Benefits, and the American Legal Perspective,* 28 J. LEGAL MED. 223, 230 (2007).

[51] Parsiyar, *supra* note 1, at 388.

[52] Mohammed Hussein et al., *The Impact of Hospital Accreditation on the Quality of Healthcare: A Systematic Literature Review,* 21 BMC HEALTH SERV. RSCH. 1, 2 (2021).

[53] *Id.*

[54] *Id.* at 4.

[55] *Id.* at 6.

[56] Fatima Mahmoud Salim & Mohammad Rahman, *The Impact of Joint Commission International Healthcare Accreditation on Infection Control Performance: A Study in Dubai Hospital*, 5 GLOB. J. OF BUS. & SOC. SCI. REV. 37, 40 (2017).

[57] *Id*. at 41.

[58] *Id.*

[59] *Id.*

significant increase in CAUTI.[60] This increase was likely due to the identification of more infections due to further developed processes and standards post-accreditation, rather than deficiencies in JCI-accreditation.[61] Lastly, for SSI, there was a month-to-month increase pre-accreditation, but immediately post-accreditation, the rate of SSI decreased by half a percent per month.[62]

Another similar study was conducted in Saudi Arabia, which ranks second on the list of countries with the highest number of JCI-accredited organizations.[63] At King Fahd Hospital of the University (KFHU), a mixed-methods approach was used to determine the efficacy of JCI-accreditation in improving quality at KFHU, as well as to investigate the perceptions of the healthcare providers of the accreditation process.[64] The first leg of the study assessed the impact of JCI-accreditation on twelve key performance indicators.[65] These indicators included: hand hygiene compliance, rate of hospital-acquired infections, patient identification, radiology reporting, lab reporting, pressure ulcer, operating room cancellations, patients leaving the emergency room without being seen, mortality rate, patient falls, length of stay, and bed occupancy.[66] The results of the study indicated that:

> Nine out of [twelve] outcomes were improved throughout the accreditation process. The outcomes that did not improve after the accreditation process included the rate of patients who left the [emergency room] without being seen, the percentage of [operating room] cancellations, and the rate of patient falls, which had both immediate and lagged increases.[67]

More specifically, in the three years following the accreditation survey, there was a statistically significant monthly improvement in hand hygiene compliance, pressure ulcer rate, and mortality rate.[68]

In the second leg of the study, which measured the attitudes and perceptions of health professionals towards the accreditation process, "all the participants interviewed had an overall positive perception of the JCI-

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[60] *Id.*

[61] *Id.*

[62] *Id.*

[63] Deema Al Shawan, *The Effectiveness of the Joint Commission International Accreditation in Improving Quality at King Fahd University Hospital, Saudi Arabia: A Mixed Methods Approach*, 13 J. HEALTHCARE LEADERSHIP 47, 48 (2021).

[64] *Id.* at 48.

[65] *Id.*

[66] *Id.* at 49.

[67] *Id.* at 52.

[68] *Id.*

accreditation process."[69] Some themes included: improvement of training and education at the hospital, improvements in quality outcomes, such as reduction of medication errors, and improved processes, policies, and procedures.[70] Overall, this study demonstrated the improvements of health services and patient safety offered through JCI-accreditation procedures.[71]

The Dubai and Saudi Arabia studies illustrate that while results are not definitive, the JCI-accreditation process possesses potential benefits. It is uncontested that JCI standards are not a one-size-fits-all solution to regulating medical tourism, and inherently possess certain disadvantages. However, requiring JCI-accreditation is a better, and more advantageous option to having no regulation at all.

Nonetheless, JCI standards also present challenges. One of the biggest shortcomings of JCI-accreditation is that it is not required for hospitals, only highly advised. While accreditation has become a "de facto" industry standard, accreditation is entirely voluntary.[72] Hospitals and other organizations are not required to apply, and many do not, because of the feasibility of the process itself.[73] The process to become JCI-accredited lacks appeal as it takes most hospitals eighteen to twenty-four months and costs about $30,000 to complete.[74] Another concern involves the quality of the JCI reviews. In assessing foreign healthcare facilities, it is very difficult to evaluate the quality of practitioners and the quality of facilities from outside the country.[75]

However, JCI-accreditation still remains the *better* alternative for regulating the industry. Hospitals and other facilities that attract medical tourists have reputational incentives to comply with these standards, and a loss of accreditation can lead to catastrophic effects.[76] As a result, nearly a thousand healthcare organizations, including hundreds of foreign hospitals, meet international quality standards, not because they are required to do so

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[69] *Id.* at 55.

