Assessing the Risks of China's Medical Tourism from the Legal Perspective

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Abstract: While China's medical tourism industry is increasingly standardized and institutionalized, the relevant research assessing its legal risks is still absent. This paper aims to evaluate the risks of medical tourism from the legal perspective by exploring the conflict between the developing new practice and the existing legal system, summarizing the legal risks in medical tourism, and proposing measures and suggestions to mitigate such risks. The empirical research method is employed to review the legal risks in Boao Lecheng International Medical Tourism Pilot Zone, which is the pioneering project of China's development within the medical tourism industry. These research methods include collecting the latest medical tourism policies and regulations, judicial decisions, and on-the-spot investigation of the Pilot Zone. It is found that the legal risks in medical tourism activities are mainly concentrated in the administrative, civil and litigious legal relations, and concern four major subjects which are regulators, medical operators, tourism operators and consumers. For regulators, their administrative supervision has not been well in place before and during medical tourism activities, and there remain legal gaps in regulation. In terms of the protection of consumers' substantive rights, service providers and operators may evade their responsibilities by exploring the vacuum area during the transition from the old laws to the new ones, and the conflicting provisions exist between the special laws and general ones. Concerning the protection of consumers' litigation rights, there are many obstacles for consumers to safeguard their interests through litigation in a foreign land. In this paper, medical tourism activities are identified among four legal subjects and involving three types of legal risks, in the hope to help improve the overall understanding of medical tourism from the legal perspective, and put forward targeted suggestions on the potential legal risks.

Keywords: medical tourism, legal risk, Boao Lecheng International Medical Tourism Pilot Zone, Free Trade Port

Introduction

Since the 1990s, the travel pattern of medical tourists has changed significantly due to the differences in medical conditions, medical costs and the waiting time among different countries. In the past, consumers from developing countries were used to travel to developed countries, but nowadays we have seen the reverse trend in which more and more consumers from developed countries are traveling to developing countries for medical tourism.¹ As a result, many new medical tourism destinations were created. Although China's medical tourism industry started relatively late it has received strong support from the central government. In February 2013, the State Council approved the establishment of Hainan Boao Lecheng International Medical Tourism Pilot Zone, which carries the important task of exploring and experimenting

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on the development of China's medical tourism industry.² In 2015–2018, China has successively built Jiangsu Changzhou, Jiangxi Shangrao and Shandong Qingdao International Medical Tourism Pilot Zones.³ Compared to the aforementioned ones, the Boao Lecheng Pilot Zone, located on Hainan Island, has a unique advantage as it enjoys abundant natural resources and the specially designed policy, given support from the central government, to build Hainan Island as an international Free Trade Port.⁴ It is a leading representative of the development of China's medical tourism industry.

Generally, medical tourism research in China has been accompanied by the development of the medical tourism industry, which has gradually gone through three stages. In the policy advocacy stage, academic research mainly includes the analysis of the internal causes and external constraints of the development of medical tourism, mainly from the aspects of management and economics, such as the analysis of the medical tourism development experience in Southeast Asian countries^{5–7} and the SWOT analysis of the medical tourism development in China.^{8–10} In the regulations support stage, relevant research started to cover the aspects of national ministries and commissions, the utilization of local legislative power,¹¹ and the simplification and adaptation of administrative management with the aim of analyzing how to create a favorable business environment and promoting the industry development through legal means.^{12,13} In the stage of legal regulation, the conflict between new practices and existing legal norms is becoming increasingly obvious and more representative and professional practical problems are studied. However, in the third stage, studies focus on specific events, and lack overall assessment.¹⁴ In view of this problem, this paper attempts to sort out the potential legal risks involved in medical tourism, improve the overall understanding of such risks and proposes countermeasures.

