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CHINESE REGULATION OF TRADITIONAL CHINESE MEDICINE IN THE MODERN WORLD: CAN THE CHINESE EFFECTIVELY PROFIT FROM ONE OF THEIR MOST VALUABLE CULTURAL RESOURCES?

Teresa Schroeder

Abstract: The global demand for traditional Chinese medicine (“TCM”) has exploded in the last thirty years. Demand for TCM products increased both domestically in the People’s Republic of China (“PRC”) and internationally. However, the stigma of “witch doctoring” associated with TCM remains. Several developed nations have established national and local regulation of TCM practitioners to protect their citizens from dangerous treatments. After almost forty years of virtually unregulated endorsement of TCM, China recently began its own standardization of TCM products and practice. The question must be asked, what inspired such a dramatic and rapid change in Chinese policy? The geysers of Chinese TCM regulation can largely be attributed to a growing international demand for alternative medical treatments. China realizes the potential profit of TCM trade, and recognizes comprehensive knowledge of its own medicine creates an obvious advantage over other sources of TCM. However, lack of standardization in products, outlandish advertising campaigns, and apprentice-based training all contribute to many nations’ unwillingness to allow the importation of TCM from China. China’s new TCM regulations respond directly to foreign countries’ concerns and display the PRC’s determination to fully enter, and possibly dominate, the global TCM market.

I. INTRODUCTION

The past thirty years have witnessed an explosion in global demand for traditional Chinese medicine¹ (“TCM”).² Demand for TCM products increased both within the People’s Republic of China (“China” or “PRC”) and internationally. However, the stigma of “witch doctoring” associated with TCM remains. Accordingly, several developed nations have regulated TCM practitioners to protect their citizens from dangerous misdiagnosis and mistreatment.³ China, itself, recently began to standardize TCM products and practice. After almost forty years of virtually unregulated endorsement

¹ Chinese legal standards define TCM as involving the use of “traditional Chinese proprietary medicines, the extract and preparation of medicinal herbs and processed traditional Chinese herbs,” although more general definitions include treatments such as massage, acupuncture, and diagnosis systems. See State Council of China, Regulations on Protection of Traditional Chinese Medicines Decree No. 106, chap. 1 art. 2 (1992) (Cn.), www.chinalaw.com (english translation).

² “Chinese medicine is used by more than 20% of the world’s population.” Donald I. Abrams & Charles Steinberg, *Complementary Therapies in HIV Disease*, 4 IMPROVING THE MANAGEMENT OF HIV DISEASE 3, (1996), reprinted in JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, at <http://www.ama-assn.org/special/hiv/treatment/updates/abrams.htm>.

³ See *infra* Part III.A (discussing United States, Australian, and British regulations).

of TCM, the national and local governments began a widespread effort to standardize TCM products, education, and distribution, both domestically and internationally. This Comment considers both the motivation for the dramatic and rapid change in Chinese policy, and whether the regulations can be effectively enforced.

Since 1949, Chinese political leaders have advocated the use of TCM as medical care for the masses.⁴ The first research center for TCM was established in 1955.⁵ However, not until the late 1980s and early 1990s did China create any comprehensive regulation of TCM. Since the 1982 Chinese Constitution,⁶ the PRC, via the State Administration of Traditional Chinese Medicine ("SATCM"), has promulgated 170 industrial rules relating to TCM.⁷ Regulations in eleven local provinces and municipalities supplement the national movement.

The geyser of Chinese TCM regulation can largely be attributed to a growing international demand for alternative medical treatments. China recognizes the potential profit of TCM trade. The comprehensive knowledge of the Chinese regarding their own medicine creates an obvious advantage over other sources of TCM. However, lack of standardization in products, outlandish advertising campaigns, and apprentice-based training in China all contribute to many nations' unwillingness to allow importation of TCM from China. Therefore, while estimated international sales of herbal medicine total \$20 billion annually, China accounts for less than 3% of this total.⁸ China's regulation of TCM directly responds to foreign countries' concerns and is evidence of the PRC's determination to fully enter, and possibly dominate, the global TCM market. Nonetheless, questions remain concerning whether this attempt will be successful in the modern legal and political climate of the PRC. Recent legislation and enforcement measures indicate a real possibility of success, provided historic pitfalls in enforcement and continuing international distrust can be alleviated.

Part II of this Comment discusses the basic history of TCM traditions, products and practitioners. Part III analyzes international TCM practice,

⁴ See DAVID M. LAMPTON, *THE POLITICS OF MEDICINE IN CHINA* 21-44 (1977).

⁵ *Id.* at 63.

⁶ "The state develops medical and health services, promotes modern medicine and traditional Chinese medicine . . . to protect the people's health." XIANFA [Constitution of the People's Republic of China] (1982) art. 21, translated in LEXIS.

⁷ *Let Traditional Medicine Benefit All*, July 28, 2000, <http://www.china.org.cn> (China Internet Information Center is a government authorized portal managing a database of Chinese news articles published under the auspices of the China International Publishing Group and the State Council Information Office in Beijing).

⁸ *Nobel Laureate Calls for Modernization of Medicine*, CHINA DAILY, Oct. 31, 2001, <http://www.chinadaily.com.cn>

standards, market pressures, and expectations. Part IV examines modern China's TCM investment, legislation, practice, and education. Part V concludes by examining the possible resolution of remaining barriers to China's increasing role in the global TCM trade.

II. HISTORICAL BACKGROUND IN CHINA

The lack of regulation of TCM may be explained by its historic status as a cultural institution.⁹ Simply stated, given the traditional use of TCM, regulation of this facet of people's lives was unnecessary, even intrusive. *The Yellow Emperor's Classic* provides the first recorded evidence of widespread use of TCM in mainland China.¹⁰ This ancient text, written prior to 85 B.C., details traditional methods of diagnosis and treatment.¹¹ Later written examples of traditional diagnosis and healing testify to China's rich medical history, as well as to some correlation between the basic theories and products used for treatment.¹²

However, despite long use by the Chinese, there is little evidence of uniformity in the preparation, ingredients, and dosage of traditional Chinese medical treatments. The early records suggest there was no centralized training or regulation of TCM practitioners. This variety and healer discretion inherent in TCM bred widespread distrust of TCM within China following the advent of Western medicine in the 1900s.¹³ Lack of standardization, scientific testing, and greater accessibility of new technologies all contributed to a perception of TCM as uncivilized quackery.

The Chinese Revolution, headed by Mao Zedong, which achieved victory in 1949, precipitated vigorous and open debate concerning TCM. In 1949, the Chinese Medical Association called for complete abolition of TCM.¹⁴ The nation's leading doctors supported the scientifically based advances of Western medicine and felt that TCM posed a serious danger to the Chinese citizenry.¹⁵ Mao Zedong rejected this movement and urged the recognition and support of Chinese medicine, specifically to treat the

⁹ *Health Minister Vows Support for Traditional Chinese Medicine*, CHINA DAILY, Jan. 1, 2002, <http://www.chinadaily.com.cn>

¹⁰ LAMPTON, *supra* note 4, at 3.