[70] *Id.*

[71] *Id.* at 58.

[72] Nathan Cortez, *Into the Void: The Legal Ambiguities of an Unregulated Medical Tourism Market, in* RISKS AND CHALLENGES IN MEDICAL TOURISM: UNDERSTANDING THE GLOBAL MARKET FOR HEALTH SERVICES 187, 197 (Jill Hodges ed., 2012).

[73] Parsiyar, *supra* note 1, at 391; *see also* Jennifer Wolff, *Passport to Cheaper Health Care,* https://www.goodhousekeeping.com/health/a17363/cheaper-health-care-1007/ (Aug. 20, 2007).

[74] Parsiyar, *supra* note 1, at 391.

[75] Wolff, *supra* note 73.

[76] Cortez, *supra* note 72, at 197.

by law, but because of competitive pressures that have made accreditation an expectation.[77]

III. THE FTC HAS LEGAL AUTHORITY TO REGULATE MEDICAL TOURISM

Broadly speaking, the FTC is a regulatory agency established for the purpose of "protecting the public from deceptive or unfair business practices" through the use of "law enforcement, advocacy, research, and education."[78] The FTC Act provides that "unfair or deceptive acts in or affecting commerce" are unlawful.[79] Further, "unfair or deceptive acts" include acts involving foreign commerce that cause or are likely to cause foreseeable injury within the United States.[80] "Deceptive," as used in the statute, includes any omission likely to mislead a consumer, acting reasonably, under the circumstances.[81] More relevant, however, is unfairness, which is defined as any "practice that causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition."[82]

Medical tourism fits into this definition. Although controlling the "travel" aspect of medical tourism is likely not feasible, it is imperative that the FTC regulate the initial step—the advertising. Medical tourism is a part of foreign commerce because U.S. consumers travel internationally for the purpose of "purchasing" healthcare, and that commerce is likely to cause foreseeable injury within the U.S. because the risks and adverse side effects would be treated stateside.

False advertising, as defined by the FTC Act means:

> An advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the *advertisement fails to*

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[77] *Id.*; *see also* The Joint Commission International, *supra* note 28.

[78] *Mission,* FEDERAL TRADE COMMISSION, https://www.ftc.gov/about-ftc/mission (last visited Nov. 4, 2022).

[79] 15 U.S.C. § 45(a)(1).

[80] 15 U.S.C. § 45(a)(4)(A).

[81] *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority*, FEDERAL TRADE COMMISSION, https://www.ftc.gov/about-ftc/mission/enforcement-authority (May 2021).

[82] 15 U.S.C. § 45(n).

> *reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement*, or under such conditions as are customary or usual.[83]

For example, a quick Google search for "medical tourism in Mexico" yields the following: Medical Tourism Corporation—"medical tourism in Mexico can help you save up to 80%. You can enjoy an exotic vacation and top notch medical services at safe locations in Mexico."[84] It continues, "with its colors and beaches, Mexico offers a great vacation stay!"[85] The website does caution that "one may want to research more," but provides statistics and factors that do not even mention the possibilities of risks or adverse side-effects.[86] Most striking, the Medical Tourism Corporation claims that "most Mexican cities have at least one world-class hospital," and although the claim may be true, it is misleading, as defined by the FTC.[87]

The FTC must mandate that advertisers of medical tourism place consumer protection at the forefront by only allowing JCI-accredited hospitals to be advertised to prospective consumers. Mexico currently has eight JCI-accredited hospitals.[88] While the Medical Tourism Corporation's claim may be true, it misleads consumers into thinking that all the "world-class" hospitals have similar accreditation standards, when in reality, the claim is likely false.[89] Mandating U.S. medical tourism agencies to advertise only JCI-accredited organizations would protect consumers from their compulsive decision-making tendencies, which are inherently aided by prospects of a vacation and top-notch medical services.[90]

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[83] 15 U.S.C. § 55(a)(1)(emphasis added).

[84] Med. Tourism Corp., *Medical Tourism in Mexico*, https://www.medicaltourismco.com/medical-tourism-in-mexico/ (last visited Nov. 6, 2022).

