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# AMERICAN MEDICAL TOURISM: REGULATING A CURE THAT CAN DAMAGE CONSUMER HEALTH

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*“The most stringent protection of free speech would not protect a man in falsely shouting fire in a theater and causing a panic. . . . The question in every case is whether the words used are used in such circumstances and are of such a nature as to create a clear and present danger that they will bring about the substantive evils that Congress has a right to prevent.” – Oliver Wendell Holmes, Jr.*

*“Observe the physician with the same diligence as the disease.” – John Donne*

## I. INTRODUCTION

“**M**edical Tourism: just what the doctor ordered,”<sup>1</sup> or so the online advertisements claim.<sup>2</sup> For example, take Ingrid,<sup>3</sup>

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<sup>1</sup> See Christine Lee, *Just What the Doctor Ordered. Medical Tourism*, 43 MONASH BUS. RW. 10 (2007) (asserting that it is “easier” to travel to emerging economies with cheaper medical costs).

<sup>2</sup> See *Incredible India*, INCREDIBLEINDIA.ORG, [http://www.incredibleindia.org/newsite/cms\\_page.asp?pageid=492](http://www.incredibleindia.org/newsite/cms_page.asp?pageid=492). Directly above the link for this brochure are several links for trip planning and experiencing India. See also Thomas R. McLean, *Shaping a New Direction for Law and Medicine: An International Debate on Culture, Disaster, Biotechnology and Public Health: Article: Telemedicine and the Commoditization of Medical Services*, 10 DEPAUL J. HEALTH CARE L. 131, 162 (2007) (“In particular, medical tourism, which combines a vacation with

an eighty-five year old woman suffering the struggles of old age who was advised that a hip replacement was necessary upon visiting her doctor for her regular checkup. Ingrid then goes home that evening and begins her research on hospitals and after-care facilities for her upcoming procedure. A simple Google search for the “cost of hip replacement surgery”<sup>4</sup> yields the following results: “average cost of \$39,299,” “\$35,000,” and “\$50,000.” Ingrid stares at her blinking computer screen as sour disbelief washes over her face. Suddenly, to her extreme delight, she spots the bolded text: “Poland hip replacement – cost of operation with a cemented prosthesis = \$6000 USD.” “That’s the one!” she cries. She then jots down the contact information and begins booking her flight to Poland for the following month. Ingrid is ecstatic that she will be able to save thousands of dollars by flying to Poland for her hip replacement surgery.

Ingrid will jump on an ever-increasing bandwagon that paradoxically risks damaging the very health it promises to enhance. Medical tourism<sup>5</sup> refers to a trend on the rise in the United States, with attractive costs and luxurious

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medical treatment, is growing at a staggering pace”). For a discussion on the marketing technique of medical tourism which offers a “getaway vacation,” see *The Globalization of Health Care: Can Medical Tourism Reduce Health Care Costs?: Hearing Before the Senate Special Committee on Aging*, 109th Cong. 47-49 (2006) (statement of Bruce Cunningham, M.D., M.S., President, American Society of Plastic Surgeons) (“Aside from the qualifications of the physician, Cunningham raised concerns about marketing practices of medical tourism as potentially luring patients abroad under the guise of a medical vacation. Cunningham is concerned that due to the combination of the low cost and marketing strategies that promote the trips as “medical vacations,” patients may devalue the precautions that should be taken before and after surgery and may fail to consider the risks of the surgery altogether”).

<sup>3</sup> Any reference to a woman named “Ingrid” and a case of medical tourism is purely coincidental, as the name of the woman and instance of medical tourism is fabricated.

<sup>4</sup> GOOGLE, <http://www.google.com> (search for “cost of hip replacement surgery”).

<sup>5</sup> See Mark S. Kopson, *Medical Tourism: Implications for Providers and Plans*, 3 HEALTH & LIFE SCI. L. 147, 150 (2010) (“How one defines medical tourism is determined, frequently, by the impact of the phenomenon upon the individual crafting the definition. The definition can range from ‘no oversight, no regulatory apparatus . . . the wild west of medical care,’ to ‘travel[ing] to another country to receive medical, dental, and surgical care while at the same time receiving equal to or greater care than they would have in their own country . . . because of affordability, better access to care, or a higher level of quality of care.’”).

accommodations.<sup>6</sup> Specifically, medical tourism is the practice of traveling to a foreign country for a medical procedure, such as major or minor surgery or alternate therapies.<sup>7</sup> In light of the ever-increasing costs of health insurance and medical procedures in the United States, consumers are deciding to take the high prices of health procedures into their own hands.<sup>8</sup> With the

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<sup>6</sup> Lee, *supra* note 1, at 10.

<sup>7</sup> *Id.* (“Whether it is for cheaper dental work in Thailand, heart surgery in India, or warm climate therapy in Monte Carlo, medical tourism is big business and getting bigger”); see also *Medical Tourism in India*, <http://www.medical-tourism-india.com/Medical-Torism.php>. This website that links prospective patients with health services abroad provides the following description of the many potential benefits (including a “holiday” experience) from medical tourism: “The idea of the health holiday is to offer you an opportunity to get away from your daily routine and come into a different relaxing surrounding. Here you can enjoy being close to the beach and the mountains. At the same time you are able to receive an orientation that will help you improve your life in terms of your health and general well being. It is like rejuvenation and cleanup process on all levels—physical, mental and emotional. Many people from the developed world come to India for the rejuvenation promised by yoga and Ayurvedic massage, but few consider it a destination for hip replacement or brain surgery. However, a nice blend of top-class medical expertise at attractive prices is helping a growing number of Indian corporate hospitals lure foreign patients, including from developed nations such as the UK and the US.”

<sup>8</sup> See THE DELOITTE CENTER FOR HEALTH SOLUTIONS, 2009 SURVEY OF HEALTH CARE CONSUMERS: KEY FINDINGS, STRATEGIC IMPLICATIONS 5 (2009), available at [http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us\\_chs\\_2009SurveyHealthConsumers\\_March2009.pdf](http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_chs_2009SurveyHealthConsumers_March2009.pdf) (“An estimated 750,000 U.S. citizens engaged in medical tourism in the year 2007”). With vast price differentials between surgeries in the United States and India, it does not come as a shock that India is one of the most popular destinations for medical tourism. See also Elizabeth Gluck, *Incredible [Accreditable] India: Trends in Hospital Accreditation Coexist with the Growth of Medical Tourism in India*, 1 ST. LOUIS U. J. HEALTH L. & POL’Y 459, 466 (2008) (explaining the cost difference for specific surgeries in the United States and in India). Gluck claims:

Healthcare in India is less expensive than it is in the United States primarily due to the value of the American dollar in undeveloped countries. This price difference translates to medical procedures in India costing approximately one-fifth to one-tenth of the U.S. price. The cost of advanced surgeries performed in India is estimated to be ten to fifteen times less than anywhere else in the world. For example, a heart surgery that would cost \$30,000 in the United States costs approximately \$6,000 in India, and a bone marrow transplant with a price tag of \$250,000 in the United States would be billed at approximately \$26,000 in India. Knee replacement

increased cost of medical procedures<sup>9</sup> and decreased access to affordable health services in the United States,<sup>10</sup> the market for medical tourism is expected to continue to flourish.<sup>11</sup>

There is no doubt that medical tourism is one of the hottest new trends in the United States. However, popularity aside, are there any dangers involved with medical procedures abroad that consumers in the United States should be made aware of before making a medical purchase?

For a consumer to be able to make an informed, autonomous decision regarding a medical purchase, the consumer must be given access to all information that has the potential to affect the safety of a medical procedure abroad. This includes information regarding the quality of patient care and any potential hazards that can arise during the procedure abroad. If consumers are provided with all-encompassing information regarding a medical purchase, only then is the consumer provided with the tools to make a safe and reliable decision concerning a choice of physician and venue. When the consumer can make a well-informed decision regarding a medical procedure abroad,

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surgery in India costs approximately \$8,500, but, if performed in the United States, the same operation would cost approximately \$40,000.

<sup>9</sup> Melissa B. Jacoby & Elizabeth Warren, *Beyond Hospital Misbehavior: An Alternative Account of Medical-Related Financial Distress*, 100 NW. U.L. REV. 535, 536 (2006) (“Long after a person recovers physically, illness and injury can have a significant financial impact on individuals and their families. In the past several years, the news media have given front-page attention to the money side of medical problems. Featured stories described how big hospital bills turn families’ lives upside down, sometimes costing them their homes, their credit ratings, access to their bank accounts, and occasionally even their liberty”).

<sup>10</sup> Kopson, *supra* note 5, at 153. Kopson’s argument provides insight on the contributing factors of medical tourism. The author provides evidence from research included in the *Wall Street Journal* that claims rapidly rising healthcare costs are one of the primary contributors to the increasing popularity of medical tourism; specifically the “percentage of U.S. residents lacking any healthcare insurance, the decreasing percentage of those with private healthcare insurance, and the increasing enrollment in high-deductible plans.” See also THE DELOITTE CENTER FOR HEALTH SOLUTIONS, *supra* note 10.

<sup>11</sup> See Vadim Schick, *Data Privacy Concerns for U.S. Healthcare Enterprises’ Overseas Ventures*, 4 J. HEALTH & LIFE SCI. L. 173, 175 (2011) (“For example, India’s medical tourism sector is expected to grow 30 percent annually from 2009 to 2015”).

medical tourism has the potential to be a beneficial check on the price and quality of the domestic market for those services.

But in the United States, consumers are not fully informed about the safety of medical tourism by intermediary business practices. For example, most prospective patients seeking health services abroad are not aware of the legal remedies they are or are not entitled to if any health care services harm the patient abroad—presumably, the specific details about legal rules and procedures concerning medical negligence in particular foreign countries is beyond the expertise of a lay person. However, despite pervasive regulatory and legal risks abroad, consumers are consistently encouraged to pursue medical tourism by intermediary businesses in the United States.<sup>12</sup> Medical tourism intermediaries (*i.e.* private businesses that make a profit by linking consumers with medical services abroad) not only fail to inform consumers of these regulatory and legal risks, but also paint a deceptive picture of the “safety” of medical tourism. Instead of informing consumers of potential risks, medical tourism businesses focus on price benefits, vacation getaways,

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<sup>12</sup> See MEDRETREAT, <http://www.medretreat.com>. The intermediary medical tourism business advertises as “America’s most trusted Medical Tourism company facilitating Medical Travel programs for North Americans seeking affordable surgery abroad.” It is the deceptive advertising of intermediary companies such as MedRetreat, which this note asserts necessitates government regulation. One version of deceptive advertising is “asymmetric information,” or imperfect consumer information. This note argues that the asymmetric information provided by American medical tourism businesses, such as MedRetreat, qualifies as “deceptive advertising” by FTC standards, and thus, should be regulated. For further discussion on asymmetrical information, see Shmuel I. Becher, *Asymmetric Information in Consumer Contracts: The Challenge That Is Yet To Be Made*, 45 AM. BUS. L.J. 723, 733 (2008) (discussing the controversies surrounding asymmetric information and consumers’ adherence to standard form contracts (“SFC”)). Becher states, “generally speaking, the term ‘asymmetric information’ refers to situations where parties are differently informed, with one party having access to better or more information than the other.” Becher’s definition of asymmetric information is applicable to consumer deceit via American medical tourism businesses. Sellers of medical tourism do not deprive consumers of material information regarding potential hazards abroad. This deprivation of consumer information inhibits consumer knowledge, creating an inequality between buyer and seller information.

For an in depth discussion about asymmetric information, see Facundo Bouzat, *Linking the Regulation of Business to Specific Market Structure: Deconstructing Three Cases to Demonstrate the Salience of “the Market” in Court Decisions*, 41 ACAD. LEGAL STUD. IN BUS. NAT’L PROC. 6 (2010).

and world-renowned doctors.

This note argues that the marketing of medical procedures abroad to American consumers is a business practice that requires a specific form of regulation. Without that regulation, promoters of less expensive medical services abroad will continue to promote medical tourism to consumers based on incomplete information that results in unnecessary deception.

The initial component of this note, Section II, compares medical safety in the United States with that in India in order to establish the potential risks consumers should be informed of before making a medical purchase. This two-fold comparison includes: 1) a comparative look at medical safety regulations in the United States versus India and 2) a brief comparison of the ability for patients to pursue legal recourse for medical negligence in the United States versus India. This comparison makes evident certain dangers of medical tourism. Specifically, it highlights regulatory pitfalls and infrequent legal remedies for medical negligence abroad.