¹¹ *Id.*

¹² *See, e.g., id.* at 3-5 (discussing the *Yellow Emperor's Classic, Classic of Local Herbs*, written in 206-222 A.D., as well as discoveries and records of the Sung, 907-1279 A.D., and Yuan, 1234-1368 A.D., dynasties).

¹³ *Id.* at 47.

¹⁴ *Id.*

¹⁵ *Id.*

millions living in rural areas.¹⁶ In 1954, Mao Zedong reorganized the health department to incorporate TCM.¹⁷ This directive spawned the largest state-run TCM organization, China Academy of Traditional Chinese Medicine ("CATCM") that continues to educate TCM professionals today.¹⁸

The Academy sprang from less than auspicious beginnings; in 1955 it controlled only four five-year colleges for training in TCM. Despite lack of support, the Academy directly challenged the Medical Association, and in 1958, the Central Committee directed all Western-trained doctors to take three-month supplemental courses in TCM.¹⁹ TCM colleges increased to thirteen by the end of 1958.²⁰ TCM doctors began staffing the bulk of commune clinics, providing the primary source of care for rural Chinese.²¹

The popularity of TCM treatments grew. In the 1960s, the PRC, still plagued by widespread disease, began a new medical campaign, the "Barefoot Doctors",²² championed largely by doctors who endorsed TCM treatments. In 1949 China had 100,000 fully trained Western style doctors; by the end of 1967 there were an additional 150,000 doctors. All doctors were trained in accordance with the six to eight year educational standards of United States and U.S.S.R.²³ Secondary medical personnel with two to four years of training increased to 500,000.²⁴ The barefoot doctors existed along the periphery of this second group. Training for barefoot doctors reportedly varied from three months to ten months.²⁵ However, by all

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Opened on December 19, 1955, CATCM is currently comprised of eleven research institutions, five clinical institutions, eight national specialization departments, and two national bases of clinical pharmacology. LAMPTON, *supra* note 4, at 63; and Medboo, *Training Center of China Academy of Traditional Chinese Medicine*, <http://www.medboo.com/eng/catcm.htm> (last visited Apr. 14, 2002) (Medboo is a TCM training center working in conjunction with the China Academy of Traditional Chinese Medicine to provide long distance training in TCM.).

¹⁹ LAMPTON, *supra* note 4, at 112.

²⁰ *Id.* at 115.

²¹ *Id.* at 113.

²² The "barefoot doctors" were common, rural citizens with basic medical training. Kenneth Levin, *Medicine & Chinese Society*, in MODERN CHINA AND TRADITIONAL CHINESE MEDICINE 116, 119 (Guenter B. Risse ed., 1973). Barefoot doctors are "chosen from among the peasants, still working and being paid as if peasants, but handling basic medical and health work." *Id.* Responding to the Communist leaders attempts to bring health care to millions of rural citizens the state sponsored basic education of these individuals. *Id.*

²³ *Id.* at 116.

²⁴ *Id.* at 116.

²⁵ See Paul Pickowicz, *Barefoot Doctors in China: People, Politics & Paramedicine*, in MODERN CHINA AND TRADITIONAL CHINESE MEDICINE 124 (Guenter B. Risse ed., 1973); Samuel Rosen, *Health Care in Modern China; an Eyewitness*, in MODERN CHINA AND TRADITIONAL CHINESE MEDICINE, at 150; and Wang Xueshao, *The Integration of Traditional Medicine in Primary Health Care in Yantai*, in WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR WESTERN PACIFIC REPORT WORKING GROUP ON THE INTEGRATION OF TRADITIONAL MEDICINE IN PRIMARY HEALTHCARE 35 (Oct. 3-7, 1983).

accounts the training included only a short period of classroom study (up to three months), followed by ongoing hands-on training.²⁶

More interesting, however, is the extensive training barefoot doctors received in TCM. The *Instruction Manual for Barefoot Doctors*, by the Revolutionary Committee of Chiang-chen commune hospital, included over 131 pages on Chinese herbal medicine, as well as thirty pages on acupuncture.²⁷ The chapters on TCM were the longest in the manual and included instruction on over 207 herbal remedies, as well as drawings, to aid the doctors in recognizing and preparing herbs for medical use.²⁸ By 1983 Chinese doctors reported that over 40% of barefoot doctors' training hours were in TCM.²⁹

TCM's popularity spread and by 1968 several urban hospitals were cultivating their own herbal gardens.³⁰ Patients began actively choosing traditional treatments over Western therapy.³¹ Acupuncture, herbal remedies, and traditional forms of massage both supplemented and supplanted modern medicine.³² Urban hospitals began integrating TCM beds.³³ By 1983, 6% of hospital beds were occupied by patients undergoing in TCM treatments.³⁴

III. THE INTERNATIONAL MOVEMENT

The popularity of TCM abroad became noticeable in the 1960s.³⁵ Possibly motivated by the general popularity of holistic healing in the United States and Europe at this time, TCM gained an international following. Notably in the United States, the United Kingdom, and Australia, acupuncture and herbal remedies became commonplace.³⁶ As awareness of

²⁶ Pickowicz, *supra* note 25, at 124.

²⁷ *Id.* at 142.

²⁸ *Id.*

²⁹ Xueshao, *supra* note 25, at 36.

³⁰ Samuel Rosen, *Health Care in Modern China; an Eyewitness*, in MODERN CHINA AND TRADITIONAL CHINESE MEDICINE 150 (Gunter B. Risse ed., 1973).

³¹ Levin, *supra* note 22, at 108.

³² Tian Jingfu, *The Role and Position of Traditional Chinese Medicine in Primary Health Care*, WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR WESTERN PACIFIC REPORT, *supra* note 25, at 31.

³³ *Id.*

³⁴ Xueshao, *supra*, note 29, at 35.

³⁵ Mike Mitka, *Alternative Medicine No Fad*, 286 JAMA 1443 (2001), at <http://jama.ama-assn.org/issues/v286n12/fpdf/jqu10008.pdf>.