[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] JOINT COMM'N INT'L, *Search for JCI-Accredited Organizations,* https://www.jointcommissioninternational.org/who-we-are/accredited-organizations/#sort=%40aoname%20ascending&f:@aocountry=[Mexico] (last visited Oct. 23, 2023).

[89] *See* Browne, *supra* note 3, at 349 (discussing how to determine if an advertisement is deceptive, as defined by the FTC; stating that the three elements include: (1) there was a representation; (2) the representation was likely to mislead customers acting reasonably under the circumstances; and (3) representation was material).

[90] Browne, *supra* note 3, at 348; Burkett, *supra* note 41.

A second example of "deceptive" advertising is *Healthtourism.com* – "medical tourism made simple."[91] Somewhat better, this website does mention that Mexico has nine JCI-accredited hospitals and clinics, yet this benefit is hidden from consumers.[92] The site allows consumers to filter healthcare facilities based on specialty or procedure, to which all hospitals and clinics appear, with no mention of the JCI-accredited facilities.

To combat deceptive advertising, the World Medical Association (WMA) recommended at the sixty-ninth WMA General Assembly that:

> Advertising for medical tourism services, whether via the internet or in any other manner, should comply with accepted principles of medical ethics and include detailed information regarding the services provided. Information should address the service provider's areas of specialty, the physicians to whom it refers the benefits of its services, and the risks that may accompany medical tourism. *Access to licensing/accreditation status of physicians and facilities and the facility's outcomes data should be made readily available.* Advertising material should note that all medical treatment carries risks and specific additional risks may apply in the context of medical tourism.[93]

Specifically, the WMA noted the importance of regulation and accreditation and the guidelines for how they should be advertised to consumers. The FTC has the legal authority to follow through on the WMA's recommendation and make it a requirement in the U.S.

More simply, the FTC has legal authority. Guidelines from the AMA and WMA already exist and emphasize the importance of consumer protection and the need for informed detailed information. The AMA and WMA do not have the authority to regulate based on these guidelines because, as is, they are simply guidelines and lack governmental authority. However, the FTC must work with the AMA and WMA to transform the guidelines into something more concrete; a regulation that provides consumer protection and allows for informed decisions to be made, all while noting the importance of the medical tourism industry.

Although the FTC does not have specific regulations in place targeting the medical tourism industry, the agency has regulated consumer safety and

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[91] Health-Tourism.com, *Medical Tourism to Mexico,* https://www.health-tourism.com/medical-tourism-mexico/ (last visited Nov. 6, 2022).

[92] *Id.* (emphasis added).

[93] WORLD MED. ASS'N [WMA] General Assembly, *WMA Statement on Medical Tourism*, ¶ 26 (Oct. 8, 2018), https://www.wma.net/policies-post/wma-statement-on-medical-tourism/#:~:text=Medical%20tourism%20must%20not%20promote,to%20treat%20the%20local%20population [hereinafter WMA Statement].

protection in analogous situations, including the tobacco industry, the prescription eyeglass industry, and, more recently, in issues surrounding COVID-19.

A. Tobacco

The FTC's regulation of the tobacco industry is a good example of how the FTC regulated advertising by expressly requiring that certain types of information be readily available and provided to consumers. Examining the FTC's regulation of other products and services may provide needed insight into whether regulation of medical tourism applies to modern legal norms and within the FTC's authority.[94] Arguably, the most important consumer protection regulation issued by the FTC is regulation in the tobacco industry. In 1964, the Surgeon General of the United States released *Smoking and Health: Report of the Advisory Committee of the Surgeon General of the Public Health Service*.[95] This report was the first of its kind, outlining the addictive, detrimental, and carcinogenic effects of tobacco.[96] The report was the topic of news headlines across the country, rated by USA Today as one of the top news stories of the twentieth century, and most importantly, it initiated the change in public perception and attitude towards smoking.[97]

In response, Congress began to impose strict regulations on the advertising of tobacco products. The Federal Cigarette Labeling and Advertising Act of 1965 made health warnings on cigarette packages mandatory.[98] In 1986, Congress passed the Comprehensive Smokeless Tobacco Health Education Act of 1986, which required a program to be established to "inform the public of any dangers to human health resulting from the use of smokeless tobacco products."[99] The FTC required manufacturers, packagers, and importers of smokeless tobacco products to place health-related warning labels on product packages and in

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[94] Browne, *supra* note 3, at 351.