To correct these pitfalls, in Section III, we outline the potential basis for legal amelioration of these harms. Specifically, Section III discusses the United States Federal Trade Commission's ("FTC") authority to regulate unfair or deceptive business practices. After analyzing the criteria created by the FTC for deeming business advertising as "deceptive," we argue in Section III that medical tourism businesses in the United States are in fact engaging in deceptive advertising, and thus, have potentially unlawful elements that require regulation. We use the *Central Hudson* test<sup>13</sup> to determine the constitutionality of the hypothetical regulation of medical tourism businesses in the United States. Hence, Section III ends with our arguing that the regulation of medical tourism businesses in the United States is constitutional according to the *Central Hudson* test.

Last, Section IV of this note discusses potential counter arguments that opponents to the business regulation advocate. Mainly, we argue that to deny the regulation of medical tourism businesses in the United States would consequently deny consumers protection from deceptive advertising. Consumers need protection by an outside entity because consumers are susceptible to cognitive heuristics and irrational decision-making

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<sup>13</sup> See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 565 (1980).

behaviors that detract from the ability to be completely in control of one's decisions. Because of a consumer's irrational decision-making, it is the duty of the government to protect consumers and regulate deceptive advertising.

In Section V of this note, we conclude that medical tourism intermediaries in the United States are neglecting to inform consumers about regulatory and legal pitfalls abroad that are hazardous to consumers. According to the Federal Trade Commission Act, this lack of material information is unlawfully deceptive.

## II. ESTABLISHING THE DANGERS OF MEDICAL PROCEDURES ABROAD: A COMPARISON OF MEDICAL REGULATIONS IN THE UNITED STATES AND INDIA

"Regulation"<sup>14</sup> refers to a government's use of coercive power to impose a range of legal constraints, such as laws, administrative rules, and guidelines, on organizations and individuals.<sup>15</sup> When a government or administrative body operates with regulations, that entity is imposing control to mandate behavior that protects public welfare or the individuals of a society. In the case of medical safety, regulations exist to protect the welfare of patients seeking medical attention.

Unfortunately, medical safety regulations abroad are not necessarily as stringent as regulations in the United States. Because of a lack of regulation in many countries abroad, poor

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<sup>14</sup> For a discussion on the importance of regulation, see Claire Cowart Haltom, *Quality in Action: Paradigm for a Hospital Board-Driven Quality Program*, 4 J. HEALTH & LIFE SCI. L. 95 (2011). According to Haltom, "law affects social norms and, therefore, the behavior of directors, indirectly. Social norms are affected in part by external factors, such as judicial decisions, which in turn modify the behavior of directors by altering internal constraints. In the corporate world, the recent trend toward a higher standard of care for directors is a result of a shift in belief systems, which was itself partly a result of the 'expressive effect of legal authorities, which clarified and added moral force to the social norm of care.' Criminal prosecution and civil suits that targeted nonprofit directors have contributed to shifting the social norms toward a more conscientious board. Likewise, increased attention to patient safety and quality assurance is likely pervading hospital corporate culture. Some notable hospitals and their directors voluntarily and actively make patient safety an institutional priority."

<sup>15</sup> See M. J. ROBERTS, *GETTING HEALTH REFORM RIGHT: A GUIDE TO IMPROVING PERFORMANCE AND EQUITY* (Oxford University Press 2004).

physician conduct and low facility standards are not always punishable by law. In addition, without regulatory impositions, physician conduct is operated by personal biases and values of the physician instead of the public welfare interest of the government.

As evidence of the crucial need for medical tourism businesses to recognize and inform consumers of the regulatory pitfalls mentioned above, the following section of this paper compares medical safety regulations in the United States to medical safety regulations in one of the most popular destinations for medical tourism, India.<sup>16</sup> As a country currently in high demand for medical tourism, India serves as an example of low-key medical regulation pervasive in several medical tourist destinations, such as Bangkok, Mexico, Sri Lanka, and Nigeria.<sup>17</sup>

#### A. The United States

Medical safety regulations exist to mandate a “standard of care”<sup>18</sup> for all patients. Regulations in the United States include the American Medical Association’s (“AMA”)<sup>19</sup> Code of Medical

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<sup>16</sup> See THE DELOITTE CENTER FOR HEALTH SOLUTIONS, *supra* note 10.

<sup>17</sup> See generally Nicolas P. Terry, *Under-Regulated Health Care Phenomena in a Flat World: Medical Tourism and Outsourcing*, 29 W. NEW ENG. L. REV. 421, 470 (2007).

<sup>18</sup> There are several U.S. landmark cases that discuss the meaning of “standard of care” or “duty of care” required by physicians. First, see Barbara Blackmond, *Health Law Developments: Health Law Year in Review: A Hospital Perspective*, 78 PA BAR ASSN. QUARTERLY 117, 117-119 (2007). Blackmond discusses the Supreme Court of Pennsylvania case, *Thompson v. Nason Hosp.*, 527 Pa. 330 (1991). In *Thompson*, the Court held that hospitals have a duty to prospective patients to exercise “reasonable care in the granting of medical staff appointment and clinical privileges and in ongoing performance oversight. Blackmond also cites *Curtsinger v. HCA, Inc.*, No. M2006-00590-COA-R3-CV, 2007 WL 1241294, at \*8 (Tenn. Ct. App. Apr. 27, 2007) (noting that the physician mandate of “duty of care” is “not limited to clinical competence, but also includes behavioral and ethical conduct.”); see also *Twitchell v. MacKay*, 434 N.Y.S.2d 516, 518 (App. Div. 1980). The Supreme Court of New York, Appellate Division held that duty of care involves “matters of science or art requiring special skill or knowledge not ordinarily possessed by the average person.” *Id.* As case law reveals, the idea of “duty of care” or “standard of care” in the medical field is highly ambiguous. The pervasive ambiguity outlined above leads to multiple contrasting interpretations of the phrases “duty” and “care.”

<sup>19</sup> The founding of the American Medical Association in 1847 sprung out of reaction to patient exploitation. See generally ROBERT BAKER, THE

Ethics,<sup>20</sup> enacted law consisting of constitutions, statutes, ordinances, and regulations,<sup>21</sup> and the Joint Commission.<sup>22</sup>

### 1. The United States Code of Medical Ethics

In the United States, the Code of Medical Ethics regulates practicing physicians and their treatment of all patients. The Code consists of ten sections: 1) Introduction; 2) Opinions on Social Policy Issues; 3) Opinions on Inter-professional Relations; 4) Opinions on Hospital Relations; 5) Opinions on Confidentiality, Advertising, and Communications Media Relations; 6) Opinions on Fees and Charges; 7) Opinions on Physician Records; 8) Opinions on Practice Matters; 9) Opinions on Professional Rights and Responsibilities; and 10) Opinions on Patient-Physician Relationship.

The Introduction of the Code, Opinion 1.01, states, “many of the Council’s opinions lay out specific duties and obligations for physicians. Violation of these principles and opinions represents unethical conduct and may justify disciplinary action such as censure, suspension, or expulsion from medical society membership.”<sup>23</sup>

### 2. Enacted Law of the United States

Besides the Code of Medical Ethics, there are additional medical safety regulations in the United States. A primary piece of regulation is The Patient Protection<sup>24</sup> and Affordable Care

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AMERICAN MEDICAL ETHICS REVOLUTION: HOW THE AMA’S CODE OF ETHICS HAS TRANSFORMED PHYSICIANS’ RELATIONSHIPS TO PATIENTS, PROFESSIONALS, AND SOCIETY. (Robert Baker, The Johns Hopkins Univ. Press 1999).

<sup>20</sup> See CODE OF MEDICAL ETHICS (Am. Med. Ass’n 2001), *available at* <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>.

<sup>21</sup> WILLIAM H. PUTMAN, *LEGAL RESEARCH* 3 (2nd ed. 2010).

<sup>22</sup> See THE JOINT COMMISSION, <http://www.jointcommission.org/>.

<sup>23</sup> CODE OF MEDICAL ETHICS, *supra* note 20.

<sup>24</sup> See Gerald Dworkin, *Paternalism*, 56 *THE MONIST* 64, 66 (1972). Gerald Dworkin defined paternalism as “the interference with a person’s liberty of action justified by reasons referring exclusively to the welfare, good, happiness, needs, interests or values of the person being coerced.” *Id.* The idea of “protection” or more specifically, “patient protection,” in the United States is exemplified by the paternalistic tendencies of our country. For example, the field of Social Work in the United States is defined by a core set of values that

Act<sup>25</sup> (“PPACA”).<sup>26</sup> This legislation is multifaceted and includes titles such as the following: Title III, Improving the Quality and Efficiency of Health Care; Title IV, Prevention of Chronic Disease and Improving Public Health; Title V, Health Care Workforce; Title VI, Transparency and Program Integrity; Title VII, Improving Access to Innovative Medical Therapies; and Title X, Strengthening Quality, Affordable Health Care for All Americans.

Furthermore, the Code of Federal Regulations<sup>27</sup> serves to

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strive to protect the vulnerable human beings of our community. *See* CODE OF ETHICS OF THE NATIONAL ASSOCIATION OF SOCIAL WORKERS (Nat’l Assoc. of Soc. Workers 2008), *available at* <http://www.naswdc.org/pubs/code/code.asp>. According to the National Association of Social Workers (“NASW”) Code of Ethics, the values and ethical principles of Social Work are as follows: service, social justice, dignity and worth of the person, importance of human relationships, integrity and competence. To separate the name of the profession into two separate words, “social” and “work” is to recognize the purpose of the vocation—to service the social, the individuals of a society. It is important to note, however, that social workers do not spend hours servicing the wealth or adept, but rather those individuals who are vulnerable, such as the poor, sick, aged, innocent (children), and disadvantaged. When integrating paternalism and social work, there are in fact elements of paternalism that contradict the value system of social work. A key goal of social work is to empower vulnerable clients. The idea of empowerment in the field of social work is related to providing clients with autonomy, a concept which opposes paternalism. *See* Kenneth R. Greene, *Paternalism in Supervisory Relationships*, 21 SOC. THOUGHT 17, 21 (2002) (“Social work practitioners often find themselves in ethical dilemmas between respecting the self-determination and autonomy of clients and promoting their welfare.”).

<sup>25</sup> RESTATEMENT (THIRD) OF TORTS: GENERAL PRINCIPLES § 4 (1999) (stating that “reasonable care” “is the same as conduct that is “reasonable,” conduct that avoids creating an “unreasonable risk of harm,” or conduct that displays “reasonable prudence”).

<sup>26</sup> *See* Rakel Meir, *The Link Between Quality and Medical Management: Physician Tiering and Other Initiatives*, 4 J. HEALTH & LIFE SCI. L. 36, 41 n.5 (2011) (“It is possible that given the focus on accountable care organizations and bundled payments, now incorporated in the Patient Protection and Accountable Care Act of 2010 (“PPACA”), greater amounts of data and emphasis on patient outcomes will become more readily available”); *see also* The Patient Protection and Affordable Care Act, 42 U.S.C. §§ 3002, 3011 et seq. (2010) (“The Patient Protection and Affordable Care Act requires the Secretary to establish a national strategy for quality improvement in both Medicaid and the private healthcare sector.”).