Key Findings and Discussions

Overview of Medical Tourism Subjects

World Tourism Organization defines medical tourism as “a type of tourism activity that involves the use of evidence-based medical healing resources and services (both invasive and non-invasive)”. Medical services provided usually include diagnosis, treatment, cure, prevention and rehabilitation.¹⁵ Scholars usually consider medical tourism as medical tourists receiving cross-border medical services.¹⁶ Medical tourism activities involve four subjects: regulators, medical service providers, tourism

operators and consumers. The legal risks are analyzed mainly from three aspects: administrative supervision, civil liability and litigation rights protection. Figure 1 shows the medical tourism subjects and their legal relations, which might help improve the overall understanding of the medical tourism activities.

A. Medical Tourism Regulator

In China, they are subordinate to government departments and perform the administrative supervision function of the government. On March 19, 2019, the People's Government of Hainan Province approved the Regulations on the Establishment and Operation of Hainan Boao Lecheng International Medical Tourism Pilot Zone Administration Bureau. The Lecheng Administration Bureau, which is directly under the Hainan provincial government, assumes corresponding administrative and public service responsibilities.¹⁷ By empowering the medical tourism regulators with the government's administrative power, it would be conducive for them to coordinating the various management tasks.

B. Medical Service Provider

At present, nine medical institutions have been set up in the Pilot Zone, including Boao Super Hospital, Boao Evergrande International Hospital, Neology Stem Cell Anti-aging Hospital, etc. The medical institutions in the Pilot Zone enjoy preferential policies, involving new technologies, new devices, new drugs (not in the list of medical technologies permitted by the state for clinical application) and overseas medical capital access.¹⁸ Medical service providers in the Pilot Zone strive to build themselves into world-class medical institutions and medical care teams.

Figure 1 Medical tourism subjects and their legal relations.

C. Tour Service Operator

According to their functions, tourism operators include organizers, intermediaries, and “food, accommodation, transportation, shopping and entertainment” service providers. Organizers and intermediaries are usually travel companies with a cooperative relationship with the Pilot Zone. Medical service providers promote their medical services with the help of tourism operators who have publicity, source of tourists and operational advantages. Organizers directly sign “package tour contracts” with consumers.^{19,20} Intermediaries facilitate the signing of medical service contracts between consumers and medical service providers. “Food, accommodation, transportation, shopping and entertainment” service providers provide catering, accommodation, transportation, sightseeing, shopping, entertainment and other services inside and outside the Pilot Zone. In this paper, tourism operators usually refers to the organizers of tourism activities, which seeks for consistency with the usage in legal norms.

D. Medical Tourist

Medical tourists are the consumers of medical tourism. Their decisions for choosing medical tourism are usually affected by three factors. First, medical conditions. Destination countries often possess advanced medical expertise and facilities,²¹ such as early cancer detection and diagnosis in Japan, anti-aging effect of sheep placenta extract in Switzerland, and cosmetic surgery in South Korea. Second, medical costs. Medical expenses in destination countries are usually significantly lower than those in developed countries. For example, medical costs of medical tourism in Southeast Asia only account for 28–88% of those in developed countries.²² Third, waiting time. Patients often have to face lengthy waiting times in their home country, while in destination countries they are able to receive timely treatment.^{23,24} In addition, medical tourism not only serves foreign consumers, it also welcomes domestic consumers. One of the objectives proposed by the Lecheng Pilot Zone is to achieve “having serious illnesses treated at home” and meet the needs of Chinese people for high-end medical services.

Generally, medical tourism has three types of modes, namely, independent travel, booking tour on behalf of tourists and group tour. In each mode, different legal relations are formed between medical tourists, medical service providers and tourism operators. For independent travel, consumers sign contracts with service providers directly and arrange tourism activities independently.²⁵ In the second mode,

tourism operators perform the intermediary function, which facilitates the consumers signing contracts with medical service providers. In a group tour, tourism operators provide “package services” for consumers, and medical service providers are entrusted by tourism operators to assist in performing contractual obligations.²⁶