[95] U.S. DEP'T OF HEALTH AND HUM. SERV., THE HEALTH CONSEQUENCES OF SMOKING- 50 YEARS OF PROGRESS. A REPORT OF THE SURGEON GENERAL 3 (2014), https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf.

[96] *Id.*

[97] *Id.*

[98] *Id.; see also* Browne, *supra* note 3, at 352.

[99] Comprehensive Smokeless Tobacco Health Education Act of 1986, S. 1574, 99th Cong. § 2(a) (1986).

advertisements.[100] Additionally, the act prohibited the advertising of smokeless tobacco products on radio, television, or other media.[101]

The Act did not eliminate tobacco products, but rather implemented regulations to protect public health better. Further, what began as a campaign to promote fair advertising by cigarette companies transformed into more transparent warnings, allowing consumers to make more informed choices regarding tobacco products.[102]

Medical tourism is similar in the sense that the industry should not be eliminated, but only better regulated to allow consumers to make more informed choices regarding their health, including when, where, and how they receive needed treatment. Medical tourism is essential since it allows people the opportunity to receive medical care and treatment that they otherwise would not be able to receive.[103] Before the Surgeon General's report, tobacco was historically regarded as medicinal and beneficial for health.[104] As more information about the risks of tobacco became known, the FTC began to regulate and control who had access to and what information must be available to the average consumer.

Similarly, medical tourism agencies hide adverse side effects and potential turn-offs from the consumer.[105] Medical tourism resources, such as Medical Tourism Corporation and Healthtourism.com, provide a one-sided view of the industry. By advertising sunny beaches and discounted low prices, the advertisements encourage consumers to overlook negative effects and lead to foreseeable injury.[106] The FTC must take a lesson from the regulation of the 1986 Act and limit medical tourism advertising to only JCI-accredited facilities to best protect consumer safety. Additionally, the FTC must regulate that *all pertinent* information is readily apparent to the average consumer before making an informed decision.

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[100] S. 1574 § 3(a)(1).

[101] S. 1574 § 3(a)(2).

[102] Browne, *supra* note 3, at 352-53.

[103] Parsiyar, *supra* note 1, at 386-387. ("It is a viable option for underinsured or noninsured Americans who do not have access to or simply do not want to use state, federal, or charitable programs or personal contributions. . . .the lower cost may mean the difference between life and death for those who are uninsured or underinsured.")

[104] Browne, *supra* note 3, at 353.

[105] *Id.*

[106] *Id.* at 353-54.

B. Contact Lens Rule

The FTC's regulation in the Contact Lens Rule is another example where the FTC has exercised its authority in the health field by requiring affirmative notice to consumers of contact lenses.[107] The Contact Lens Rule requires prescribers to give patients a copy of their contact lens prescriptions at the end of a contact lens fitting, *even if the patient doesn't ask for it.*[108] Further, the Rule places restrictions on "any person who engages in the manufacturing, processing, assembly, sale, offering for sale, or distribution of contact lenses" by not allowing representations "by advertisement, that contact lenses may be obtained without a prescription."[109]

Emphasized in the rule is the patient notice, which invariably heightens consumer safety and provides them with the information needed to make an informed decision. Similarly, the FTC must mandate and emphasize notice in medical tourism to allow prospective consumers to make informed decisions about their healthcare needs. Under the same approach, U.S.-based medical tourism agencies must provide readily accessible, not hidden, information about *all* benefits and risks, including JCI-accredited facilities, *even if the consumer doesn't ask for it.* In other words, the information must be made so readily apparent that the consumer would have no choice but to look at it. This would further the FTC's goal of consumer protection and curbing deceptive advertisements.

C. COVID-19

The COVID-19 pandemic is a strong example of how the FTC can rapidly respond to ongoing events by readily creating regulations that protect the public at large. Specifically, the FTC has worked to protect consumers from scams and frauds related to the pandemic. An April 2021 staff report noted that "one of the FTC's strengths is the ability to anticipate and respond to current events and the predatory behavior that capitalizes on those events."[110] As a result of the pandemic, the world shifted more digital,

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[107] *See generally* 16 C.F.R. § 315.3 (2023).

[108] Availability of Contact Lens Prescriptions to Patients, 16 C.F.R. § 315.3 (a)(1) (2023).

[109] Content of Advertisements and Other Representations, 16 C.F.R. § 315.7 (2023).