<sup>27</sup> *See* UNITED STATES CODE OF FEDERAL REGULATIONS, National Archives and Records Administration, *available at*

outline patient rights and the responsibilities of physicians, medical staff, hospitals, and centers of care in the United States. The Code of Federal Regulations contains three titles that are essential to mandating patient care in the United States: 1) Title 21, Food and Drugs; 2) Title 42, Public Health; and 3) Title 45, Public Welfare.<sup>28</sup>

Title 21, Food and Drugs, contains Chapter 1: Food and Drug Administration, which is regulated by the Department of Health and Human Services. Within Chapter 1 is Subchapter H: Medical Devices.<sup>29</sup> This Subchapter contains extensive regulation regarding the requirements of sterility, tamper-resistance packaging, patient examination gloves and surgeons' gloves, and overall reliability and cleanliness of medical devices used on patients.<sup>30</sup>

Title 42 of the Code of Federal Regulations, Public Health, contains two chapters pertinent to maintaining adequate care for patients: 1) Chapter I, Public Health Service, and 2) Chapter IV, Centers for Medicare and Medicaid Services.<sup>31</sup> Chapter I, Public Health Service, regulates hospital and station management and administrative functions, practices, and procedures.<sup>32</sup> Chapter IV, Centers for Medicare and Medicaid Services, contains Subchapter G, which regulates standards and certifications of hospitals and medical centers in the United States.<sup>33</sup> Within this subchapter exists the "conditions of participation for hospitals."<sup>34</sup> These "conditions" mandate the conduct of physicians and hospitals participating in the medical field of the United States. Specifically, the Code of Federal Regulations states:

- 1) Hospitals must comply with federal, state, and local laws. Hospitals must be in compliance with applicable federal laws related to the health and safety of patients. The hospital must be licensed or approved as meeting standards for licensing established by the agency of the

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<http://www.gpoaccess.gov/cfr/>.

<sup>28</sup> *Id.*

<sup>29</sup> 21 C.F.R. §§ 800.10 - 800.20 (1982).

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*; 42 C.F.R. §§ 482.11, 482.13(1982).

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

state or locality responsible for licensing hospitals. And the hospital must assure that personnel are licensed or meet other applicable standards that are required by state or local laws.<sup>35</sup>

2) The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.<sup>36</sup>

3) A hospital must protect and promote each patient's rights.<sup>37</sup>

Chapter IV of the Code of Federal Regulations contains

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<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* According to Chapter IV of title 42 of the Code of Federal Regulations, "patient's rights" include the following mandates by physicians and hospitals:

Notice of rights —(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible. (2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization.(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part, §489.102 of this part (Requirements for providers), and §489.104 of this part.(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.(5) The patient has the right to receive care in a safe setting. (6) The patient has the right to be free from all forms of abuse or harassment. (7) The patient has the right to the confidentiality of his or her clinical records.

additional regulations for mandating patient care, such as (1) the development, implementation, and maintenance of a quality assessment and performance improvement program;<sup>38</sup> (2) the operation of a medical staff responsible for the quality of medical care under an organized system of bylaws approved by the governing body;<sup>39</sup> (4) 24-hour nursing services serviced or furnished by a registered nurse;<sup>40</sup> (5) a medical record service that has administrative responsibility for medical records which must be maintained for every individual evaluated or treated in a hospital;<sup>41</sup> (6) pharmaceutical services that meet the needs of the patients;<sup>42</sup> (7) diagnostic radiologic services in all hospitals;<sup>43</sup> (8) laboratory services to meet the needs of patients either directly or through a contractual agreement with a certified laboratory;<sup>44</sup> (9) construction and maintenance of hospitals that ensures the safety of the patient and provides facilities for diagnosis and treatment;<sup>45</sup> (10) a sanitary environment to avoid sources and transmission of infections and communicable diseases as well as a program for prevention, control, and investigation of infections and communicable diseases;<sup>46</sup> (11) written protocols that regulate organ, tissue, and eye procurements;<sup>47</sup> (12) and extensive regulations of surgical services.<sup>48</sup>

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<sup>38</sup> See 42 C.F.R. § 482.21 (2003).

<sup>39</sup> See 42 C.F.R. § 482.22 (2008).

<sup>40</sup> *Id.* § 482.23.

<sup>41</sup> *Id.* § 482.24.

<sup>42</sup> *Id.* § 482.25.

<sup>43</sup> *Id.* § 482.26.

<sup>44</sup> See 42 C.F.R. § 482.27 (1992).

<sup>45</sup> See 42 C.F.R. § 482.41 (2008).

<sup>46</sup> *Id.* § 482.42.

<sup>47</sup> *Id.* § 482.45.

<sup>48</sup> *Id.* § 482.51. The Code of Federal Regulations outlines extensively the regulations for surgical procedures in U.S. hospitals. The Code contains the following provisions:

- (1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.
- (2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as “scrub nurses” under the supervision of a registered nurse.
- (3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.
- (4)

Finally, in addition to the Patient Protection and Affordable Care Act and the Code of Federal Regulations, there are additional regulatory statutes such as the Public Health Service Act,<sup>49</sup> the Health Insurance Portability and Accountability Act (“HIPAA”),<sup>50</sup> and the Patient Safety and Quality Improvement Act of 2005.<sup>51</sup>

In the United States, when there are violations of any of the above regulations, patients have the ability to seek legal recourse by suing for “medical negligence,”<sup>52</sup> which is a form of “medical malpractice.”<sup>53</sup>

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Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

Further, the Code requires the following prior to any surgery:

(i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration. (ii) An updated examination of the patient, including any changes in the patient’s condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.

<sup>49</sup> Public Health Service Act, 42 U.S.C. §§ 201-300m-21 (2011).

<sup>50</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996). (The HIPAA Privacy Rule provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes).

<sup>51</sup> Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-13, 119 Stat. 242 (2005) (“The Patient Safety and Quality Improvement Act signifies the Federal Government’s commitment to fostering a culture of patient safety. It creates Patient Safety Organizations (“PSOs”) to collect, aggregate, and analyze confidential information reported by health care providers. Currently, patient safety improvement efforts are hampered by the fear of discovery of peer deliberations, resulting in under-reporting of events and an inability to aggregate sufficient patient safety event data for analysis. By analyzing patient safety event information, PSOs will be able to identify patterns of failures and propose measures to eliminate patient safety risks and hazards.”).

<sup>52</sup> See BALLENTINE’S LAW DICTIONARY, (3d ed. 1998) (defining the term “negligence”).

<sup>53</sup> See BLACK’S LAW DICTIONARY 400 (Pocket ed. 1996) (“Specifically, professional negligence is defined as “a tort that arises when a doctor violates the standard of care owed to a patient and the patient is injured as a result”); see also 1 AM. JUR. 2d *Abatement, Survival, and Revival* § 83 (Regarding

### 3. The Joint Commission

In the United States, the Joint Commission functions primarily to implement provisions set forth in the Joint Commission on Accreditation of Hospitals (“JCAH”).<sup>54</sup> The Joint Commission provides certification or licensing of hospitals in the United States. To obtain JCAH accreditation, hospitals must comply with JCAH’s hospital-wide standards, including standards for organizing and controlling medical staffs.<sup>55</sup> Under the JCAH, the hospital’s medical staff is held more responsible for assuring the high quality of physician care within the hospital. According to the Joint Commission Hospital Accreditation Standards,<sup>56</sup> “hospitals seek Joint Commission accreditation because [*inter alia*] it: [1] Helps organize and strengthen patient safety efforts. [2] Strengthens community confidence in the quality and safety of care, treatment and services.”<sup>57</sup> Today, the Joint Commission accredits eighty-eight percent of the nation’s hospitals.<sup>58</sup> Though not legally required for operation in the United States, Joint Commission accreditation indicates that the accredited organization “meets at least minimum acceptable standards of care as recognized by the federal government and

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medical malpractice: “Although under the common law an action for a personal injury caused by the negligence or lack of skill of a surgeon does not survive the death of either party, there is authority to the contrary. Such a cause of action may survive under a survival statute, or may be construed as an action for breach of a contract, which survives under state law. If a patient asserts the right to recover for damages for medical malpractice by filing a claim prior to death, the suit creates a property right that can be maintained by a succession representative”); Jennifer Brown-Cranstoun, *Kringen v. Boslough and Saint Vincent Hospital: A New Trend for Healthcare Professionals Who Treat Victims of Domestic Violence*, 33 J. OF HEALTH L. 629 (2000) (“The essential element of a cause of action for medical malpractice is the physician-patient relationship. This special relationship gives rise to a duty of care. This duty of care involves matters of science or art requiring special skill or knowledge not ordinarily possessed by the average person. The breach of these professional duties of skill and care that results in injury to the patient constitutes actionable malpractice.”).

<sup>54</sup> See Karen G. Seimetz, *Medical Staff Membership Decisions: Judicial Intervention*, 1985 U. ILL. L. REV. 473, 474 (1985).

<sup>55</sup> *Id.*

<sup>56</sup> Joint Commission, *supra* note 22.

<sup>57</sup> *Id.*

<sup>58</sup> See Brian M. Peters & Robin Locke Nagele, *Promoting Quality Care and Patient Safety: The Case for Abandoning the Joint Commission’s “Self-Governing” Medical Staff Paradigm*, 14 MICH. ST. J. MED. & L. 313, 321 (2010).

most states.”<sup>59</sup>

### B. India

Medical regulations in India<sup>60</sup> include the Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, enacted law of India, and the Joint Commission International.

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<sup>59</sup> See Heather T. Williams, *Fighting Fire with Fire: Reforming the Health Care System Through a Market-Based Approach to Medical Tourism*, 89 N.C. L. REV. 607, 632 (2011).

<sup>60</sup> In India, medical regulations exist to provide patients with a “standard of care” by physicians. See *Jacob Mathew v. State of Punjab & Anr.*, Supreme Court of India, Criminal Appellate Jurisdiction 144-45 (2005). The Supreme Court of India held that standard of care refers to “the skill which he professes to possess shall be exercised and exercised with reasonable degree of care and caution.” See also *Bolam v. Friern Hosp. Mgmt. Comm.*, 2 All ER 118 (1957). *Bolam* established the *Bolam Rule*, which is used in India to assess the applied standard of care by physicians, and thus, whether or not a physician has acted negligibly. The *Bolam Rule* defines a physician’s standard of care as follows:

A professional man should command the corpus of knowledge which forms part of the professional equipment of the ordinary member of his profession. He should not lag behind other ordinary assiduous and intelligent members’ of his profession in knowledge of new advances, discoveries and developments in his field. He should have such an awareness as an ordinarily competent practitioner would have of the deficiencies in his knowledge and the limitations on ‘his skill. He ‘should be’ alert to the hazards and risks in any professional task he undertakes to the extent that other ordinarily competent members of the profession would be alert. He must bring to any professional task he undertakes no less expertise, skill and care than other ordinarily competent members of his profession would bring, but need bring no more. The standard is that of the reasonable average. The law does not require of a professional man that he be a paragon combining the qualities of polymath and prophet.” *Id.* The Indian Supreme Court continued the discussion on medical negligence by stating that deviation from normal practice is not necessarily evidence of negligence. *Id.* To establish liability on the basis of medical negligence, it must be shown 1) that there is a usual and normal practice; 2) that the defendant has not adopted it; and 3) that the course in fact adopted is one no professional man of ordinary skill would have taken had he been acting with ordinary care.” *Id.* Last, the Supreme Court of India noted that a medical practitioner is not liable to be held negligent simply because things went wrong “from mischance or misadventure or through an error of judgment in choosing one reasonable course of treatment in preference to another. *Id.*

## 1. The Indian Medical Council Regulations

In India, there are Professional Conduct, Etiquette, and Ethics Regulations,<sup>61</sup> much like the Medical Code of Ethics in the United States. These regulations were previously maintained by the primary body governing medical practice in India: the Medical Council of India.<sup>62</sup> However, as of May 15, 2010, the Medical Council of India has been repealed<sup>63</sup> due to the alleged corrupt behavior of the former President, the Vice-President, and additional members of the Council.<sup>64</sup>

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<sup>61</sup> See THE MEDICAL COUNCIL OF INDIA, <http://www.mciindia.org/> (last visited Apr. 10, 2013) (“The prime object of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. Whosoever chooses his profession, assumes the obligation to conduct himself in accordance with its ideals. A physician should be an upright man, instructed in the art of healings. He shall keep himself pure in character and be diligent in caring for the sick; he should be modest, sober, patient, prompt in discharging his duty without anxiety; conducting himself with propriety in his profession and in all the actions of his life.”).

<sup>62</sup> *Id.* The Medical Council of India (“MCI”) was the statutory body for maintenance of uniform and high standards of medical education in India. The Council grants recognition of medical qualifications, gives accreditation to medical colleges, grants registration to medical practitioners, and monitors medical practice in India.