³⁶ See *AMA Report 12 of the Council on Scientific Affairs (A-97) Alternative Medicine*, AMERICAN MEDICAL ASSOCIATION, at <http://www.ama-assn.org/ama/pub/article/2036-2523.html> May 9, 2002. See also ALAN BENSOUSSAN & DR. STEPHEN MYERS, VICTORIAN DEPT. OF HUMAN SERVICES, TOWARDS A SAFER CHOICE: THE PRACTICE OF TRADITIONAL CHINESE MEDICINE IN AUSTRALIA, at

TCM among foreigners grew, the China Academy of Traditional Chinese Medicine received more attention from international researchers and Chinese scientists.³⁷ Investigation of TCM treatments resulted in scientific indicators, which are widely interpreted as proof, of medical benefits from TCM therapy. Controlled, scientific studies became more common.³⁸

In 1983, the World Health Organization (“WHO”) held a conference in the Philippines on integrating traditional medicine into primary healthcare.³⁹ The conference featured several Chinese TCM scholars.⁴⁰ A similar WHO conference occurred in Guangzhou in October of 1985 to aid the education of the international community.⁴¹ In 1991, representatives from over forty countries attended, and governmental officers from twenty countries participated in an international conference in Beijing.⁴² These large conferences, with high-ranking international delegations in attendance, indicated the status gained by TCM in the international community. Skyrocketing healthcare costs, longer life expectancy, perceived failure of Western trained doctors to practice preventive medicine, lack of effective communication with patients, and new diseases all contributed to the international community’s motivation to search for alternative, preferably cheaper medical treatments.⁴³

<http://dhs.vic.gov.au/phb/hce/Chinese/booklet/title.htm> (last visited Jan. 30, 2002) (see Executive Summary).

³⁷ Since 1955, the Academy has received thirteen Albert Einstein Work Awards of Science from the World Cultural Council, http://china-window.com/zhong/gamy/e_zyyjy.html (last visited Oct. 8, 2001). The Albert Einstein World Award of Science is the highest recognition granted to a scientist for his outstanding labor in benefit of science and mankind by the World Cultural Council. See The World Cultural Council, *Albert Einstein Award of Science*, http://www.umanitoba.ca/academic_support/research_admin/ors/funding/pages/index_uz/tz146c.htm (last visited Apr. 14, 2002). An interdisciplinary Committee of 120 world-renowned scientists (among them twenty-five winners of the Nobel prize) elect the recipient of the award. *Id.* The award covers fields such as: environmental protection, energy use, human nutrition and increasing natural food reserves, and is awarded annually. *Id.* The award consists of diploma, medal and \$10,000. *Id.*

³⁸ See BENSOUSSAN & MYERS, *supra* note 36; and Abrams & Steinberg, *supra* note 2.

³⁹ WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR WESTERN PACIFIC REPORT, *supra* note 25.

⁴⁰ *Id.*

⁴¹ STATE ADMINISTRATION OF TRADITIONAL CHINESE MEDICINE, PEOPLES’ REPUBLIC OF CHINA, INTERNATIONAL EXCHANGE AND COOPERATION, http://www.satcm.gov.cn/English_satcm/guojijiaoliu.htm (last visited Mar. 26, 2002) [hereinafter SATCM].

⁴² *Id.*

⁴³ See AMA Report 12 of the Council on Scientific Affairs (A-97) *Alternative Medicine*, *supra* note 36 and M. J. Friedrich, *Chinese and US Health Care Leaders Discuss Challenges of the 21st Century*, 286 JAMA 659 (2001).

A. *Global Market Pressures*

The international community continues to debate the benefits of TCM. There is apprehension regarding the standardization of TCM products, practitioners and treatment. New Chinese regulations regarding product quality, licensing, foreign investment, and regulatory enforcement all affect the international TCM climate.

1. *The United States*

Despite questionable benefits and quality control procedures, the use of alternative medicine in the United States continues to expand. Expenditures on herbal remedies have doubled in the United States since 1985 and now total \$1.13 billion annually.⁴⁴ In a national survey, one-third of Americans claimed use of an alternative therapy (not necessarily TCM) in 1996, and total annual alternative medicine expenditures in 1996 were estimated at \$13.7 billion.⁴⁵ This expenditure exceeded the cost of hospital care in the United States in 1990 (estimated at \$12.8 billion).⁴⁶ Moreover, U.S. physicians are displaying greater interest in alternative therapies. A national study determined 94% of family physicians were willing to refer patients to at least one form of alternative therapy.⁴⁷

The United States lacks national regulation on the practice of TCM. However, several U.S. states regulate the practice of TCM; some have even created their own exams to test practitioners applying for licenses.⁴⁸ However, most of this regulation is aimed solely at acupuncture and ignores growing segments of the population utilizing Chinese herbal remedies.⁴⁹

Lack of independent testing, research, and labeling of herbal supplements in the United States allows for false or misleading advertising

⁴⁴ *AMA Report 12 of the Council on Scientific Affairs (A-97)*, *supra* note 36:

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ Currently Alaska, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Florida, Hawaii, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin have regulatory legislation in place. Medboo, *TCM Distance Training FAQ*, <http://medboo.com/eng/training/faq.htm> (last visited Mar 26, 2002). Eleven other states have introduced legislation to regulate various types of TCM. *Id.*

⁴⁹ BENSOUSSAN & MYERS, *supra* note 36.

as well as potentially dangerous directions for use.⁵⁰ Herbal supplements in the United States may not be advertised as “cures” or “drugs,” and herbal remedies do not face the intense scrutiny of the U.S. Food and Drug Administration (“FDA”).⁵¹ Instead, Chinese medicines are regulated as herbal supplements by the Dietary Supplements Health Education Act (“DSHEA”).⁵² Passed 1994, this act responded to popular outcry for the allowance of a class for herbal remedies separate from food and drugs.⁵³ U.S. citizens desired immediate and uncomplicated access to herbal remedies, something that would not be available if herbal supplements were subject to FDA regulation. DSHEA calls for only minimal standards in labeling and advertising and requires no specific approval to make claims.⁵⁴ Instead, the supplements packages must contain a simple disclaimer: “This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease.”⁵⁵ Despite the lack of research or seals of approval by government agencies, use of herbal remedies continues to increase dramatically in the United States.⁵⁶ Arguably, China’s recently updated pharmaceutical laws,⁵⁷ which include regulation of Chinese herbal medicines, are better equipped than U.S. domestic laws to ensure the quality of herbal remedies.⁵⁸ DSHEA limits regulation to control over labeling claims, and in certain circumstances may prescribe “good manufacturing

⁵⁰ For a discussion on continuing concerns with supplement labeling, see Dietary Supplements, Comments on the Report of the Commission of Dietary Supplement Labels, 63 Fed. Reg. 23633 (Apr. 29, 1998).

⁵¹ Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 13, 108 Stat. 4334 (codified as amended at 42 U.S.C. § 485C (c) (2)).

⁵² *Id.*

⁵³ Over one million letters were sent to Congress in support of DSHEA. *Rooted in Folk Medicine, Many of These Botanical Anti-diabetic Agents are Used Successfully for Diabetes Control*, <http://www.alternativediabetes.com> (last visited Apr. 14, 2002).

⁵⁴ *Id.*

⁵⁵ BENSOUSSAN & MYERS, *supra* note 36. See also .Adapted from National Center for Complementary & Rooted in Folk Medicine, *Many of These Botanical Anti-diabetic Agents are Used Successfully for Diabetes Control*, *supra* note 53.