[110] STAFF REPORT, FED. TRADE COMM'N, PROTECTING CONSUMERS DURING THE COVID-19 PANDEMIC: A YEAR IN REVIEW 1 (2021),

enabling marketers to make deceptive COVID-19 claims, and schemes proliferated to exploit people's financial situations.[111] The emergence of the pandemic illustrated the ways in which the FTC worked to address consumer protection: "[t]he Commission developed systems to track and alert the public to shifts in reports from consumers, launched a public dashboard providing information on reports associated with COVID-19, and used COVID-related reports to identify law enforcement targets."[112]

The FTC's COVID-19 response is the most illustrative on how the FTC can work to regulate medical tourism. The FTC is a fluid agency with the ability to respond to current events. As such, the FTC has the legal authority to respond to medical tourism issues. More importantly, the pandemic illustrated the FTC's ability to educate the general public in real time. For example, "[t]he FTC. . .reached out to the business community, warning of COVID-related frauds even before the ramifications of the pandemic were widely recognized."[113] The FTC has the legal authority to reach out to U.S.-based medical tourism agencies to mandate that all pertinent benefits and harms are displayed to potential consumers, as well as to require that only JCI-accredited facilities are used.[114]

IV. INTERNATIONAL REGULATION

U.S. regulatory agencies will sometimes rely on international regulatory bodies to assist in regulating what the U.S. may not reach alone. The FTC should use the JCI in the same fashion—to assist in regulating international healthcare facilities for U.S. domestic marketing regulation. One example is from the Federal Aviation Administration's (FAA) International Aviation Safety Assessment Program (IASA).[115]

Under the IASA program, the FAA determines whether another country's oversight of its air carriers that operate or seek to operate, in the U.S. comply with safety standards established by the International Civil Aviation Organization (ICAO).[116] Countries are categorized as either

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https://www.ftc.gov/system/files/documents/reports/protecting-consumers-during-covid-19-pandemic-year-review/covid_staff_report_final_419_0.pdf.

[111] *Id.*

[112] *Id.* at 2.

[113] *Id.* at 11.

[114] *See generally* Browne, *supra* note 3, at 348-349.

[115] *International Aviation Safety Assessment Program*, FED. AVIATION ADMIN., https://www.faa.gov/sites/faa.gov/files/about/initiatives/iasa/FAA_Initiatives_IASA.pdf (Nov. 11, 2022).

[116] *Id.*

Category 1—the country meets ICAO standards and thus, permitted to operate in the U.S.; or Category 2—the country does not meet the ICAO standards and thus is prohibited from initiating commercial service into the U.S. [117] However, it may be allowed with certain restrictions.

In conducting the IASA assessments, the program administrators focus on compliance with eight critical elements of safety oversight, established by the ICAO.[118] An in-country assessment is conducted over the course of one week by a specially trained IASA team consisting of a team leader, at least one aviation safety inspector, and an FAA international aviation law attorney, after which a determination of a country's category is published.[119] Category 1 countries meet ICAO standards for each of the eight critical elements, while Category 2 countries are noncompliant with at least one critical element.[120]

Another example of the U.S.'s ability to regulate and monitor foreign conduct is through the Federal Drug Administration's (FDA) inspections of foreign drug manufacturing facilities. Drugs sold in the U.S. are manufactured throughout the world, with an estimated 60% of manufacturing occurring internationally.[121] As such, increased scrutiny and regulation are needed to ensure that drugs manufactured overseas meet the same statutory and regulatory requirements as in the U.S.[122] The FDA's Office of Regulatory Affairs (ORA) inspects both domestic and foreign establishments to "ensure that drugs are produced in conformance with applicable laws of the U.S."[123] The FDA generally conducts three main types of drug manufacturing establishment inspections: preapproval inspections, surveillance inspections, and for-cause inspections.[124]

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[117] *See id.*

[118] FED. AVIATION ADMIN., *supra* note 102 (stating that the eight critical elements include: primary aviation legislation; specific operating regulations; state civil aviation system and safety oversight functions; technical personnel qualification and training; technical guidance; licensing, certification, authorization, and approval obligations; surveillance obligations; and resolution of safety concerns).

[119] *Id.*

[120] *Id.*

[121] *Challenges for FDA with Foreign Inspections* (Feb. 2, 2020), https://www.pharmatutor.org/articles/challenges-for-food-and-drug-administration-with-foreign-inspections.