<sup>63</sup> *Id.*

<sup>64</sup> The Government of India has essentially dissolved the Medical Council of India. See The Indian Medical Council (Amendment) Act, 2010, Acts of Parliament, 2010 (India). The Act was published by the Ministry of Law and Justice, Legislative Department of New Delhi. The Act states the following:

On and from the date of commencement of the Indian Medical Council (Amendment) Act, 2010, the Council shall stand superseded and the President, Vice President and other members of the Council shall vacate their offices and shall have no claim for any compensation, whatsoever. The Council shall be reconstituted in accordance with the provisions of section 3 within a period of one year from the date of supersession of the Council. The Central Government shall, by notification in the Official Gazette, constitute the Board of Governors which shall consist of not more than seven persons as its members, who shall be persons of eminence and unimpeachable integrity in the fields of medicine and medical education. The decision of the Central Government whether a question is a matter of policy or not shall be final: The Indian Medical Council (Amendment) Ordinance, 2010 is hereby repealed.

See also Roger Collier, *Dark Days for Medical Profession in India*, Canadian Medical Association Journal (2010). Collier notes that “On Apr. 22, Desai and three colleagues were arrested by India’s Central Bureau of Investigation for

The Code consists of eight chapters: Chapter 1, Code of Medical Ethics; Chapter 2, Duties of Physicians to their Patients; Chapter 3, Duties of Physician in Consultation; Chapter 4, Responsibilities of Physicians to Each Other; Chapter 5, Duties of Physician to the Public and to the Paramedical Profession; Chapter 6, Unethical Acts; Chapter 7, Misconduct; and Chapter 8, Punishment and Disciplinary Action.<sup>65</sup>

Acts of professional misconduct include: violation of any of the regulations of the Code of Medical Ethics Regulations; adultery or improper conduct; sex determination tests; certificates; reports; and other documents which are untrue, misleading, or improper; refusal of services on religious grounds; the disclosure of secrets of patients; performing an operation without consent of patient; using touts touting of by agents for to procuring procure patients; claiming to be a specialist without a special qualification; clinical drug trials or other research involving patients or volunteers; absence on more than two occasions during inspection by the Head of the District Health Authority; and absence on more than two occasions during assigned periods of duty in a medical college or institute.<sup>66</sup>

## 2. Medical Acts of India

Medical regulations provided by the Medical Council of India, which is currently superseded by the Central Government of India,<sup>67</sup> included the Indian Medical Council Act (1956),<sup>68</sup>

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their alleged roles in a 20-million-rupee (\$440,000) bribery case. They are alleged to have accepted a bribe from a medical college that wanted to increase enrolment despite lacking capacity for more students. At the time of his arrest, Desai was the president of the MCI. He subsequently resigned both the presidency and his position as head of the urology department at the B.J. Medical College in Ahmedabad.” For further discussion on alleged corruption of the Medical Council of India, see Sunil K. Pandya, *Medical Council of India: The Rot Within*, 6 INDIAN J. MED ETHICS 125 (2009).

<sup>65</sup> See Professional, Etiquette, and Ethics Regulations 2009, MEDICAL COUNCIL OF INDIA, <http://www.mciindia.org/RulesandRegulations/CodeofMedicalEthicsRegulations2002.aspx>.

<sup>66</sup> See MEDICAL COUNCIL OF INDIA, *supra* note 61.

<sup>67</sup> *Id.*

<sup>68</sup> See The Indian Medical Council Act, 1956, Acts of Parliament, 1956 (India). The Indian Medical Council Act (1956) outlines the regulations for practitioners of medicine to be constituted under law by the State Medical Register. The Act also notes the right of inspection of medical institutions,

which enabled inspection of medical facilities by the Medical Council of India, and the Indian Medical Degrees Act,<sup>69</sup> which focused on ensuring the legal qualifications of practicing physicians in India. Due to the dissolving of the Indian Medical Council by the Central Government of India, the Indian Medical Council Act has been amended as of 2010.<sup>70</sup> According to the amended Indian Medical Council Act:

The Central Government [of India] shall constitute the Board of Governors which shall consist of not more than seven persons as its members, who shall be persons of eminence and of unimpeachable integrity in the fields of medicine and medical education. . .the Board of Governors shall exercise the powers and perform the functions of the Council under this Act.<sup>71</sup>

Any specifications regarding the qualifications of the new Board of Governors is not included in the Amendment beyond the required “integrity in the fields of medicine and medical education.”<sup>72</sup>

The primary piece of regulation created by the Indian Medical Association is The Clinical Establishments (Registration and Regulation) Rules, 2010.<sup>73</sup> These Regulations specify the systems of medicine that are permitted, the type of testing that is permitted, and the records to be maintained by clinical establishments.<sup>74</sup> The Regulations also require every clinical establishment to maintain medical records of all patients treated, copies of all records and statistics, and to comply with the Standard Treatment Guidelines.<sup>75</sup> The Rules classify clinical establishments by (1) systems of medicine (Allopathy, Ayurveda, Unani, Siddha, Homeopathy, and Yoga & Naturopathy); and (2) type of establishment (providing out-patient care, providing in-

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including the inspection of the adequacy of staff, equipment, accommodation, and training facilities.

<sup>69</sup> See MEDICAL COUNCIL OF INDIA, *supra* note 61.

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> See *The Clinical Establishments (Registration and Regulation) Rules*, THE INDIAN MEDICAL ASSOCIATION, available at <http://www.ima-india.org/>.

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

patient care, providing testing and diagnostic services).<sup>76</sup> The Rules list several records that must be maintained by a clinical establishment in India.<sup>77</sup> Lastly, the Rules contain a minimum list of services for which fees must be displayed in a clinical establishment.<sup>78</sup>

Additional acts relevant to medical procedures in India include the Transplantation of Human Organs Act,<sup>79</sup> which contains a chapter titled “Regulation of Hospitals.” This chapter outlines the regulation of hospitals conducting the removal, storage or transplantation of human organs.<sup>80</sup>

### 3. The Joint Commission International

Similar to the Joint Commission on Accreditation of Hospitals in the United States, Indian hospitals seek accreditation from the Joint Commission International (“JCI”),<sup>81</sup> a subsidiary of the Joint Commission in the United States.<sup>82</sup> According to the international website for JCI, benefits of JCI accreditation and certification include improved trust as an organization that values quality and patient safety, a culture open to learning from adverse events and safety concerns, a safe and efficient work environment that contributes to staff satisfaction, and leadership that strives for excellence in quality and patient safety.<sup>83</sup> Accreditation generally signals that a facility meets minimum standards of competence and quality.<sup>84</sup>

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<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> See The Transplantation of Human Organs Act, 1994, MINISTRY OF LAW, JUSTICE AND COMPANY AFFAIRS (July 11, 1994), available at [http://www.medindia.net/indian\\_health\\_act/the-transplantation-of-human-organs-act-1994-preliminary\\_print.htm](http://www.medindia.net/indian_health_act/the-transplantation-of-human-organs-act-1994-preliminary_print.htm).

<sup>80</sup> *Id.*

<sup>81</sup> See *JCI Accredited Organizations*, THE JOINT COMMISSION INTERNATIONAL (2013), available at <http://www.jointcommissioninternational.org/JCI-Accredited-Organizations/>.

<sup>82</sup> See *Accreditation and Certification Process*, THE JOINT COMMISSION INTERNATIONAL (2013), available at [www.jointcommissioninternational.org/common/pdfs/jcia/QuestionsandAnswersCL.pdf](http://www.jointcommissioninternational.org/common/pdfs/jcia/QuestionsandAnswersCL.pdf).

<sup>83</sup> *Id.*

<sup>84</sup> See Nathan Cortez, *Patients Without Borders: The Emerging Global Market for Patients and the Evolution of Modern Health Care*, 83 IND. L.J. 71, 84 (2008).

*C. Comparison of the Medical Regulations and Medical Negligence in the United States and India*

1. Comparison of Medical Safety Regulations

When comparing the medical regulations of the United States versus India, there is evidence that the United States relies on regulations to a higher degree than India.<sup>85</sup> The safety of

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<sup>85</sup> See Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Health, Human Rights Council, U.N. Doc. A/HRC/14/20/Add2 (April 15, 2010) (by Paul Hunt). Hunt describes India's private-sector of healthcare as unregulated. Hunt commends that India's health workforce is in crisis because of lack of regulation; the author states:

Despite (or because of) its enormous power, India's private health sector is largely unregulated. Moreover, there are few signs that it is willing to adequately regulate itself. In these circumstances, the Government has a legally binding responsibility to introduce, as a matter of urgency, an appropriate, effective regulatory framework for the private health sector, including public-private partnerships.

See also *India: Country Specific Information*, U.S. DEPARTMENT OF STATE, [http://travel.state.gov/travel/cis\\_pa\\_tw/cis/cis\\_1139.html](http://travel.state.gov/travel/cis_pa_tw/cis/cis_1139.html) ("Medical tourism is a rapidly growing industry. Companies offering vacation packages bundled with medical consultations and financing options provide direct-to-consumer advertising over the internet. Such medical packages often claim to provide high quality care, but the quality of health care in India is highly variable. People seeking health care in India should understand that medical systems operate differently from those in the United States and are not subject to the same rules and regulations."); Nicolas P. Terry, *The Politics of Health Law: Under-Regulated Health Care Phenomena in a Flat World: Medical Tourism and Outsourcing*, 29 W. NEW ENG. L. REV. 421, 454-55 (2007). Terry discusses the quality of medical care and inspection in India:

The difference, however, is in the level of inspection and scrutiny. For example, serious questions have been raised about the adequacy of the medical infrastructure in India to support quality trials, the training of Indian researchers, the quantity and quality of Indian IRBs, and the local ethical standards (including informed-consent deficiencies) applied in dealing with subjects. In a 2001 report, which was triggered by *The Body Hunters* and confirmed the dramatic increase in the number of offshore clinical trials, the U.S. Department of Health and Human Services' Office of Inspector General (OIG) found key differences in the scrutiny of offshore trials. Specifically, the OIG noted deficiencies in the FDA's tracking of non-IND trials, the absence of FDA inspection of foreign IRBs, the lack of any "attestation" requirement for non-IND investigators and a failure to enforce attestation for foreign-based INDs, and generalized staffing, political, and logistical deficiencies that challenged rigorous FDA inspection of foreign

Indian hospitals is heavily determined by accreditation<sup>86</sup> as opposed to regulation. While the United States also relies on the Joint Commission for accreditation of hospitals, the extensive government regulations in the United States provide a backbone for the shortcomings of accreditation.<sup>87</sup> Government standards of medical safety provide extensive details for physician and facility requirements, whereas accreditation services provide an umbrella

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research sites.

<sup>86</sup> See *Accreditation*, SHIVA MEDICAL DIAGNOSTICS, <http://www.shivamdiagnostics.com/accreditation.html> (n.d.) (“In India health care delivery system has remained largely fragmented and uncontrolled. The focus of accreditation is on continuous improvement in the organizational and clinical performance of health services, not just the achievement of a certificate or award or merely assuring compliance with minimum acceptable standards.”); *but see* Cortez, *supra* note 84 (“Hospitals around the world are seeking JCI accreditation, which may help them apply for coverage from U.S. insurers. Thus, patients that leave the United States for medical care increasingly find hospitals that meet U.S. standard.”). Cortez assumes that because many medical tourist locations rely on an accreditation system approved by the United States, those accredited medical facilities maintain a standard of excellence. However, Cortez later contradicts his argument when stating: “accreditation generally signals that a facility meets minimum standards of competence and quality.” *Id.* While the JCI accreditation system approves those hospitals that meet “minimal” safety standards, Cortez asserts that JCI accreditation is substantial evidence to deem a foreign hospital safe for a major surgical procedure. Cortez fails to address those circumstances of a hospital that deem the facility “minimally safe” instead of “extremely safe.” The accreditation system’s standards can be ambiguous, and relying on these standards may lead to a misconstrued representation of the safety of hospitals in both the United States and India. See also Meryl Davids Landau, *A Guide to Getting Good Care*, 147 U.S. NEWS & WORLD REPORT 47 (2010), available at <http://health.usnews.com/health-news/best-hospitals/articles/2010/07/14/what-hospital-certifications-say—and-dont-say> (“Still, minimal is often a far cry from excellent, cautions Charles Kilo, chief medical officer at the Oregon Health and Science University and an expert on healthcare improvement. Critics also charge that to ensure enough hospitals will qualify, certifying groups typically set the bar so that the process weeds out awful institutions but does not truly signify top quality.”).