⁵⁶ David M. Eisenberg et al., *Unconventional Medicine in the United States*, 328 NEW ENGLAND JOURNAL OF MEDICINE 246 (1993); David M. Eisenberg et al., *Trends in Alternative Medicine Use in the United States, 1990-1997, Results of a Follow-Up National Survey*, 280 (18) JAMA 1569 (1998), available at <http://jama.ama-assn.org/issues/v280n18/abs/joc80870.html> (last visited Apr. 08, 2002); and 4 of 10 *People Use Alternative Medicine in the United States*, SCIENCE NEWS UPDATE, Nov. 11, 1998, available at <http://www.ama-assn.org/sci-pubs/sci-news/1998/snr1111.htm>

⁵⁷ See State Drug Administration, New Pharmaceuticals Examination and Approval Procedures (Apr. 22, 1999) [hereinafter New Pharmaceuticals Examination and Approval Procedures] and PRC Administration of Pharmaceuticals Law (Revised) (Adopted 7th Session of the Standing Committee of the 5th National People’s Congress, Sept. 20, 1984, last amended by the 20th Session of the Standing Committee of the 9th National People’s Congress Feb. 28, 2001) [hereinafter Administration of Pharmaceuticals Law (Revised)].

⁵⁸ See *infra* Part IV.B (discussing Chinese law regarding TCM definition, regulation, and testing).

guidelines.”⁵⁹ Conversely, Chinese pharmaceutical regulations specifically apply to TCM products and require testing, clinical trials and extensive informational labeling.⁶⁰

Perhaps in response to the perceived leniency of U.S. regulations, or perhaps in response to the growing concerns voiced by the citizens, the U.S. federal government created the Office of Alternative Medicine (“OAM”) in 1995.⁶¹ This office evaluates a variety of alternative treatments and provides support for research training.⁶² The initial annual budget of the OAM was \$2 million dollars, while in 1997 the budget was approved at \$11.1 million.⁶³ However, the office does not directly support training in alternative medicine via fellowships or scholarships, as the federal government does for other medical training programs. The OAM is primarily concerned with the investigation and dissemination of information on TCM.

The role the United States government will take in regulation of TCM is still unclear. Despite the gap in federal regulation of quality, the U.S. federal government recognizes the increased popularity and touted benefits of alternative medicine. Responding to millions of Americans dependent upon social security, Congress amended the Social Security Act in conjunction with the establishment of the OAM, and now provides Medicare coverage for qualified acupuncturist’s services not exceeding 65% of the scheduled fee for a service provided by a physician.⁶⁴ In addition, insurance companies in the United States have begun to cover the costs of TCM treatments.⁶⁵ This coverage, and the ongoing debate on the viability of TCM, affects all segments of the U.S. population.⁶⁶

2. *Australia*

Unlike the United States, Australia regulates acupuncture and herbal remedies under existing general laws. Australian laws on skin penetration

⁵⁹ DSHEA regulates “herbal and other botanical substances” presumably including herbal TCM products. See Dietary Supplement Health and Education Act of 1994 *supra* note 51, §§ 3 (a), 9.

⁶⁰ See *infra* Part IV.B.3. (describing recent pharmaceutical laws and quality control procedures in China). Generally relevant Chinese pharmaceutical law is contained in New Pharmaceuticals Examination and Approval Procedures, *supra* note 57, and Administration of Pharmaceuticals Law (Revised), *supra* note 57.

⁶¹ BENSOUSSAN & MYERS, *supra* note 36.

⁶² *Id.*

⁶³ *AMA Report 12 of the Council on Scientific Affairs (A-97)*, *supra* note 44.

⁶⁴ BENSOUSSAN & MYERS, *supra* note 36.

⁶⁵ Kathleen M. Boozang, *Is the Alternative Medicine? Managed Care Apparently Thinks So*, 32 CONN. L. REV. 567, 575 (2000).

⁶⁶ For a good analysis, see Boozang, *supra* note 65. See also Kathleen Boozang, *Western Medicine Opens the Door to Alternative Medicine*, 24 AM. J. L. AND MED. 185 (1998).

and use of medical implements are interpreted to include acupuncture.⁶⁷ Herbal remedies are regulated as therapeutic goods or medical substances.⁶⁸ These regulations, while not specifically directed at TCM products, are nonetheless effective, ensuring most TCM products meet the general standards for medicines within the country. In addition, Australia recently created a commission to draft legislation on the training and practice of TCM in Australia, including specific clauses regulating Chinese practitioners and other long-time practitioners currently working in alternative medicine fields.⁶⁹

3. *Europe*

In contrast to the United States, European nations generally allow traditional products to claim actual medical benefits based upon known traditional uses.⁷⁰ In the case of Germany, the products' actual manufacturing process is regulated to ensure potency.⁷¹ The German Federal Health Agency is a special commission working to approve TCM products.⁷² The efficacy information used in the approval process is supplemented by case reports, historical data, and data from other scientific literature.⁷³ Similarly, the United Kingdom allows approval based upon prior use.⁷⁴ Arguably, this regulation provides as target for the new national Chinese regulations.

B. *China and the International Market*

The growth in demand for TCM did not create corresponding economic benefits in China. While TCM has been encouraged since 1955, and its development was specifically promoted in the 1982 PRC Constitution,⁷⁵ little direct and enforceable legislation oversaw TCM

⁶⁷ BENSOUSSAN & MYERS, *supra* note 36.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ Workshop on Alternative Medicine, *Alternative Medicine: Expanding Medical Horizons: A Report to the National Institutes of Health on Alternative Medical Systems and Practices in the United States* (1992), <http://www.naturalhealthvillage.com/reports/rpt2oam/toc.htm>.

⁷¹ *Id.*

⁷² *AMA Report 12 of the Council n Scientific Affairs (A-97)*, *supra* note 44.

⁷³ *Id.*

⁷⁴ The rule of prior use is "hundreds of years of use with apparent positive effects and no evidence of detrimental side effects are enough evidence-in lieu of other scientific data that the product is safe." Workshop on Alternative Medicine, *supra* note 70.