[122] *Id.*

[123] *Id.*

[124] *Id.* (stating that preapproval inspections are designed to verify the accuracy and authenticity of drug application data, in connection with a new brand name or generic drug to be marketed in the U.S.; surveillance inspections focus on drugs already marketed in the U.S., and

ORA investigators, who are assigned to and live in countries where the FDA has foreign offices, conduct the process to determine whether a foreign drug manufacturing facility complies with FDA requirements. During the investigation, "ORA investigators are responsible for identifying any significant objectionable conditions and practices and reporting these to the [foreign] establishment's management."[125] Additionally, the investigators suggest that management directly communicates with the FDA regarding any concerns stemming from the investigative process.

Based on their findings, ORA investigators categorize the establishments based on three classifications: no action indicated (NAI); voluntary action indicated (VAI); and official action indicated (OAI).[126] Foreign establishments that are classified as OAI are those where the ORA identified serious deficiencies. Such facilities may then be subject to regulatory action, such as issuing warning letters, which puts not only the establishment on notice, but also the U.S. supplier.[127]

In relation to medical tourism, the FTC has the authority and support to regulate and manage both domestic and foreign conduct. The JCI contains panel members who guide the development and revision process of the accreditation standards and includes members from the U.S., which invariably increases the likelihood of conformity with U.S. standards, such as in the FAA and FDA arenas.

V. JCI-ACCREDITED FACILITIES ARE MORE TRUSTED

The World Health Organization (WHO) has long recognized a need for accrediting foreign bodies to ensure healthcare safety, but has stopped short of advocating for a single, specific standard.[128] Rather, the WHO collaborates with the JCI to promote patient safety standards.[129] One such example of the collaboration between the WHO and JCI was the High 5s Project.

The High 5s Project was launched in 2007 as a global safety initiative to "facilitate the development, implementation, and evaluation of [standard operating protocols] that were developed to address known patient safety

inspection focuses on compliance with safety goals in manufacturing; for-cause inspections are conducted to investigate specific issues).

[125] *Id.*

[126] *Id.* (stating that NAI classification is analogous to Category 1 in the ICAO classification.)

[127] *Id.*

[128] Hill, *supra* note 15, at 281.

[129] *Id.* at 281-82.

problems."[130] More simply stated, the project sought to develop standardized interventions that could be applied in any hospital in any country.[131] In healthcare, standardization is key, as differences in care can result in worse clinical outcomes.[132] The project further noted that:

> [s]tandardization can be seen as enhancing the portability of expertise, irrespective of the country, the facility or the health care worker implementing the protocol. The standardization of hospital processes should enable trained health care workers to perform effectively in any facility in the world.[133]

The WHO has noted that a lack of unified standards is most likely reasonable, since accreditation is a holistic approach.[134] Yet, the WHO recognized the importance of promoting safety standards through standardization, and chose the JCI as a trusted partner through the project.

Given the importance of medical tourism, many countries and organizations provide advisory information or guidelines to best promote safe practices. Both the AMA and the WMA publish guidelines, which include provisions urging patients to consider the licensing or accreditation of the destination facilities. The AMA guidelines state: "[p]atients should only be referred for medical care to institutions that have been accredited by *recognized international accrediting bodies* (e.g., the Joint Commission International or the International Society for Quality in Health Care)."[135] The WMA takes a similar approach, stating that "[a]ccess to licensing/accreditation status of physicians and facilities and the facility's outcomes data should be made readily available."[136]

The guidelines illustrate the trustworthiness of the JCI. For one, they are mentioned, by name, by respected governing bodies in medicine and world health. Secondly, the guidelines may be interpreted less like guidelines, but rather more like "strong recommendations," as evidenced by the AMA and WMA guidelines including words like "should only" and "should be." More so, they direct prospective patients to facilities that are JCI approved.

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[130] Agnes Leotsakos et al., *Standardization in Patient Safety: the WHO High 5s Project,* 26 INT'L J. QUALITY HEALTH CARE 109, 110 (2014).

[131] *Id.*

[132] *Id.* at 111.

[133] *Id.*

[134] Hill, *supra* note 15, at 281.

[135] Am. Med. Assoc., *supra* note 29.

[136] WMA GEN. ASSEMBLY, *supra* note 93.