<sup>87</sup> See Angeleque Parsiyar, *Medical Tourism: The Commodification of Health Care in Latin America*, 15 LAW & BUS. REV. AM. 379, 393 (2009) (“Further, governmental safeguards ensuring quality of care are generally lacking, with the closest thing being accreditation by the JCI, which causes many people to question the quality of care received abroad. 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.”).

structure of guidelines for safety.<sup>88</sup>

For example, according to the U.S. Department of State's travel website, the Joint Commission International is a body whose mission is to "continuously improve the safety and quality of health care in the United States and in the international community through the provision of education, publications, consultation, and evaluation services" that "attempts to continuously improve the safety and quality of care in the international community through the provision of education and consultation services and international accreditation."<sup>89</sup> An "attempt" to improve safety and quality is not ideal for consumers, and while attempting to improve the safety and quality of the international community is commendable, it is not reliable. Furthermore, the Joint Commission encourages the "American Model" or "self-governing" of medical staffs.<sup>90</sup> The Joint Commission's philosophy of self-governance and autonomy result in the Commission's "guiding" of behavior, instead of "governing" behavior.

This analysis of the weaknesses in accreditation suggests that there is an important role to be played by U.S. regulation in the protection of consumers—regulation that is absent in India. In other words, while it is true that both the United States and India engage in the promotion of accreditation, the United States government has a backdrop of regulations to address any potential health hazards that seep past accreditation processes. On the other hand, India's complete reliance on their system of accreditation exposes consumers to health and safety risks that could otherwise be avoided under the presence of stricter regulation.<sup>91</sup>

In addition to the contrast in size of regulation between the United States and India, there are also significant differences in the content of government regulations between the two countries. For example, when comparing the United States Code of Medical Ethics with the Medical Council of India (Professional, Etiquette, and Ethical) Regulations, 2010, although both Codes seek to regulate the ethical conduct of physicians, the

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<sup>88</sup> Peters & Nagele, *supra* note 58.

<sup>89</sup> See *Our Mission*, JOINT COMMISSION RESOURCES, available at <http://www.jcrinc.com/Our-Mission/> (last viewed Apr. 8, 2013).

<sup>90</sup> Peters & Nagele, *supra* note 58, at 315.

<sup>91</sup> See *supra* notes 38-49 (providing a detailed outline of U.S. medical safety regulations regarding patient rights and surgical procedures).

constituent elements are dissimilar.

The United States Code of Medical Ethics contains regulations of physician conduct, clinical standards, medical procedures, and patient-doctor relationships. The regulations for these areas of patient care are extensive, and are as follows: Organ Transplantation Guidelines, Nonscientific Practitioners, Nurses, Allied Health Professionals, Compulsory, Economic Incentives and Levels of Care, Organized Medical Staff, Confidentiality, Privacy in the Context of Health Care, Ethical Guidelines for Physicians in Administrative or Other Non-clinical Roles, Conflicts of Interest: Guidelines, Ethical Implications of Surgical Co-Management, Financial Incentives and the Practice of Medicine, Prescribing and Dispensing Drugs and Devices, Informed Consent, Neglect of Patient, Patient Information, Ethical Responsibility to Study and Prevent Error and Harm, Substitution of Surgeon without Patient's Knowledge or Consent, Invalid Medical Treatment, Free Choice, Quality, and Fundamental Elements of Patient-Physician Relationship.<sup>92</sup>

More than double the number of regulations listed above are included in the U.S. Code of Medical Ethics in total. However, the sections mentioned above are those that are most pertinent to patient rights and patient protection.<sup>93</sup>

In contrast, the Medical Council of India (Professional, Etiquette, and Ethical) Regulations, contains regulations for the character of the physician, maintenance of good medical practices, maintenance of medical records, display of registration numbers, use of generic names of drugs, the highest quality assurance in patient care, exposure of unethical conduct, payment of professional services, and evasion of legal restrictions;<sup>94</sup> regulations for obligations to the sick, patience, delicacy and secrecy, prognosis, neglect of the patient, and engagement for an obstetric case;<sup>95</sup> regulations of consultation for the patient's benefit, punctuality in consultation, statements to patient after consultation, treatment after consultation, patients referred to specialists, and fees;<sup>96</sup> regulations of conduct in consultation, appointments of substitute, and visiting another physician's

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<sup>92</sup> CODE OF MEDICAL ETHICS, *supra* note 20.

<sup>93</sup> MEDICAL COUNCIL OF INDIA, *supra* note 61.

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

case;<sup>97</sup> and regulations of public and community health, and pharmacists and nurses.<sup>98</sup>

The major difference between the two ethical codes is the degree of explanation and detail contained in the regulations. Where India's code of ethics contains 103 regulations regarding physician conduct, the United States contains 216 regulations.<sup>99</sup> The point of comparing the length of the ethical codes is not to claim that a longer ethical code is more reliable than a shorter ethical code; in fact, a shorter ethical code could signal more concise language. Unfortunately, clarity is not the reason India's code of medical ethics is shorter than the United States code of medical ethics.

India's code uses ambiguous language. Regulations such as "character of the physician," "good medical practice," and "patience, delicacy, and secrecy," are all feel-good phrases that lack explanation.<sup>100</sup> For example, Regulation 1.1.2 of the Indian Code states, "[h]e shall keep himself pure in character and be diligent in caring for the sick; he should be modest, sober, patient, prompt in discharging his duty without anxiety; conducting himself with propriety in his profession and in all the actions of his life."<sup>101</sup> The Code does not attempt to define words such as "modest," "patient," or "propriety." The ambiguous phrases in this particular regulation create opportunities for multiple interpretations by the reader regarding the meaning of the appropriate behavior of the physician.

In contrast, the United States Code of Medical Ethics, section 8.021 states:

Adherence to professional medical standards includes:  
(1) Placing the interests of patients above other considerations, such as personal interests (e.g., financial incentives) or employer business interests (e.g., profit). This entails applying the plan parameters to each patient equally and engaging in neither discrimination nor favoritism. (2) Using fair and just criteria when making care-related determinations. This entails contributing professional expertise to help craft plan

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<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

guidelines that ensure fair and equal consideration of all plan enrollees. In addition, medical directors should review plan policies and guidelines to ensure that decision-making mechanisms are objective, flexible, and consistent, and apply only ethically appropriate criteria, such as those identified by the Council in Opinion 2.03, 'Allocation of Limited Medical Resources.' (3) Working towards achieving access to adequate medical services. This entails encouraging employers to provide services that would be considered part of an adequate level of health care, as articulated in Opinion 2.095, 'The Provision of Adequate Health Care.'<sup>102</sup>

While the United States Code of Medical Ethics contains double the regulations of the Medical Council of India (Professional, Etiquette, and Ethical) Regulations, the U.S. Code, more importantly, contains more explanations of the implied meanings of standards of care for patients.

## 2. Comparison of Legal Recourse for Medical Negligence against Consumers

When patients travel to foreign destinations that do not have extensive medical regulations or medical regulations that contrast with the patient's country of citizenship, it is difficult for the patient to receive the same protection by courts for medical negligence or lack of physician care.<sup>103</sup>

The systems of litigation for medical negligence differ vastly between the United States and India.<sup>104</sup> This is in part because India's definition of medical negligence differs from that of the United States. In the United States, medical negligence is defined as a violation of the duty of care owed to a patient by a

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<sup>102</sup> CODE OF MEDICAL ETHICS, *supra* note 20.

<sup>103</sup> See Kerrie S. Howze, *Medical Tourism: Symptom or Cure?* 41 GA. L. REV. 1013, 1029 (2007).

<sup>104</sup> *Id.* at 1030 ("Medical tourism company IndUSHealth informs patients that 'in instances where medical mistakes or malpractice is believed to have occurred, patients have the right to seek redress in the Indian court system similar to the procedure followed here in the U.S.' While the Indian court system may be similar to the U.S. system, the redress for medical negligence could not be more dissimilar. In the United States, damage awards for medical negligence can be in the millions, whereas in India, medical negligence claims are rare and multimillion dollar awards are nonexistent.").

physician.<sup>105</sup> Because the United States has extensive regulation regarding the definition of “duty of care,” medical negligence cases in the United States are frequent.<sup>106</sup> In India, to establish liability on the basis of medical negligence, it must be shown “1) that there is a usual and normal practice; 2) that the defendant has not adopted it; and 3) that the course in fact adopted is one no professional man of ordinary skill would have taken had he been acting with ordinary care.”<sup>107</sup> Because of the ambiguity of Indian medical regulations, which exist to define the “standard of care” required by physicians, it is difficult to seek legal assistance as a medical tourist if an injury were to occur.<sup>108</sup>

In addition to differences in medical terminology and medical regulations between the United States and India, there are also cultural differences<sup>109</sup> that influence the ability of

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<sup>105</sup> *Seimetz, supra* note 54.

<sup>106</sup> See Kenneth C. Chessick & Matthew D. Robinson, *Medical Negligence Litigation is Not the Problem*, 26 N. ILL. U. L. REV. 563, 565 (2006) (discussing the prevalence of medical negligence litigation and the controversies surrounding the rise in medical negligence litigation).

<sup>107</sup> See MEDICAL COUNCIL OF INDIA, *supra* note 61.

<sup>108</sup> See Williams, *supra* note 59, at 646-47 (“Furthermore, malpractice law in other nations is not as protective of patients, or even as clearly defined, as U.S. medical malpractice law. Foreign jurisdictions may be reluctant to recognize even valid malpractice claims by foreign patients against domestic providers because doing so would create unfavorable precedent encouraging similar suits and potentially harm their medical tourism industry.”).

<sup>109</sup> There are several cultural differences between the United States and medical tourist hotspots regarding the practice of medicine. See, e.g., Barrett P. Brenton & Helen E. Sheehan, *The Annals of the American Academy of Political and Social Science: Preface*, 583 ANNALS AM. ACAD. POL. & SOC. SCI. 6 (2002). Brenton and Sheehan describe the practice of medicine among cultures other than that outside that of the United States. In Eastern cultures, such as Asia and India, medicine often falls into the category of indigenous, or “folk medicine.” In India specifically, “some cases, such as Unani medicine and homeopathy, long history and interaction with other medical systems, such as Ayurveda in India, have led to their being considered indigenous Indian medical systems.” Still today in India, a large hotspot for medical tourists from the United States, a chief contributory factor for “hospitals of excellence” is that of “total well being.” See Incredible India, *supra* note 2, at 20. The brochure reads:

In Ayurvedic teaching, three vital forces govern the body, and combine to create an individual’s physiological make-up: vata, linked to the wind, governs movement and relates to the nervous system; pitta, the force of the sun, rules digestion and metabolism; and kapha, likened to the moon, governs the body’s organs. . . . In contrast to the Western approach to medicine, Ayurveda works to

patients to seek legal recourses for medical negligence. Medical negligence cases rely on the court's understanding of medical terminology such as "normal practice" and "standard of care," which in turn rely on the pervasive customs and ideologies of a country.<sup>110</sup>

#### *D. The Consequential Need for Consumer Protection*

The brief comparison above sheds light on international inconsistencies regarding medical safety regulations and the ability of patients to seek legal recourses for medical negligence. But this note is not commending the need for stricter regulatory standards in the country of India; such a claim would be insensitive and intolerant to the cultural, political, and historical ideologies and value preferences of India that have shaped the current regulatory environment. Instead, this note argues that there is an imperative need for consumer protection in the United States. More specifically, this note asserts that the duty of medical tourism businesses in the United States is to inform consumers about regulatory pitfalls in the country where a consumer plans on seeking medical care. This duty of an informed consent decision is essential to providing consumers with as much safety information as possible *before* the consumer makes a medical purchase. Without all-encompassing information regarding medical hazards abroad, consumers may make a medical purchase that is not consistent with the best interest of their own health.

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remove the cause of illness, not just treat the disease, by suggesting lifestyle and nutritional guidelines to reduce the excessive dosha. Though Ayurveda is found across the country, its heart lays deep in the south, in Kerala, where there's plenty of choice, whatever your needs. So close your eyes, and cast your mind east. The spirit of India lives on.

*See also* Gluck, *supra* note 8, at 471. Gluck highlights the stigma surrounding Ayurvedic medicine in the United States due to lack of standardization: "The lack of standardization of Ayurvedic treatments is a major reason why Ayurvedic doctors cannot practice medicine in the United States. Thus, patients have the unique opportunity to pursue this combination therapy in India, where such limitations on the practice of medicine by Ayurvedic doctors do not exist."