⁷⁵ "The state develops medical and health services, promotes modern medicine and traditional Chinese medicine, encourages and supports . . ." XIANFA *supra* note 6, art. 21.

development. Irregular application of TCM has resulted in wary international consumers. China is the world's largest trader of medicinal plants, the raw materials for herbal TCM.⁷⁶ These raw exports account for 65% of China's contribution to the global TCM market. However, Chinese finished products account for only 2% of the international TCM drug market.⁷⁷ International consumers turn to Japan and Korea for TCM products, arguably due to the lack of standardization and quality control in China.⁷⁸

In addition to concerns about the quality of Chinese manufacturing, foreigners worry about the preparation and prescription of Chinese products. Many TCM medicines available directly from China are essentially raw materials that must be boiled by the patient to achieve a usable medicine.⁷⁹ In countries where tablets, mists, injections or some other form of standardized dosage is prescribed, it is unlikely that the existing pharmaceutical systems can accommodate raw materials that must be prepared by the patient.⁸⁰ This type of treatment also makes it difficult to determine exact dosages, because the potency of raw materials varies. In addition, Western doctors and pharmacists regularly deal in uniform, tested medicines. Western pharmacies have difficulty accommodating alternative raw products. The most popular alternative products in Western nations are those actually manufactured outside of China, neatly packaged in capsules or as teas.⁸¹ Regardless of the actual accuracy of these easily administered dosages, the uniformity and appearance inspire confidence, and users continue to increase globally.⁸²

Beyond simple regulation of incoming herbal products and TCM procedures, communities increased their demand for local TCM practitioners. Escalating numbers of international medical students are studying TCM in China or via correspondence courses with Chinese professors.⁸³ The first program accepting international acupuncture students

⁷⁶ *China Becomes World's Largest Medicinal Plant Trader*, XINHUA, Oct. 29, 2001, <http://www.china.org.cn>.

⁷⁷ Zeng Min, *Tech Remedy Prescribed for TCM Sector*, CHINA DAILY HONG KONG EDITION, Jun. 4, 2001, <http://www1.chinadaily.com.cn/hk/index.html>.

⁷⁸ *Id.*

⁷⁹ *Chinese Medicine Gets a Booster*, CHINA DAILY, Sept. 25, 2001, <http://www.chinadaily.com.cn>.

⁸⁰ *Id.*

⁸¹ Dagmar Ehling, *Oriental Medicine: An Introduction*, 7 ALTERNATIVE THERAPIES no. 4, 71 n. 81 (2001). See also Lisa Corbin Winslow & David J. Kroll, *Herbs as Medicines*, 158 ARCHIVES OF INTERNAL MEDICINE 2192, 2194 (1998).

⁸² "[T]he global herbal medicine market is growing by 10% annually." *Let Traditional Medicine Benefit All*, *supra* note 7.

⁸³ Medboo, *supra* note 48. See also SATCM, *Scientific Research*, available at <http://www.satcm.gov.cn> (visited Nov. 9, 2001), Medboo Health, *Training Center of China Academy of*

opened in 1992 at Shanghai Hospital with twenty students; today, 100 international students are in training there.⁸⁴ Other students have entered programs sponsored by the Ministry of Foreign Trade and Economic Cooperation⁸⁵ or the Medical College of International Studies for Chinese Medicine in Tianjin.⁸⁶ The first joint study program was created in 1997 between Middlesex University and Beijing University.⁸⁷ This program is a five-year, full-time Bachelor of Science program studying TCM.

International demand for holistic healing continues to grow. More than 120 countries and regions have established schools, programs, and hospitals utilizing TCM.⁸⁸ Increasingly, medical professionals recognize and recommend the benefits of TCM.

IV. THE CHINESE RESPONSE

The global market for TCM is growing by approximately 10% annually, while the domestic Chinese market is growing at a rate of almost 20% annually.⁸⁹ This growth arouses the interest of both international and domestic businesspeople. However, the lack of technology and enforceable standards limit China's market share.⁹⁰ Currently, native Chinese have patented 5,000 TCM drugs that are produced in China, while foreigners have patented 10,000 TCM drugs in China for both domestic and international manufacturing.⁹¹ China primarily supplies the raw materials for these foreign drugs, but production occurs elsewhere.⁹² The completed medicines are then sold back to China as "advanced finished products."⁹³ As a result, the country responsible for the development of TCM is unable to compete in its own market.

Traditional Chinese Medicine available at <http://www.medboo.com/eng/catcm.htm> (last visited Mar. 26, 2002). See also SATCM, *supra* note 41.

⁸⁴ *Needle Medicine Attracts Foreign Students*, at <http://www.eastday.com.cn>, Dec. 12, 2000; English translation available at <http://www.china.org.cn>.

⁸⁵ *Medical Training Course Attract Foreigners*, PEOPLE'S DAILY, Aug. 13, 2001, available at <http://english.peoplesdaily.com.cn>.

⁸⁶ *Traditional Medicine Draws West* PEOPLE'S DAILY, Nov. 28, 2000, available at <http://english.peoplesdaily.com.cn>.

⁸⁷ Henry Lee, *The First Chinese Medicine Degree Programme Outside China*, at <http://www.positivehealth.com/permit/Articles/Chinese%20Medicine/lee32.htm> (last visited March 26th, 2002).

⁸⁸ *Let Traditional Medicine Benefit All*, *supra* note 7.

⁸⁹ *Id.* See also Zeng, *supra* note 77.

⁹⁰ *Chinese Medicine Goes Global*, May 17, 2001, <http://www.english.eastday.com.cn>. See also Nobel Laureate Calls for Modernization of Medicine, *supra* note 8.

⁹¹ *Let Traditional Medicine Benefit All*, *supra* note 7.

⁹² Zeng, *supra* note 77.

⁹³ *Id.*

A. *Development of TCM Industry in China*

1. *Private Investment*

Both international and domestic investors are attempting to profit from ancient Chinese medical knowledge. While there are currently over 1000 TCM companies in China, less than 20% of them could be considered large or mid-sized companies capable of effectively competing with foreign pharmaceutical companies.⁹⁴ In 2001, leading Chinese distributors, manufacturers, and innovators created the China Medical Materials Group.⁹⁵ This conglomerate intends to invest in research and development as well as new high-tech methods of production for TCM.⁹⁶ In addition, venture capitalists invested \$12 million in a three-year program run by the Shanghai Biotechnology and Pharmaceutical Industry Office.⁹⁷ Similar programs at the Shanghai Innovation Centre, the TCM Standardization Research Centre, and the National TCM Pharmaceutical Engineering and Technology Centre race toward the same goal: the creation of high-tech methods of mass production of standardized herbal medications in the form of easily taken tablets, sprays, and injections.⁹⁸ These organizations expect sales to increase by \$12 million within the next year.⁹⁹ These developments are aimed at the foreign consumer, who is concerned with neat, consistent packing, and standardized dosage.

Private enterprise in China is severely limited by the international community's perception that the medications manufactured are of low quality.¹⁰⁰ The lack of standardization in medicinal quality led Nobel laureate Ning Yang to call for a modernization of TCM production at an international symposium held in October 2001.¹⁰¹ In response to the international call for standardization, a flurry of attention has focused on a new technology, chromatographic fingerprint analysis.¹⁰²

⁹⁴ Zeng Min, *Traditional Medicine Gets Tonic*, CHINA DAILY, May 21, 2001, at 2.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Chinese Medicine Gets a Booster*, *supra* note 79.

⁹⁸ *Id.* See also *China to Have its Largest "Medicine Valley,"* (Dec. 19, 2001), <http://www.china.org.cn>.

⁹⁹ *Chinese Medicine Gets a Booster*, *supra* note 79.