Ex-Post Regulation Risks in Medical Tourism Administrative Supervision

Ex-post regulation usually occurs after the consumers’ rights and interests have been infringed, which prevents achieving the regulatory goal of “nipping the problem in the bud”. In March 2019, the Yinfeng Healthcare International Hospital in the Lecheng Pilot Zone conducted illegal vaccinations. That hospital had not obtained the outpatient license for vaccination, and vaccinated consumers with fake HPV vaccines. Subsequently, the Health Commission of Qionghai city issued an administrative penalty of revoking the medical institution license of the Yinfeng Healthcare International Hospital.²⁷ In this event, consumer remedies could not be fulfilled with the ex-post regulation given that the harm to consumers’ health by the fake vaccine is hard to be determined. This reflects on the problem of the regulation for medical tourism, as ex-post regulation fails to eliminate such risk in advance or in the process of medical tourism activities.

ExAnte Regulation Risks in Medical Tourism Administrative Supervision

Ex-ante regulation maintains the thresholds for the eligibility of medical tourism institutions entering into the medical tourism market. After the investigation of this paper, it was found that due to the lack of “medical tourism institution accreditation standards”, there are nine medical tourism institutions in the Pilot Zone that were accredited by the old “medical institutions” accreditation standards. The old standards are insufficient to assess on the qualification of the medical institutions that meet the thresholds for eligibility of medical tourism in the Pilot Zone. In addition, various accreditation standards with different focuses are being used for evaluating on the qualification of the medical institutions. These include the three-level general hospital accreditation and Joint Commission International (JCI) hospital accreditation.²⁸ Three-level general hospital accreditation is widely used for Chinese hospitals. According to the Measures for the Administration of Hospital Classification, Chinese

hospitals are divided into three levels (Primary, Secondary and Tertiary) and three subsidiary levels (A, B and C), resulting in a total of 9 levels of classification. There are seven indicators for the three level accreditation method, which are the number of beds, department setting, ratio of medical staff to beds, ward area, equipment, rules and regulations, and registered capital respectively.²⁹ Although such accreditation standards might well reflect on the level of medical expertise of these medical institutions, it fails to evaluate on the quality of medical services provided by the medical institutions in medical tourism.

For the JCI accreditation, it is usually adopted to reflect the internationalization level of medical tourism institutions, but its application in China might be controversial. The JCI accreditation is not used to regulate the medical tourism market, let alone the assessment for the overall performance of medical institutions in the medical tourism market of a specific country. The JCI accreditation originates from the Joint Commission (JC) accreditation of the United States, but JCI and JC are different in various aspects. The biggest difference is that the domestic accreditation of the JC system contains the legal provisions of local, state and federal laws of the United States, while JCI does not have these legal provisions.³⁰ Since the JCI accreditation does not incorporate the law and regulatory norms of the home countries of the medical institutions, it might not offer a thorough and fair assessment of the accredited institutions. If medical tourism institutions are allowed to choose freely of the various accreditation standards, it may create problems for the ex-ante regulation by forming a regulatory blind area.

Interim Regulation Risks in Medical Tourism Administrative Supervision

Interim regulation focuses on the regulation of business activities in medical tourism. The current legal system and regulatory scheme have shown an inadequate response to the emergent issues associated with the medical tourism activities. From the judicial aspect, there is a “gene-edited babies” case, in which a young Chinese scientist He Jiankui and his research team members used CRISPR/Cas9 technology to edit the CCR5 gene of human embryos that would make the infants acquire the ability of innate immunity against HIV infection. However, there may be gene defects in the babies whose embryos have been transformed. Once the infant was born, the modified

genes may inevitably enter the human gene pool and might bring some unpredictable risks to human gene security.³¹

The current legal system lacks the specific legal norms applicable to regulate on the “gene editing practice”. In China’s criminal law, there is a crime called “illegal medical practice”, which refers to a person engaging in medical activities without obtaining the qualification of medical practitioner and causing serious harm. The gene-edited practice that seeks to prevent HIV infection might arguably be regarded as a medical “activity”, and people conducting this experiment were scientific researchers, not medical practitioners. Following this logic, the court ruled that the parties concerned were convicted of “illegal medical practice”. However, this event has shown the current loophole in the legal system. If the parties concerned are qualified medical practitioners and carried out this experiment, then they would not be convicted of the crime for “illegal medical practice”. It remains a problem for future legislation that needs to prevent and punish medical practitioners from conducting such experiments.