<sup>110</sup> Brenton & Sheehan, *supra* note 109.

### III. REGULATION OF MEDICAL TOURISM BUSINESSES IN THE UNITED STATES

With any business, there is a natural temptation to deceive buyers into purchasing those products that maximize profits. This deceit is possible when the relationship between the buyer and seller is unequal, and the seller has more knowledge about a given product than the consumer.<sup>111</sup> Unless the flow of information is abundant, accurate, and readily accessible, then consumers may be on the receiving end of seller deceit.

The business of medical tourism is not immune to this temptation to deceive. When medical tourism facilities in the United States<sup>112</sup> connect consumers with doctors and facilities abroad,<sup>113</sup> the seller of medical tourism has more knowledge than the consumer regarding the safety regulations, licensing, and legal elements of a foreign medical procedure. Because sellers of medical tourism in the U.S. have more knowledge than consumers, there is a natural temptation to deceive, and thus, gain the most profit. Medical tourism intermediaries in the United States have succumbed to this business temptation, leaving consumers in the dark.

Unfortunately, consumers do not always have the necessary knowledge or training<sup>114</sup> to recognize seller deceit. The

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<sup>111</sup> See Gerard J. Tellis & Birger Wernerfelt, *Competitive Price and Quality under Asymmetric Information*, 6 *MARKETING SCI.* 240 (Summer 1987) (discussing the potential negative effects on consumers that result from purchasing transactions that take place under the existence of asymmetrical information. When consumers lack important information about the quality and input costs of a product, sellers have an advantage in this business relationship in that they can charge inflated prices for low quality products without the consumer's knowing).

<sup>112</sup> See *MEDRETREAT*, *supra* note 12.

<sup>113</sup> See Glenn Cohen, *Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument*, 95 *IOWA L. REV.* 1467, 1484 (2010).

<sup>114</sup> Specifically, patients do not have the training to recognize medical deceit. See *id.* at 1494. ("Patients often cannot assess the quality of care they receive, either before or after it is delivered. In theory, patients can attempt to correct their information deficiencies by acquiring the necessary information. Doing so may be very costly, however. It is costly to collect raw data and to create and disseminate meaningful quality measures. It is also costly to use quality measures: patients must take the time to read through them and assess their relevance to their decision-making. Problems of bounded rationality may prevent patients from using data appropriately. If the perceived costs of obtaining and using data exceed the perceived benefits from doing so,

consumer's inability to protect himself from seller deceit stems from irrational decision-making tendencies, such as cognitive heuristics.<sup>115</sup> Because consumers cannot protect themselves from seller deceit, it becomes the responsibility of the government, the regulatory body in charge of protecting this country's citizens, to protect consumers. The United States government has the power to protect consumers from seller deceit by regulating the natural effects of business motivation in those markets where there is unbalanced decision-making power. This business regulation is termed consumer protection law.<sup>116</sup>

Consumer protection law is essential to establishing a balanced decision-making power. To establish a balanced business transaction, consumer protection law mandates that businesses provide consumers with information regarding any aspect of the product that is essential to the consumer's ability to make an informed decision.<sup>117</sup> Specifically, the federal government created the Federal Trade Commission ("FTC")<sup>118</sup> under the Federal Trade Commission Act ("FTCA")<sup>119</sup> to regulate unfair trade and product advertising.<sup>120</sup> The FTCA states that businesses in the United States that practice "unfair methods of competition in or affecting commerce, and unfair or deceptive acts in or affecting commerce, are hereby declared unlawful."<sup>121</sup>

#### *A. Deceptive Advertising According to the Federal Trade Commission*

As mentioned previously in this note, medical tourism businesses in the U.S. do not inform consumers about regulatory pitfalls or lack of legal recourse for medical negligence in foreign destinations. To determine if the omission of this information is deceptive, one must look at the legal criteria for establishing deceptive advertising. According to the FTC, the three elements necessary to establish deceptive advertising are as follows: "(1)

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individual patients will likely decline to seek out this information.")

<sup>115</sup> Lee, *supra* note 1.

<sup>116</sup> See *Legal Resources-Statutes Relating to Consumer Protection Mission*, FEDERAL TRADE COMMISSION, <http://www.ftc.gov/ogc/stat3.shtm> (last visited April 20, 2013).

<sup>117</sup> *Id.*

<sup>118</sup> Federal Trade Commission Act, 15 U.S.C. §§ 45-58 (2011).

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

there was a representation; (2) the representation was likely to mislead customers acting reasonably under the circumstances; and (3) the representation was material.”<sup>122</sup>

First, it is clear that medical tourism businesses create a “representation.” This representation models medical tourism as safe and reliable for consumers.<sup>123</sup> Second, consumer trust in American medical tourism businesses is “reasonable” when medical tourism businesses represent themselves as trustworthy. For example, one of the most popular medical tourism intermediaries, *MedRetreat*, states the following on its website: “America’s most trusted Medical Tourism company: facilitating Medical Travel programs for North Americans seeking affordable surgery abroad.”<sup>124</sup> The website makes additional claims, such as, “*MedRetreat* is America’s most trusted provider of medical tourism services to savvy North Americans seeking safe, highly effective, personalized programs to receive world-class surgery abroad.”<sup>125</sup> Last, this representation is material because it establishes consumer trust, thus having the power to persuade consumers to purchase a medical procedure abroad.

The representation cited above omits vital information. Nowhere in the business’s representation of medical procedures abroad is there mention of lack of safety regulation or lack of legal recourse for medical negligence. These regulatory and legal elements are vital information because they may contribute to a consumer’s trust in foreign doctors and facilities as well as a consequential purchasing of a medical procedure abroad. According to the FTC, it is deceptive to fail to disclose different types of product information to consumers.<sup>126</sup> Based on the criteria of the FTC, the lack of informed consent to consumers regarding regulatory pitfalls and lack of legal recourse abroad is probably deceptive.

### *B. Applying the Central Hudson Test*

Before the government can regulate the advertising of a business, the courts must determine whether or not it is

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<sup>122</sup> Robert Sprague & Mary Ellen Wells, *Regulating Online Buzz Marketing: Untangling a Web of Deceit*, 47 AM. BUS. L.J. 415, 425-26 (2010).

<sup>123</sup> See MEDRETREAT, *supra* note 12.

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

<sup>126</sup> Sprague & Wells, *supra* note 122, at 427.

constitutional to regulate a business's commercial speech.<sup>127</sup> One way to determine the constitutionality of regulating commercial speech is the *Central Hudson* test, established by the Supreme Court in *Central Hudson Gas & Electric Corp. v. Public Service Comm'n.*

The *Central Hudson* test has four prongs: 1) whether the expression is protected by the First Amendment to the extent that it concerns lawful activity and is not misleading; 2) whether the asserted governmental interest to be served by the restriction is substantial; 3) if both (1) and (2) yield positive answers, whether the restriction directly advances the governmental interest asserted; and 4) whether the restriction is no more extensive than necessary to serve such an interest.<sup>128</sup>

According to the *Central Hudson* test, commercial speech that is unlawful or misleading cannot pass the first test, and thus, should not be protected by the First Amendment. As established in the previous section of this paper, the "lawfulness" of medical tourism businesses in the United States is questionable. After assessing the legal regulations enforced by the Federal Trade Commission Act, this paper argues that the FTC has grounds to deem medical tourism intermediaries in the U.S. deceptive, and thus unlawful. Such unlawful commercial speech would prevent the deceptive advertising of a business from passing the first prong of the *Central Hudson* test, deeming government regulation constitutional.

### C. What the Tobacco Industry Can Teach Us About Advertising

*"Medical Tourism: just what the doctor ordered."* – Dr. Christine Lee on Medical Tourism<sup>129</sup>

*"Just what the doctor ordered."* – L&M Cigarette Company<sup>130</sup>

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<sup>127</sup> See *Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n* case, 447 U.S. 557, 565 (1980). *Central Hudson* established the *Central Hudson* test, a four-prong criteria which determines the constitutionality of government regulation on commercial speech.

<sup>128</sup> *Id.*

<sup>129</sup> Lee, *supra* note 1.

<sup>130</sup> Cigarette ad slogans and advertisements were compiled by Robert N. Proctor, Laurie M. Jackler, and Rachel Jackler. See *Stanford Research into the Impact of Tobacco Advertising*, STANFORD SCHOOL OF MEDICINE, LANE

“*More doctors smoke Camels than any other cigarette.*”  
– Camel Cigarette Company<sup>131</sup>

Thinking about the U.S.’s regulation of advertisements of other products and services can provide us with insight into whether the regulation of medical tourism is consistent with contemporary legal norms regarding advertising and consumer protection.<sup>132</sup> Perhaps the most important consumer protection law issue in the past century is the regulation of advertising in the tobacco industry.<sup>133</sup>

In the 1960’s, public health scientists began to learn more about the addictive and detrimental effects of cigarette use on an individual’s health.<sup>134</sup> New research also revealed the deceptive nature of cigarette advertising.<sup>135</sup> The U.S. Chief of the Special

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LIBRARY, [http://tobacco.stanford.edu/tobacco\\_main/index.php](http://tobacco.stanford.edu/tobacco_main/index.php) (last visited Apr. 8, 2013).

<sup>131</sup> *Id.*

<sup>132</sup> See Nim Razook, *Obeying Common Law*, 46 AM. BUS. L.J. 55, 88 (2009). Razook notes that changes in the development and applications of laws are in large part a function of changing social norms. Razook calls the tendency of courts to refer to contemporary norms and institutions when ruling on the validity of a law as “environmental scanning:”

In general, those who would tend to bifurcate legal and moral reasoning or view law simply as a product of moral sentiments could gain a good deal by scanning the literature on and cases of common law making. It is, after all, the organic process of listening to arguments, judicial reflection, environmental scanning, decision making, more reflection and scanning, and more decision making that both borrows from and creates moral standards.

<sup>133</sup> See generally ALLAN BRANDT, *THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA* (2007).

<sup>134</sup> See Mark Parascandola, *Tobacco Harm Reduction and the Evolution of Nicotine Dependence*, 101 AM. J. PUB. HEALTH 632, 634 (2011). During 1960’s, publicly funded studies primarily focused on the addictive nature of nicotine. For a more extensive look at the negative effects of smoking, see also C. Divyalakshi & Mahjabeen, *Attitude And Awareness On The Ill-effects of Tobacco Consumption Among Adolescents-an Intervention Programme*, GOLDEN RES. THOUGHTS, July 2012, at 1-4 (“As daily intake of nicotine increases, people become physically dependent on it and experience withdrawal symptoms. Tobacco use becomes necessary to relieve the effects of nicotine withdrawal, symptoms of which include: restlessness, anxiety, irritability, hunger and lack of concentration and loss of energy.”).

<sup>135</sup> The Lucky Strikes® cigarette company is probably as guilty as any other cigarette company could be in terms of deceptive advertising. One of their ads told consumers: “11,105 doctors say Lucky Strikes prevent throat

Action Office for Drug Abuse Prevention, Jerome Jaffes, known as the “Drug Czar” for having promoted methadone treatment for heroin addicts, commented at the 1975 World Health Conference on Smoking and Health: “The major difference between tobacco dependence and other drug addictions is tobacco’s social acceptability.”<sup>136</sup>

Realizing that cigarettes had similar effects in terms of dependency and addiction to other illegal drugs, Congress decided to impose stricter regulations on the advertising of cigarettes.<sup>137</sup> For example, through the Federal Cigarette Labeling and Advertising Act of 1965,<sup>138</sup> Congress made it mandatory for cigarette packages to contain health warnings. In 1970, the Federal Trade Commission formed an agreement with the cigarette industries’ major producers to disclose information regarding “tar” and nicotine content in cigarettes,<sup>139</sup> and later in 1971, television and radio advertisements of cigarettes were banned.<sup>140</sup> Shortly thereafter, the law’s conception of what constituted fair advertising by cigarette companies had transformed to include more transparent warnings,<sup>141</sup> allowing consumers to presumably make more informed choices in their

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irritation.” See *Stanford Research into the Impact of Tobacco Advertising*, *supra* note 130.