¹⁰⁰ *Nobel Laureate Calls for Modernization of Medicine*, *supra* note 8.

¹⁰¹ *Id.*

¹⁰² *China to Use Fingerprint Technique to Control Quality of Traditional Chinese Medicine*, XINHUA, Nov. 10, 2001, available at <http://www1.chinadaily.com.cn/news/cn/2001-10-23/40102.html>.

Chromatographic technology can be used to analyze both medicinal crops and finished TCM medicines.¹⁰³ The technology compares the TCM crop or medicine to a standard specimen and determines the quality and ingredients, and hence the potency of a particular dosage.¹⁰⁴ Unlike spectrophotometric technology, used to examine and determine the potency of the active ingredients of most Western drugs, chromatographic analysis allows evaluation of the potency of multi-component medicines.¹⁰⁵ The State Drug Administration has already announced its intent to utilize chromatographic fingerprint analysis for its new quality assessment programs.¹⁰⁶

Questions remain as to whether this new process, virtually unknown in the West, will be accepted by the world market. While both domestic and foreign consumers will benefit from better quality control, private investment will be easier to obtain for a globally accepted production process. If chromatographic analysis is primarily a tool to benefit Chinese consumers, the Chinese national government will stand virtually alone as principal advocate of the process.

2. *Government Investment*

The Chinese have made the development of TCM a priority since 1982.¹⁰⁷ Stiffer regulations and increased educational opportunities received further attention when the industrialization of high-tech TCM development was made a key task in the Chinese tenth Five Year Plan (2001-2005).¹⁰⁸ Furthermore, municipalities and local governments have made direct monetary investments in the modernization of TCM.¹⁰⁹ Largely due to fears concerning the growth of foreign pharmaceuticals companies, the municipal governments set aside money for basic research and development, as well as modern techniques, to make the discoveries economically viable in the fiercely competitive global market.¹¹⁰ The results can be impressive: one corporation's TCM sales increased by one-quarter in a single year.¹¹¹

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ See XIANFA, *supra* note 6, art. 21 (1982).

¹⁰⁸ Zhang Feng, *Traditional Medicine Fostered*, CHINA DAILY, Feb. 21, 2001, at 2.

¹⁰⁹ *Chinese Medicine Gets a Booster*, *supra* note 79. See also Zeng, *supra* note 94.

¹¹⁰ In 2001-2002 Shanghai municipal government alone set aside \$14.5 million for basic TCM research. *Chinese Medicine Gets a Booster*, *supra* note 79.

¹¹¹ *Chinese Medicine Goes Global*, *supra* note 90.

Most of the state sponsored TCM research and development occurs within state institutions, most notably the Beijing University of Chinese Medicine. By 1995 there were 100 TCM scientific research organizations based in these institutions and over 20,000 part-time scientific researchers with college educations.¹¹² In addition, recent research has focused on the creation of synthetic materials as substitutes for traditional ingredients extracted from endangered species.¹¹³ This research has been successful and state institutions no longer use endangered species in research.¹¹⁴

The government invests not only in actual research, development, and production, but also in increasing Chinese visibility in the TCM arena. The nation's top advisory body suggested and is currently constructing a national TCM museum that will "collect, preserve and exhibit the traditional medical heritage of China's various groups."¹¹⁵ The Chinese focus on TCM in recent years displays a mounting recognition of TCM as a national treasure, intended to benefit Chinese citizens as well as satisfying international demand. Various municipalities house international symposiums, conventions, and even festivals to honor and investigate Chinese medicine.¹¹⁶ These international events emphasize China's determination to enter the global TCM market as a member of the international community. Moreover, the sharing of ideas and information solidifies China's image as a quality care provider.

China actively fosters its relationship with the World Health Organization. For example, China issued a statement exhibiting great pride when the WHO officially proposed acupuncture therapy for forty-three diseases.¹¹⁷ Perhaps more interestingly, China actively seeks cooperative relationships with other countries. Governmental exchange has occurred in response to ravenous diseases such as AIDS and cancer.¹¹⁸ TCM remedies

¹¹² SATCM, *Scientific Research*, State Administration of Traditional Chinese Medicine People's Republic of China, http://www.satcm.gov.cn/english_satcm/keyan.htm (last visited May, 14 2002).

¹¹³ Amy E. Vulpio, *From the Forests of Asia to the Pharmacies of New York City: Searching for a Safe Haven for Rhinos and Tigers*, 11 *Geo. Int'l Envtl. L. Rev.* 463, 482-83 (Winter 1999).

¹¹⁴ *Endangered Species Well Protected*, CHINA DAILY, Apr. 3, 2001, available at <http://www.chinadaily.com.cn>. For a more complete discussion of the trade of endangered species for use in TCM, see William Carroll Muffett, *Regulating the Trade in Bear Parts for Use in Asian Traditional Medicine*, 80 *Minn. L. Rev.* 1283 (May 1996). See also Vulpio, *supra* note 113.

¹¹⁵ *China to Build a Museum of Traditional Herbal Medicine*, XINHAU, Nov. 8, 2001, available at <http://www.china.org.cn>.

¹¹⁶ The second China International Health-Care Festival sponsored by the Yunnan Provincial government housed 400 enterprises from the United States, Canada, Japan, China and various other countries to focus on the development of TCM products and technology. *Health-Care Festival Highlights Traditional Chinese Medicine*, XINHUA NEWS AGENCY, Nov. 21, 2001, available at www.china.org.cn.

¹¹⁷ SATCM, *supra* note 41

¹¹⁸ See Abrams & Steinberg, *supra* note 2.

offer some relief of symptoms, and via government cooperation, China exports herbal medicines to 130 countries.¹¹⁹

B. Regulation of TCM Industry in China

1. State Administration of TCM

The Chinese government's Ministry of Public Health oversees a growing organization, the State Administration of Traditional Chinese Medicine ("SATCM"), dedicated solely to TCM. This organization's duties are:

formulating guidelines, policies, law, and regulation of TCMP [Traditional Chinese Medicine and Pharmacology], working out department rules and regulations and supervising their implementation; formulating and organizing the implementation of the development strategies of TCMP, drawing up intermediate and long-term developing projects and annual programs; supervising appropriation of special funds and loans and emergency allocation of TCMP resources in cases of disasters, pestilence and for military requirements; guiding the therapy, nursing, rehabilitation and health care of traditional Chinese medicine, integration of traditional Chinese medicine and Western medicine and national medicine; supervising the production and trade of the Chinese medicines; organizing personnel training, scientific research, technological development and protection of intellectual property; developing international scientific exchange and cooperation; and making plans on export and import of Chinese medicines.¹²⁰

This organization, in conjunction with several regional and municipal governments, has promulgated 170 pieces of TCM legislation since 1982.¹²¹

¹¹⁹ SATCM, *supra* note 41.