The JCI, as an organization, is also accredited by the International Society for Quality in Health Care (ISQua) for its role and development of standards that focus on the quality of healthcare.[137] The ISQua is a non-profit, non-governmental organization that aims to "provide services to guide health professionals, providers, researchers, agencies, policymakers, and consumers to achieve excellence in healthcare delivery to all people and to continuously improve the quality and safety of care."[138] In other words, ISQua "accredits the accreditors" and allows organizations, such as JCI, to demonstrate that their standards meet best international practices.[139] To qualify for a ISQua assessment, an organization must be an "external evaluation organization or a standards developing body within the health or social care sector," such as JCI.[140]

The framework for ISQua accreditation was developed focusing on patient safety and continuous quality improvement. ISQua bases its evaluation on the key principles: standards development; standards measurement; organizational role, planning, and performance; safety and risk; patient focus; and quality performance.[141]

ISQua accreditation is essentially an international umbrella organization under which the JCI and other foreign governing accreditation bodies lie.[142] As such, requiring international health care facilities to be accredited by both ISQua and JCI standards would not only be repetitive, but futile and costly, with no added benefit.[143]

While this note largely analyzed the effect and need of JCI-accreditation, other accrediting bodies, such as the ISQua, are equally as

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[137] *Accreditation of Overseas Hospitals - JCI or ISQua?*, Medical Tourism Magazine, https://www.magazine.medicaltourism.com/article/accreditation-of-overseas-hospitals-jci-or-isqua (last visited July 6, 2024).

[138] *Guidelines and Principles for the Development of Health and Social Care Standards*, ISQUA, 1, 2 (Sep. 2015), https://isqua.org/media/attachments/2018/03/20/guidelines_and_principles_for_the_development_of_health_and_social_care_standards__4th_edition_v1.2.pdf.

[139] *JCI is Pleased to Announce the Accreditation of the JCI Standards for Primary Care, 2nd Edition from the International Society for Quality in Healthcare*, JOINT COMM'N INT'L, (Sep. 2018), https://store.jointcommissioninternational.org/assets/3/7/September_JCInsight_Final.pdf.

[140] *Am I Eligible?*, INT'L SOC'Y FOR QUALITY HEALTH CARE EXTERNAL EVALUATION ASS'N https://ieea.ch/check-eligibility/am-i-elegible-accreditation.html (last visited Dec. 22, 2022).

[141] *See supra* note 137, at 14 (stating that these principles assess if the organization, such as JCI, has adequate standards development, consistent and transparent measurement of activity, risk management, and adequate monitoring systems in place).

[142] *Accreditation of Overseas Hospitals – JCI or Isqua?,* MEDICAL TOURISM MAG., https://www.magazine.medicaltourism.com/article/accreditation-of-overseas-hospitals-jci-or-isqua (last visited Dec. 22, 2022).

[143] *See id.*

beneficial for medical tourism. JCI focuses its accreditation on the hospitals, clinics, and similar facilities, while ISQua focuses on the bigger picture—the accreditation organizations. Therefore, JCI-accredited facilities may be more readily available and feasible to prospective consumers, based on the popularity of JCI and its closeness to U.S. standards.

CONCLUSION

The boom of medical tourism will only continue to rise.[144] With the increased cost of healthcare and inequality in accessibility, medical tourism provides prospective consumers with affordable, quality healthcare that they could not access otherwise. Yet, there remains a need for caution. Medical tourism is beneficial and necessary to level the playing field, but it is highly unregulated. Different organizations, such as the AMA and WMA, understand the value of the industry, but also understand the downside. Through published, nonbinding guidelines, both agencies advocate for patient safety and include provisions emphasizing the importance of accredited international facilities. The JCI is one of these accreditation standards.

While both the AMA and WMA guidelines are not binding laws, the FTC can offer binding regulations. Therefore, the FTC must regulate the way that medical tourism is conducted, mainly through its authority in the first step in the chain—marketing. When U.S. consumers at home first begin to consider medical tourism, they most likely begin by researching the industry, the commonly visited countries, and the cost. This is in the FTC's ballpark. The agency controls advertising and regulates what information is published and visible to prospective consumers. The FTC must, therefore, limit medical tourism to only accredited international facilities, such as those accredited by the JCI.

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[144] *See* Hill, *supra* note 15, at 280. ("The potential for industry growth, however, receives universal agreement.").