<sup>136</sup> See Parascandola, *supra* note 134, at 636. To Access Jaffes’ quote, Parascandola provides the following source: Jerome Jaffe, “Cigarette Smoking as an Addiction,” in *Smoking and Health II: Health Consequences, Education, Cessation Activities, and Governmental Action*, p.627, DHEW publication no. 77-1413 (1977).

<sup>137</sup> For a list of countries that have adopted smoke-free laws, see *World Health Organization Report on the Global Tobacco Epidemic, 2009: Implementing smoke-free environments*, available at The World Health Organization, <http://www.who.int/tobacco/mpower/2009/en/index.html>.

<sup>138</sup> Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 4, 79 Stat. 282-83 (1965).

<sup>139</sup> See Addison Yeaman, *Letter to the Federal Trade Commission*, Oct. 23, 1970, available at <http://legacy.library.ucsf.edu/tid/dvy28e00>.

<sup>140</sup> See Scott Olstad & Randy James, *A Brief History Of: Cigarette Advertising*, *TIME*, June 15, 2009, at 14.

<sup>141</sup> Tobacco Master Settlement Agreement (“MSA”), 1998. The companies of Philip Morris, R.J. Reynolds Tobacco Company, Brown & Williamson Tobacco Corp. and Lorillard Tobacco Company entered into an agreement, along with 46 states, to restrict cigarette advertising practices. One of the more significant aspects of the agreement was a focus on regulating youth-targeted advertising. For example, the parties to this agreement agreed to prevent the use of cigarettes in cartoons.

purchasing of tobacco products.<sup>142</sup>

To this day, legal reform continues against the tobacco industry in an ongoing effort to subdue the leading cause of preventable deaths in the U.S.; cigarettes. For example, in 2009, President Obama signed a bill allowing the Food and Drug Administration (“FDA”) regulation power over tobacco products.<sup>143</sup> Now, it is even illegal in many places for tobacco companies to advertise outdoors,<sup>144</sup> and regulations have been implemented that require cigarette print advertising in stores and publications to appear only in black and white text.<sup>145</sup>

But what does this discussion about the regulation of cigarettes have to do with medical tourism? Similar to cigarette companies that historically advertised that cigarettes were potentially good for our health, and even recommended by doctors, medical tourism businesses in the United States advertise in ways that emphasize the positive benefits of medical tourism while concealing the negative risks (see the three quotations at the beginning of this section). This lack of crucial information puts the consumer at risk in the marketplace for medical tourism. In other words, consumers of medical tourism often have little to no idea regarding about the potential hazards of engaging in the medical tourism that U.S. businesses advertise. The consequent possibility that consumers might be prevented from seeking legal

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<sup>142</sup> *Contra*, in response to regulations of nicotine levels in cigarettes by the Federal Trade Commission, cigarette companies found ways to surpass regulations by manipulating nicotine delivery in ways that would not be detected by the standardized tests that the FTC conducted on cigarettes. See Terrell Stevenson & Robert N. Proctor, *The secret and soul of Marlboro: Phillip Morris and the origins, spread, and denial of nicotine freebasing*, 98 AM. J. PUB. HEALTH 1184 (2008); see also Richard D. Hurt & Channing R. Robertson, *Prying open the door to the tobacco industry's secrets about nicotine: the Minnesota Tobacco Trial*, 280 JAMA 1173 (1998).

<sup>143</sup> *Obama signs bill putting tobacco products under FDA oversight*, CNN (June 22, 2009), <http://www.cnn.com/2009/POLITICS/06/22/obama.tobacco/>; see also Parascandola, *supra* note 134, at 632 (“[T]he Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111–131) granted the U.S. Food and Drug Administration authority to regulate tobacco products, including establishing product standards for harmful constituents and nicotine content, with the aim of protecting public health.”).

<sup>144</sup> David L. Hudson, Jr., *Tobacco Ads, Advertising and First Amendment*, FIRST AMENDMENT CENTER, Sept. 13, 2002 (updated April, 2012), available at <http://www.firstamendmentcenter.org/tobacco-ads/print/>.

<sup>145</sup> See Debra Cassens Weiss, *Challenge Likely for Law Limiting Tobacco Ads to Black and White Text*, ABA JOURNAL (June 16, 2009).

remedies against acts of medical negligence is discounted by the attractiveness of low prices and the positive light that advertising shines on medical tourism. To help correct consumer oversight of the negative effects of medical tourism that result from deceptive advertising tactics, this note argues that more stringent regulation of U.S. intermediaries is needed.

#### IV. OPPOSITION TO BUSINESS REGULATION: ARGUMENTS OF INDIVIDUALISM AND AUTONOMY

The United States is a country rooted in individualism<sup>146</sup> and freedom of choice.<sup>147</sup> Because these values are pervasive in

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<sup>146</sup> American individualism is rooted in the ideas of atomism and self-determination. For discussion on atomism, see Andrea Giampetro-Meyer et al., *Advancing the Rights of Poor and Working-Class Women in an Individualistic Culture*, 2 LOYOLA POVERTY L.J. 41, 41 (1996) (explaining that a fundamental assumption of atomism is that human beings are “independent disembodied entities.”) The idea of atomism assumes that human beings are separate from the society, and thus, society’s external influences. Because atomistic thought proclaims a disconnect between the individual and societal influences, atomistic thought also assumes that the individual creates their own reality; an atomist assumes that the conditions and circumstances surrounding a human being are caused only by that human being his/herself. Essentially, humans self-determine their realities. The understanding of these assumptions of atomism and self-determination are of the essence to understanding individualism as a dominant ideology in the United States. Although individualism predominates American culture, see Ernest Wallwork, *Ethical Analysis of Research Partnerships with Communities*, 18 KENNEDY INST. ETHICS J. 57, 58 (2008) (defining the individual as “embedded in narrative traditions, institutions, roles, shared goals, and environments (natural and social), without which human beings can neither survive nor flourish morally.”) While the United States bleeds individualism, Wallwork commends that Americans can also have characteristics of collectivism. Wallwork’s ontological assumption about human nature, mentioned above, reflects the fundamental assumption of collectivism. To contradistinguish the root assumptions of individualism and collectivism, it is vital to note that while individualism characterizes the individual as atomistic and responsible for their own reality and state of being, collectivism characterizes the individual as tied to society; the collectivist commends that human beings are products of socialization and external influences.

<sup>147</sup> See ROBERT N. BELLAH, *HABITS OF THE HEART: INDIVIDUALISM AND COMMITMENT IN AMERICAN LIFE* 142 (Univ. of Cal. Press ed., 1985) (“We [Americans] believe in the dignity, indeed the sacredness, of the individual. Anything that would violate our right to think for ourselves, judge for ourselves, make our own decisions, live our lives as we see fit, is not only morally wrong, it is sacrilegious.”).

our systems of law and government, arguments for business regulation in the United States do not stand uncontested. Individualism assumes that human beings are self-sufficient and in control of their own destinies,<sup>148</sup> and thus, government intervention of any kind is distasteful. Essentially, because an individualist believes he has control over his own reality, government regulation is interpreted as a violation of that individual's self-sufficient behavior.

In the United States, market thinking is guided by an individualistic view of human beings.<sup>149</sup> For instance, neoclassical conceptions of the market assume that if a consumer has access to a plethora of information, that consumer will have the ability to sift through information and make a rational, self-informed decision.<sup>150</sup> However, once a market is regulated by the government, a chain reaction inhibits the consumer's ability to make an autonomous uncontrolled purchase. First, businesses lose the freedom to choose how and what to produce. As a consequence, businesses are inhibited and no longer feel autonomous. This loss of autonomy results in a lack of incentives to maximize production and provide a variety of goods and services to consumers.

In other words, assuming consumers value a variety of goods and services, the individualist contends that when businesses lose autonomy, consumer choice also suffers. For example, the reduction of consumer purchasing options, resulting from government regulation, limits the consumer's freedom to make autonomous choices and create their own reality.

In regards to medical tourism, the individualistic argument claims that consumers are self-sufficient and have the ability to make rational decisions.<sup>151</sup> If medical tourism businesses are regulated, consumer information will be diminished. Consequently, decreased consumer information detracts from the consumer's ability to engage in rational discernment and calculate the best medical purchase.

This individualistic opposition to business regulation is not without its weaknesses. The following section of this note will address the flaws of assuming consumers are rational decision

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<sup>148</sup> *Id.*

<sup>149</sup> *See Smoking and Health, supra* note 136.

<sup>150</sup> *Id.*

<sup>151</sup> THE MEDICAL COUNCIL OF INDIA, *supra* note 61.

makers, and thus, that government regulation should not be imposed on medical tourism facilities in the United States.

### A. *The Irrational Consumer*

Contrary to individualistic assumptions about human beings, extensive psychological research provides evidence that consumers are not always “rational”<sup>152</sup> decision makers.

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<sup>152</sup> For a discussion on the inhibiting nature of America’s dependence on consumers to make “rational” decisions, a conversation that is pertinent to the ethicality of medical tourism, see Gil Siegal et al., *An Account of Collective Actions in Public Health*, 99 AM. J. PUB. HEALTH 1583 (2009). Siegal first addresses the popular American reliance on the economic “rational actor theory.” This theory states that individuals act as rational agents:

Economists have advanced the rational actor theory, in which each individual (satirically termed Homo Economicus) is expected to act as a rational agent using available information to maximize his or her own interests—pursuing wealth and well-being, avoiding suffering or unnecessary labor—all in accordance with his or her own predetermined and stable goals and utilities. *Id.*

After detailing the assumptions behind the rational actor theory, Siegal denounces the validity of these assumptions in his discussion of cognitive heuristics. Cognitive heuristics are the habitual cognitive methods individuals tend to use to solve a problem. Siegal commends that these cognitive heuristics inhibit the individual’s ability to think “rationally.” For example, one cognitive heuristic that immeasurably affects consumer decisions regarding medical procedures is the “framing effect;” the framing effect occurs when, “decisions are irrationally influenced by modes of presentation and context—e.g., discussing a 10% chance of failure in a medical procedure is perceived differently from discussing a 90% chance of success in the same procedure.” *Id.* For further elaboration on pervasive human cognitive heuristics, see also Gregory Mitchell, *Mapping Evidence Law*, MICH. ST. L. REV. 1065, 1115 (2003). Mitchell outlines several cognitive heuristics including the conjunction fallacy, outcome bias, confirmation bias and the framing effect; the author reveals the destructive nature of these entities to rational consumer decisions. The economic assumption outlined above, that consumers are rational thinkers who are capable of making decisions free of logical shortcomings, is further epitomized in P. Gretchen Browne’s, *The Conversation Between Economic Man and the Psychological Character: Ontology and Feminist Economics*, *Western Social Science Conference* (1996) (discussing the rational decision-making process of Robinson Crusoe, the “economic man”). Crusoe, a popular literary character invented in the 18<sup>th</sup> century, is believed to be a one-man model of the ideal rational decision-maker; Because Crusoe is stranded on an island, free of any societal influences, the character is portrayed as a being whose decisions are carefully calculated; Crusoe meticulously weighs all potential costs and benefits. Robinson Crusoe embodies the theoretical “economic man” because he is a man of rationality and individualism—he is

Specifically, human beings are victim to cognitive heuristics.<sup>153</sup> A cognitive heuristic is a method for reducing efforts associated with decision-making processes, often termed “mental shortcuts.”<sup>154</sup> Cognitive heuristics provide consumers with cognitive closure,<sup>155</sup> a psychological phenomena which is defined as “the desire for a definite answer on some topic, *any answer* as opposed to confusion and ambiguity.”<sup>156</sup> Cognitive heuristics, or mental shortcuts, lead to illogical reasoning. Because of this tendency for humans to be irrational decision-makers, a given consumer’s decision regarding a doctor or procedure abroad may be ill-reasoned. Although a medical tourist may initially think their choice of doctor and facility is well-researched, reliable, and safe, often times, the medical procedure abroad falls short of success.<sup>157</sup>

For the medical tourist, the process of finding a doctor, medical facility, and place of recovery abroad, is a process that has been made simple and fast with internet advertising.<sup>158</sup> What

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economically ideal because he is free of damaging cognitive heuristics.

<sup>153</sup> See Anuj K. Shah & Daniel M. Oppenheimer, *Heuristics Made Easy: An Effort-Reduction Framework*, 134 PSYCHOL. BULL. 207, 208 (2008).

<sup>154</sup> *Id.* at 207.