¹²⁰ *State Administration of Traditional Chinese Medicine*. at http://www.cintcm.ac.cn/gam/e_index6.html (note original translation slightly modified for readability) (last visited March 26th, 2002).

¹²¹ *See, e.g.*, Law on Drug Management 1985; Law on Certified Physicians 1998; Regulations on the Protection of Wild Medicinal Resource; Regulations on the Protection of TCVM Drug Varieties; Regulations on the Management of Medical Institutions; The Regulation of Anhui Province on the Development of Traditional Chinese Medicine (July 28, 2001); The Regulation of Beijing Municipality on the Development of Traditional Chinese Medicine (June 22, 2001); The Notice of the Ministry of Health Concerning Restriction the Production of Health Foods Using Licorice Root; Chinese Ehedra; Desert Cistanche; Snow Lotus and Their Product in Raw Materials (June 1, 2001); The Regulations of Shanxi

This legislation is primarily concerned with the domestic development, production, and sale of TCM.

National regulation of TCM accelerated in 1992 with the Regulations on Protection of Traditional Chinese Medicines, effective January 1, 1993.¹²² This regulation aims to raise the quality of all varieties of traditional Chinese medicines, promote the development of TCM medicines, and perhaps most importantly, protect the legal rights and interests of enterprises engaging in the production of TCM.¹²³ Formerly, businesses could patent specific medical compounds, including TCM compounds.¹²⁴ Unfortunately, due to undeveloped intellectual property laws and the general lack of awareness regarding intellectual property rights, few TCM providers patented their products.¹²⁵ It is estimated that foreigners currently own 70% of the intellectual property rights in herbal medicine globally.¹²⁶

The Regulations on Protection of Traditional Chinese Medicines protect all TCM products¹²⁷ prepared or produced in China with minimal filing hassle and extended periods of protection, including secrecy.¹²⁸ Unlike the U.S. patent system which discloses all patent application material,¹²⁹ TCM products applying for protection under the Regulations on Protection of Traditional Chinese Medicine are guaranteed complete secrecy, by both the applicant and the government bodies possessing the application materials, for a minimum of seven and up to thirty years,¹³⁰

Province on the Development of Traditional Chinese Medicine (May 21, 2001); The Measures of Tianjin Municipality for Administration of Chinese Traditional Medicine Pieces for Decoration (Apr. 30, 2001); The Regulations of the Inner Mongolia Autonomous Region on Traditional Mongolian Medicine and Traditional Chinese Medicine (Feb. 12, 2001); The Regulations of Gansuu Province on Developing Traditional Chinese Medicine (Nov. 27, 2000 & Dec. 2, 2000); The Regulations of Jiangxi Province on the Development of Traditional Chinese Medicine (June 27, 2000) (www.chinalegalchange.com); Circular of State Administration of Chinese Traditional Medicine Ministry of Foreign Trade and Economic Cooperation State Administration of Import and Export Commodity Inspection and Customs General Administration on Implementing the Quality Registration; Inspection and Releasing System of Chinese Traditional Medicines to be Exported.

¹²² Regulation on Protection of Traditional Chinese Medicine, *supra* note 1.

¹²³ *Id.* at art. I.

¹²⁴ The Regulations on Protection of Traditional Chinese Medicines specifically precludes individuals otherwise applying for patent rights under 'the law governing patent rights' from applying for protection under the Regulations on Protection of Traditional Chinese Medicines. Regulation on Protection of Traditional Chinese Medicine, *supra* note 1.

¹²⁵ *Experts Call for Protection of Traditional Chinese Medicine*, CHINA DAILY, Nov. 25, 2001, available at <http://www.chinadaily.com.cn>.

¹²⁶ *Id.*

¹²⁷ TCM products are defined as "traditional Chinese proprietary medicines, the extract and preparation of medicinal herbs and processed traditional Chinese herbs." Regulations on the Protection of Traditional Chinese Medicines, *supra* note 1, chap. 1 art. 2.

¹²⁸ Regulation on Protection of Traditional Chinese Medicine, *supra* note 1.

¹²⁹ 35 U.S.C.S § 112.

¹³⁰ Regulation on Protection of Traditional Chinese Medicine, *supra* note 1.

depending upon the grade assigned to the medicine.¹³¹ Moreover, this period of protection and secrecy may be extended upon request, provided the extended period does not exceed the initial period of protection.¹³² For example, if the applicant was initially awarded thirty years of protection, the extension can be an additional thirty years (for a total of sixty years protection), but nothing greater.

Special departments under the State Council work in conjunction with experts of traditional Chinese medicine in areas of clinical and scientific research, laboratory experimentation, administration and management to determine the viability of an application.¹³³ Once a medication is approved for protection, the applicant is issued a "Certificate of Variety of Traditional Chinese Medicine under Protection" that protects the rights of the applicant.¹³⁴

The law does provide an exception for medications found to be "much in need of clinically."¹³⁵ While the terminology is undefined by the regulation, presumably "much in need of clinically" refers to an epidemic that the local, municipal, or national government feels compelled to curtail. Utilizing this provision, the national government may allow health departments in a municipality, region, or province to replicate the medication. However, the national government is responsible for giving reasonable compensation to the applicant for the loss of the protected medical variety.¹³⁶ Unfortunately, Chinese government's historic idea of compensation has differed greatly from both domestic and international patent holders. There are also continuing concerns with the general lack of respect in China for intellectual property rights.¹³⁷ Lack of definitions seems to maintain a legal loophole ripe for government abuse. However, the law strictly punishes applicants who fail to abide by its provisions.¹³⁸

Violation of the Regulation on Protection of Traditional Chinese Medicine may result in fines, removal of the certificate of authority, confiscation of fraudulent products, and criminal sanctions.¹³⁹ This strict punishment structure indicates a desire to strongly discourage any violation.

¹³¹ *Id.*, art. VI & XII.

¹³² *See id.*, art. XV & XVI.

¹³³ *Id.*, chap. II art. 5.

¹³⁴ *Id.*, chap II Art. 9.

¹³⁵ *Id.*, art. XIX.

¹³⁶ *Id.*

¹³⁷ *See Experts Call for Protection of Traditional Chinese Medicine*, *supra* note 125.

¹³⁸ Regulation on Protection of Traditional Chinese Medicine, *supra* note 1, art. XXII-XXIV.

¹³⁹ *See Administration of Pharmaceuticals Law (Revised)*, *supra* note 57.