Beyond the discussion of the dilemma of the application of the appropriate laws, scholars also examine the case from an ethical perspective.³² There is a call for a sound “ethical review of the clinical application of cutting-edge medical technologies” and to improve the ethical awareness of the whole society.³³ In addition, cross-border surrogacy in medical tourism presents a similar problem.³⁴ In terms of legislation, Article 1009 of the Civil Code issued in June 2020 states in principle that “medical and scientific research activities related to human genes and human embryos” should be carried out

In accordance with laws, administrative regulations and relevant provisions of the State, and shall not endanger human health, violate ethics and morality, or damage public interests.

The available legal provisions for the regulation of cutting-edge medical technologies are too vague and general, more specific and detailed regulations are not yet in place. The crux of the issue is the controversial situation between the fast paced development of science and technology and the law lag, which imposes the risks to the interim regulation of medical tourism activities.

Risks Associated with “Exemption Clause” of the Medical Tourism Operators

In light of three types of medical tourism modes, the responsibilities of medical tourism operators to consumers can be roughly divided into contractual liability and tort liability. The contractual liability based on the contract signed by both parties, is the obligation to relieve the expected interests of the infringement.³⁵ Tort liability is usually a remedy obligation for the damage of the inherent rights of one party caused by the intentional or negligent act of the other party. While the essence of liability is the obligation to provide remedies, the exemption of the operator's civil liability will lead to the situation that the consumer's rights and interests cannot be compensated. The following discussion highlights the scenarios where the medical tourism operators claim exemption, which will impose the risks for consumers of the medical tourism.

Analysis of the tourism operator's liability exemption. In terms of contractual liability exemption, tourism operators in China usually play the roles of the intermediaries. They might claim that they only assist consumers to sign contracts with medical service providers, but they are not a party to the contract and thus do not bear the contractual liability. In terms of the exemption of tort liability, although China's Tourism Law stipulates the relevant legal provisions for the tourism operators to be responsible for tort behaviors, it also has an exemption clause for specific agents such as the transport service providers in tourism. The first part of Article 71 (2) of China's Tourism Law states that tourism operators should be responsible for the infringement act by other service providers entrusted by them to provide services for consumers.³⁶ For the purpose of promoting the development of the tourism industry in China, the second part of Article 71 (2) stipulates that when the tort behavior is caused by the transport operator, the liability of the tourism operators may be exempted.³⁷ Tourism operators who can be exempted from the liability, because of the fact they have little control on the transport providers, plus that transport providers have strong compensation ability. Similarly, the tourism operators have little control over medical providers, who also have strong compensation ability. If tourism operators argue that the tort behaviors caused by the medical service providers should be analogically applying the exemption clause of the transport operators, there exist

some legal grounds for tourism operators to claim for exemption of liabilities.

Analysis of the medical service provider's liability exemption risks. In terms of contractual liability exemption, medical service providers can claim exemption of liability on the principle of “privity of contract”, for the “package tour contract” signed between tourism operators and consumers, since they are not party to the contract. Article 522 of China's new Civil Code allows consumers to claim liability of medical service providers beyond the “privity of contract”.³⁸ However, the Civil Code is coming into effect in 2021. At present, medical service providers can still claim exemption of contractual liability on the basis of “privity of contract”. In the aspect of tort liability exemption, medical service providers usually claim that medical activities are often invasive and risky in nature, and that their infringement of consumers' rights is caused by accidents, thus claiming the exemption of tort liability.