<sup>155</sup> See Amir N. Licht, *The Maximands of Corporate Governance: A Theory of Values and Cognitive Style*, 29 DEL. J. CORP. L. 649, 668 (2004).

<sup>156</sup> *Id.* (emphasis added).

<sup>157</sup> See Leigh Turner, *First World Health Care at Third World Prices: Globalization, Bioethics and Medical Tourism*, 2 BIOSOCIETIES 303, 318 (2007) (citing the death of a twenty-three year old woman who suffered mycobacterial infections after receiving cosmetic surgery in the Dominican Republic, as well as “substandard tissue matching in organ transplants that occurred in Pakistan and India”).

<sup>158</sup> See Cortez, *supra* note 84, at 118 (“Most foreign providers and brokers market their services on the Internet, and a sampling of these sites shows they can be aggressive and potentially misleading. Sites include patient testimonials, breezy descriptions of idyllic sightseeing tours, and even quality comparisons that disparage U.S. providers. [One] broker assures patients who may be concerned about medical malpractice that they ‘have the right to seek redress in the Indian court system similar to the procedure followed here in the U.S. [sic],’ a claim that is woefully misleading.”) See also Roy G. Spece, Jr., *Medical Tourism: Protecting Patients from Conflicts of Interest in Broker’s Fees Paid by Foreign Providers*, 6 J. HEALTH & BIOMEDICAL L. 1, 7 (2010) (“The foreign providers advertise through the internet and various print and broadcast media, which allows a patient not to have to use a broker. There are, however, almost two million entries under ‘medical tourism’ in Google and patients often work through medical tourism brokers rather than attempt to find their way directly to a foreign provider.”).

is not so simple for the consumer is the ability to understand the differences in medical regulations and cultural practices, complexities and potential hazards of medical procedures,<sup>159</sup> doctor credentials, and the validity and reliability of medical advertising.<sup>160</sup> In the case of medical tourism, consumers are often

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<sup>159</sup> See Steven J. Katz et al., *From Policy to Patients and Back: Surgical Treatment Decision Making For Patients With Breast Cancer; Information has never been more widely available, and treatment decision making has never been more complicated*, 26 HEALTH AFF. 761, 763 (2007) (explaining the procedural complexities of a single medical diagnosis, such as breast cancer). Katz explains that the severe and rapid nature of breast cancer necessitates a multifaceted attack, “[p]atients are confronted with a life-threatening disease that requires many treatment decisions related to surgery, radiation, chemotherapy, and hormone therapy, with widely ranging effects on themselves and their families. These myriad decisions are often made quickly in consultation with many physicians whom patients are meeting for the first time.” *Id.* at 763.

After elaborating on the complex nature of breast cancer treatment, Katz commends that these medical complexities inhibit the consumer’s ability to fully comprehend the medical terminology:

Wide variations in patients’ ability and willingness to absorb complex clinical information, particularly competing risk information, is a challenge for many physicians. Information has never been more available. At the same time, treatment decision making has never been more complicated. Some patients arrive for their first consultation visit with a family member armed with information from Internet-based sources; others arrive alone with little preparation. *Id.* at 766.

But see Mitchell S. Berger, *A Tale of Six Implants: The Perez v. Wyeth Laboratories Norplant Case and the Applicability of the Learned Intermediary Doctrine to Direct-to-Consumer Drug Promotion*, 55 FOOD & DRUG L.J. 525, 550 (2000) (revealing that some individuals argue that explaining medical nuances to consumers is “unnecessary”). Berger states that “on the other hand defenders of the [case] respond that attempting to render complex medical language into simple terms risks ‘both dilution and unnecessary hysteria’.”

<sup>160</sup> *J.C. Baccus v. State of La.*, 232 U.S. 334 (1914) (displaying an instance where an individual falsely advertised “medical” products to citizens on the street). The plaintiff sought to repeal a past court decision that banned him from the “freedom to peddle medical entities” as his vocation. The plaintiff in this case sought repeal from a court decision from the Third Judicial District Court, Parish of Claiborne, state of Louisiana. The judge in the District Court decision adhered to a state statute that banned the practice of itinerant vending of “any drug, nostrum, ointment or application of any kind intended for the treatment of disease or injury,” to penalize the plaintiff in question. While the plaintiff in the case felt they had the right to freely advertise their “medical” product to community members on the street, the court denied the plaintiff’s request. The Supreme Court decided that the Third Judicial District

persuaded by vacation getaways<sup>161</sup> and low procedural costs, advertised by medical tourism intermediaries in the U.S., instead of doctor credentials and facility reliability and regulation.

The individualistic argument ignores the above evidence of consumer irrationality. Instead, individualists appeal to values of autonomy and self-sufficiency to support the claim that consumers should have the freedom to determine their own destinies, without government imposition or guidance.

### 1. Dangerous Consumer Beliefs about Physicians as Unbiased and Scientific

In addition to the irrational decision-making tendencies of human beings, consumers also have dangerous assumptions about the physicians and medicine: the belief that physicians are unbiased deliverers of medical science.<sup>162</sup> The word “science” has various interpretations;<sup>163</sup> however, the common meaning of the

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Court made an acceptable decision to regulate the marketing of the peddler/ itinerant vendor, as the individual was selling a medical product that belonged to a previous patent/ proprietor: Rawleigh Medical Co. of the State of Illinois. In addition, the Court ruled under the assumption that drugs or medical compounds are within the power of the government to regulate.

<sup>161</sup> For a discussion on the “luxury factor” of medical tourism, see Williams, *supra* note 59, at 623-24.

<sup>162</sup> See Chester N. Mitchell, *Deregulating Mandatory Medical Prescription*, 12 AM. J.L. & MED. 207, 212 (1986) (“The rise of scientific medicine in the late 1800’s is partially responsible for the medical profession’s special success”). See also Olli S. Miettinen, *Evidence-based medicine, case-based medicine; scientific medicine, quasi-scientific medicine. Commentary on Tonelli* (2006), *Integrating evidence into clinical practice: an alternative to evidence-based approaches*, 12 J. EVALUATION CLINICAL PRAC., 248, 260 (2006) (discussing “evidence-based medicine”). Miettinen highlights the Western understanding of “evidence-based medicine” as “empirical evidence derived from clinical research.” In contrast to the standard western assumptions about evidence-based medicine, Miettinen asserts that medical decisions are instead influenced by values, and personal preferences towards a treatment and patient.

<sup>163</sup> See Miettinen, *supra* note 162, at 261. The author commends that in the case of scientific medicine, the phrase “scientific” refers to “a commitment to reasoning that is ‘rigorous and explicit.’” Miettinen then critiques this common interpretation of scientific medicine by stating that scientific medicine is instead based on probability calculations, “[t]he knowledge base of scientific medicine thus is one of known probability functions—in practice ‘known’ to the physician’s computer and evaluated by the physician at the gnostic indicators’ realizations constituting the gnostic profile at hand.” *Id.* at 262.

word “scientific” in the United States is one that is associated with words such as “reliable,” “factual,” and “unbiased.”<sup>164</sup>

If the physicians are perceived as “scientific” by a consumer, and that consumer has assumptions regarding science such as those mentioned above, it is not surprising that the consumer would then rely on the advertising of physicians abroad as factual, and unbiased. This scientific characterization of the physicians can be perilous.

The scientific characterization of physicians as unbiased is perilous because the consumer often forgets that the instrument making an incision, or creating prescription drugs, or administering medical diagnosis, is human; patients forget that the medical field is operated by imperfect human beings.<sup>165</sup> Further, because these doctors are in fact human, they are subsequently prone to the same illogical decision-making tendencies mentioned above. In fact, according to a study in 2007, “the medical community’s failure to routinely apply known scientific principles to patient care translates to a 20 percent incidence of misdiagnosis—a figure that has remained unchanged for seventy years.”<sup>166</sup>

The above evidence, including susceptibility to cognitive heuristics and dangerous beliefs about the reliability of physicians, demonstrates that in fact, consumers are not always capable of recognizing deceptive information and making rational decisions.

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<sup>164</sup> *But see* George A. Taylor et al., *Diagnostic Errors in Pediatric Radiology*, 41 PEDIATRIC RADIOLOGY 327, 332 (2011) (“attempts to be constantly vigilant and eliminate cognitive biases are neither possible nor desirable because many of the mental activities in which we engage are outside of conscious awareness and heuristics used in clinical medicine evolve because they yield better overall outcomes than more careful or rational approaches”).

<sup>165</sup> *See* Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 374 (2002) (quoting George Bernard Shaw, “I presume nobody will question the existence of a widespread popular delusion that every doctor is a man of science. . . . As a matter of fact, the rank and file of doctors are no more scientific than their tailors”). *See also* McLean, *supra* note 2, at 151. (“The origin of misdiagnosis in treatment is sometimes due a physician’s lack of knowledge. More often, however, misdiagnosis can be traced to the financial incentives given to physicians.”).

<sup>166</sup> *See* McLean, *supra* note 2, at 150-52.

#### IV. CONCLUSION

In comparing and contrasting the medical safety regulations of the United States and India, and the ability for medical tourists to seek legal recourse for medical negligence abroad, this note provides evidence that there are significant regulatory and legal pitfalls that make medical tourism a risky purchase for consumers. Medical tourism hotspots, such as India, rely primarily on accreditation as a regulatory system. Regulations outside of the accreditation system in India are limited and ambiguous. In fact, governing bodies such as the Indian Medical Association fight government regulation as an invasion of privacy of medical facilities.<sup>167</sup>

Despite these regulatory and legal risks, consumers are continually informed by U.S. intermediary businesses that medical procedures abroad are safe and reliable. In fact, instead of informing consumers of the regulatory and legal hazards of medical tourism, sellers zone in on vacation features and low-cost procedures. This omission of material information by medical tourism businesses creates consumer deceit, and further, facilitates uninformed consumer decisions. This deceit is unlawful according to consumer protection laws in the United States. Specifically, the Federal Trade Commission Act bans deceptive advertising.

In past U.S. cases of deceptive advertising, the courts have relied on the *Central Hudson* test to determine the constitutionality of regulating the commercial speech of businesses. The *Central Hudson* test contains four prongs that determine the constitutionality of business regulation. When applied to medical tourism businesses in the United States, a hypothetical *Central Hudson* test deems regulation constitutional.

But business regulation in the United States often results in a clash of ideologies. In general, government regulation usually results in a value conflict of individualism versus paternalism, autonomy versus protection. The United States is a country rooted in individualism and autonomy. Today, rising costs of

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<sup>167</sup> K. Vijayakumar, Presidential Address at the 87th Annual National Conference (Dec. 27-28, 2012) available at <http://www.ima-india.org/downloads/Presidential%20Address.pdf>. This Presidential Address was posted in response to the Central Government of India's removal of the Medical Council of India due to fraud and corruption by the President of the Medical Council of India. See also Collier & Pandya, *supra* note 64.

health services in the United States lead the autonomous patient to take high costs of medical procedures into their own hands.

But individualists that argue consumers should have complete autonomy speak with dangerous assumptions about human ontology. For one to claim that consumers should be able to practice autonomy when making medical decisions, one must assume that medical tourists have the ability to make rational medical decisions.

Medical tourists are *human beings*. There is extensive research that human beings are in fact *not* rational decision makers, but instead, are susceptible to cognitive heuristics. In addition to irrational decision-making tendencies, there is also evidence that consumers make medical purchases reliant on dangerous assertions that physicians and the practice of medicine are unbiased and objective. These stereotypes about physicians and the practice of medicine are incorrect. In reality, almost 100,000 patients die each year from medical errors.<sup>168</sup>

The fact that medical tourism consumers are susceptible to irrational decision-making serves as evidence that chips away at the cracks of the individualistic opposition to government regulation. Further, evidence of irrational consumer behavior supports this paper's argument for consumer protection from the deceptive advertising of medical tourism in the United States.

To properly inform consumers about regulatory and legal hazards abroad, and to battle irrational consumer behavior, medical tourism businesses in the U.S. desperately need government regulation. Once government regulation is established, consumers will have access to full information regarding medical tourism: the benefits and the risks, the low costs, and the hazards. With this information, consumers will have the tools to make informed autonomous medical purchases, instead of autonomous medical purchases based on deception.

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<sup>168</sup> See Inst. of Med., *To Err is Human: Building a Safer Health System* 31 (Linda T. Kohn et al. eds., 2000).