Risks in Realizing the Litigation Rights of Medical Tourists

The realization of consumers' substantive rights requires the guarantee of civil procedural law, which currently has some deficiencies in this respect. The infringement of the rights and interests of medical tourists usually occurs in a foreign land. When dispute arises, the viable solution for consumers to protect their rights under the foreign judicial system might not be easy,³⁹ as they are facing multiple obstacles from problems of jurisdiction, applicable law, exemption clause and execution of judgment.⁴⁰ In terms of jurisdiction, consumers can generally file a lawsuit against the overseas medical institutions at the domestic court of their own country, if there are no provisions in the contract that agree upon the exclusive jurisdiction of some specific court. However, medical service providers may use the choice of court clause in the contract to bring the dispute to the local court at the place of the medical service providers for settlement, which means they can take an unfair advantage over medical tourists. When determining on whether the consumer's choice of court has jurisdiction on the dispute at stake, the convenience of litigation, the way of compensation for damages and the effectiveness of dispute settlement are the factors that need to be considered.

In addition, the application of the law of the place where the damage occurred and the exemption clause

stated in the medical service contract may make the plaintiff unable to win the lawsuit. In view of the public interest involved in medical services, consumers signing the waiver of liability clause are generally determined to be not tenable.⁴¹ However, when the medical tourism country is recognized as enjoying the immunity from extraterritorial jurisdiction, the rights and interests of consumers will not be protected. Finally, when the defendant is an extra-territorial organization, it is possible that the award cannot be effectively enforced. Even if there are scenarios of international mutual legal assistance, many countries also require that the judgment applied for enforcement be final, meaning the exhaustion of all remedies for the dispute settlement. For example, Mexico, South Africa, and Canada do not recognize that the judgment of the United States trial courts has finality, and different medical tourism countries might have different interpretations and recognition on the meaning of finality.³ Even if the final decision is obtained, there exist other complicated problems on the issue of enforcement. For instance, medical dispute rulings for British patients are easier to be enforced in the European Union (EU), but the enforcement of which outside the EU can be very difficult.⁴² From a practical point of view, a judgment that cannot be enforced would not have much meaning in terms of safeguarding the substantive rights of medical tourism consumers.⁴³ The lack of viable dispute settlement solutions in the legal system of the medical tourism country will increase the risk associated with the medical tourism and distract the potential medical tourism consumers who are looking for timely and effective judicial assistance in the case of disputes. Therefore, future efforts ought to be made by China to explore and test convenient and plausible dispute settlement channels in the Lecheng Pilot Zone in order to provide better judicial assistance to medical tourists.

Dealing with Legal Risks in Medical Tourism

Improving Regulatory Measures

Medical tourism regulators in China should strengthen and improve on the measures for ex-ante, interim and ex-post regulations. For ex-ante regulation, it is necessary to confirm and improve the unified accreditation standards for medical tourism institutions in the Pilot Zone, with references to practices of other countries, such as the Guidelines on Medical Tourism issued by the American

Medical Association (AMA) in 2008,⁴⁴ Laws related to Medical Dispute Mediation and Remedies for Medical Malpractice issued by Korea in 2012,⁴⁵ and Directive (EU) 2015/2302 of the European Parliament and of the Council of 25 November 2015 on package travel and linked travel arrangements.⁴⁶ In terms of interim regulation, there is an urge to impose stricter and detailed regulation on medical tourism activities, and non-medical institutions should not be allowed any involvement in diagnosis and treatment activities and medical beauty activities;⁴⁷ medical institutions' diagnosis and treatment behavior should meet the regulatory requirements of the health administrative department; frontier medical activities should not exceed the boundary of the existing legal framework, nor should it be allowed to impair ethics or the public interest.⁴⁸ In addition, the future legislation of the relevant laws and regulations ought to be in place, which provides the legal basis for the medical tourism regulators to supervise on frontier medical activities, and narrow the gap between the the rapid development of science and technology and the need for the evolution of the regulatory norms in the legal system.

The Assumption of Liability by Operators and Service Providers

The assumption of liability can be strengthened from two aspects: timeliness and effectiveness. In terms of timeliness, regulators in the Pilot Zone might set up the liaison office in the medical institutions to ensure medical disputes are settled in a timely manner. The liaison office may establish a dispute mediation center, which recruits experts from medical and legal fields to offer advisory opinions and facilitate the mediation. In medical disputes, dispute mediation requires legal expertise, and for the fact finding it needs the medical expertise.⁴⁹ Consumers usually are lacking the legal and medical professional knowledge, and it is also difficult to trust the authenticity and objectivity of service providers' self correction. Therefore, it calls for the need of neutrality of medical tourism regulators, who are in a better position to facilitate the mediation and help settle the dispute in a timely and fair manner. In terms of effectiveness, it is necessary to establish a sound insurance system. The regulators in the Pilot Zone shall encourage medical institutions to purchase medical liability insurance⁵⁰ or establish medical risk funds,⁵¹ and encourage patients to participate in medical malpractice insurance.

Protecting Consumers' Litigation Rights

Medical tourism disputes are foreign-related civil and commercial disputes. In respect to the dispute settlement mechanisms of cross-border litigation, arbitration and mediation, China had signed the Convention on the Recognition and Enforcement of Foreign Civil and Commercial Judgement (the Hague Judgements Convention), the Convention on the Recognition and Enforcement of Foreign Arbitral Awards, and the United Nations Convention on International Settlement Agreements resulting from Mediation (Singapore Mediation Convention). The legal framework of the diversified international civil and commercial dispute settlement mechanism has taken shape.⁵² However, the provisions of relevant international treaties do not aim at solving the problems arising in medical tourism. The application of the normative provisions in the practice of medical tourism needs to be refined by domestic legislation and the relevant international treaties need to be given legal effect by incorporating them into the domestic legal system. As stipulated in Article 33 of the Master Plan released and implemented on June 1, 2020, the centralized trial mechanism for international commercial dispute cases will be further improved to provide international commercial arbitration, international commercial mediation and other non-litigation dispute settlement methods. In addition, the establishment of Hainan's First International Civil and Commercial Courts 2019, would serve to provide a professional judicial service for the settlement of foreign-related cases occurring in the Pilot Zone, and the competence of the court is expected to be gradually improved given the accumulated experience of handling the cross-border medical dispute cases in the Pilot Zone.

Conclusion

The establishment of the Boao Lecheng International Medical Tourism Pilot Zone is an important attempt by the Chinese central government to explore the development of medical tourism in China. In the context of building Hainan Island as an International Free Trade Port with Chinese characteristics, the development of the medical tourism industry in the Pilot Zone is an integral part of such a masterplan. The development and experiment of the medical tourism industry in the Pilot Zone is of utmost importance to China's initiative of building its medical tourism industry nationwide. Recognizing the lack of legal assessment on the risks of the medical tourism in the Pilot Zone, this essay serves to fill this gap through empirical studies and finds that there are mainly three legal

risks involved in medical tourism of the Pilot Zone. These are risks in medical tourism administrative supervision, risks associated with the "exemption clause" of the medical tourism operators and risks in realizing the litigation rights of medical tourists respectively.

In light of the aforementioned risks, this paper has proposed some recommended measures to help the development of the medical tourism of the Pilot Zone from a legal perspective. First, it proposes improved regulatory measures for ex-ante, interim and ex-post regulations. Second, it suggests the establishment of a liaison office by the medical regulators in the medical institutions, which will facilitate the meditation between medical tourists and medical service providers in case of disputes. Last, it advocates the development of multiple dispute settlement channels in the Pilot Zone, which will protect the litigation rights of medical tourists and attract and anchor future consumers of medical tourism from home and abroad.

This paper hopes to provide some practical and theoretical references for the medical tourism regulators to guide future practical work. For medical service providers and tour operators, this paper has clarified the various responsibilities that need to be assumed by different players in medical tourism, so as to improve their awareness of risk prevention and control. For consumers, this paper might make them more informed as to the potential risks associated with medical tourism in the Pilot Zone. Future research would place a prime focus on the improvement of a medical tourism dispute settlement mechanism and the construction of a medical ethics review system. The deficiency of this paper is that more extensive research and cross-reference of the practices of other countries is needed, it will be improved in future, follow-up, studies.

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