Despite the strong wording of this regulation, the success of actual enforcement is generally unknown.¹⁴⁰

As with most Chinese legislation, enforcement is problematic without cooperation by local government officials and bureaucrats.¹⁴¹ Chinese legal scholars debate the simple existence of a Chinese legal system.¹⁴² Enforcement of national laws occurs only with the support of local officials, many of whom may have interests conflicting with the new regulation.¹⁴³ For example, enforcement of SATCM legislation occurs primarily through investigation by local authorities.¹⁴⁴ If a local investigation occurs at all, collection of fines or retrieval of the plant's license would be left to local government officials.¹⁴⁵ A public official who maintains substantial interests in a nonconforming TCM manufacturing plant, as a part of the State Owned (or aided) Enterprise ("SOE"), is unlikely to fine the plant for any violations. The problem is compounded by increased difficulties with enforcement in port cities used for international trade.¹⁴⁶ These areas experience greater marketization than interior cities and are less likely to adhere to government regulations.¹⁴⁷

Despite problems with local enforcement of national laws, directives and regulations, international TCM consumers should begin to feel more

¹⁴⁰ Some evidence exists that as many as one-half of China's drug producers should be shut down because they fall below WTO standards or produce pirated products. Although some evidence is available concerning shutdowns of illegal factories and confiscation of medicines, the investigations are still considered preliminary. See Financial Times Information, *EFE NEWS SERVICE China-WTO-Drugs Low Standards, Pirated Brands Threaten Chinese Drug Industry* Mar. 12, 2002, available at LEXIS, EFE News Service. See also BBC Summary of World Broadcasts, *Law and Order: Hebei Illegal Pharmacy* May 7, 1980, available at LEXIS, BBC Summary of World Broadcasts.

¹⁴¹ Donald C. Clarke, *What's Law Got to Do with It? Legal Institutions and Economic Reform in China*, 10 U.C.L.A. PAC. BASIN L.J. 1, 30-37 (1991).

¹⁴² See THOMAS V. STEVENS, *ORDER AND DISCIPLINE IN CHINA* 3-12 (1992).

¹⁴³ See generally XIAOYING MA & LEONARD ORTOLANO, *ENVIRONMENTAL REGULATION IN CHINA: INSTITUTIONS, ENFORCEMENT, AND COMPLIANCE* 15 (Rowman & Littlefield, 2000). See also Clarke, *supra* note 141.

¹⁴⁴ Circular of State Administration of Chinese Traditional Medicine, Ministry of Foreign Trade and Economic Cooperation, State Administration of Import and Export Commodity Inspection and Customs General Administration on Implementing the Quality Registration, Inspection and Releasing of Chinese Traditional Medicine Apr. 1, 1996. See also Regulation on Protection of Traditional Chinese Medicine, *supra* note 1, chap II, art. 9 (1).

¹⁴⁵ Regulation on Protection of Traditional Chinese Medicine, *supra* note 1, chap. IV art. 23.

¹⁴⁶ For an examination and report of smuggling and corruption in several customs areas and special economic zones, see Cary Huang and Fong Tak-ho *Hundreds Detained in \$5b Tax-Scandal Probe*, HONG KONG EMAIL, Sept. 22, 2000, Qin Jie et al, *Xinhua Feature on Xiamen Smuggling Case*, BEIJING XINHUA DOMESTIC SERVICE, July 25, 2001. See also Liu Xiaosen and Gai Jindong, *China Urges Crackdown on Coastal, Cross-Territorial Crime*, BEIJING XINHUA DOMESTIC SERVICE, Jan. 22, 2000.

¹⁴⁷ For a discussion of corrupt party members, military cadres, government officials and law-enforcement officers aiding in smuggling and customs avoidance, see Cong Yaping, *A Heavy Blow to Smuggling—Commentary on China's Anti-Smuggling Struggle Since the Beginning of This Year*, BEIJING XINHUA DOMESTIC SERVICE, Dec. 17, 1998.

confident in TCM product quality. Since May of 1996, all exported Chinese traditional medicines and their manufacturing processes have been subjected to inspection by SATCM designated organizations.¹⁴⁸ Manufacturers in compliance receive a quality registration certificate.¹⁴⁹ This certificate is revocable upon the investigative organization finding quality control problems.¹⁵⁰

Generally, investigative organizations face many of the corruption problems noted above, but the ability of SATCM to investigate product quality using independent organizations should minimize the problems.¹⁵¹ Moreover, product quality violations are subject to criminal sanctions.¹⁵² The criminal law system receives more positive attention than the civil law structure.¹⁵³ Enforcement of criminal sanctions is more likely to occur than enforcement of fines or other equitable remedies.¹⁵⁴ However, there is concern due to the enforcement issues outlined above concerning local protectionism, as well as a general focus on confession and re-education of criminal elements, that criminal sanctions may be less likely to be imposed at all.¹⁵⁵

A finding of substandard product quality domestically or in products for import results in imposition of Article 140 of the Criminal Law.¹⁵⁶ This article details the penalties for producers and sellers of products that are substandard for a variety of reasons. Punishment is based upon the intent and possible repercussions of using the substandard product.¹⁵⁷

The investigation of TCM exports brings together the State Administration of Chinese Traditional Medicine, Ministry of Foreign Trade and Economic Cooperation, and the State Administration of Import and

¹⁴⁸ "As of May 1, 1996, Chinese traditional medicines to be exported and their manufacturing enterprises shall undergo inspection by quality inspection organizations designated by the State Administration of Chinese Traditional Medicines." *Circular of State Administration of Chinese Traditional Medicine, Ministry of Foreign Trade and Economic Cooperation, State Administration of Import and Export Commodity Inspection and Customs General Administration on Implementing the Quality Registration, Inspection and Releasing of Chinese Traditional Medicine*, *supra* note 144.

¹⁴⁹ Regulation on Protection of Traditional Chinese Medicine, *supra* note 1, chap. II art. 9 (3).

¹⁵⁰ *Id.* chap. IV art. 23.

¹⁵¹ *Id.* chap. II art. 9 (2).

¹⁵² National People's Congress, *Clarifications on Criminal Liability for Dealing in Counterfeit or Inferior Goods*, Mar. 15, 2001, available at CHINA LEGAL CHANGE, Issue 7, Apr. 18, 2001.

¹⁵³ Donald C. Clarke, *The Execution of Civil Judgments in China*, 141 CHINA QUARTERLY 65, 70 (1995).

¹⁵⁴ *Id.* at 153 (general discussion of civil judgment decisions and enforcement).

¹⁵⁵ Several individuals and enterprises were treated leniently after voluntary confessions and agreeing to self-investigation in smuggling cases. See Qin Jie et al., *Xinhua Feature on Xiamen Smuggling Case*, BEIJING XINHUA DOMESTIC SERVICE, July 25, 2001.

¹⁵⁶ National People's Congress, *supra* note 152.

¹⁵⁷ Providing a product that could result in serious injury to more than three people can result in a death sentence. National People's Congress, *supra* note 152.

Export Commodity Inspection to issue yearly statements of exportable TCM and TCM producers.¹⁵⁸ The support of a variety of organizations indicates that this regulation is more likely to be enforced than other regulations originating from a single department, council, or ministry. Collaboration among the branches ensures not only completion of the investigation, but also of any follow-up measures. As this policy is aimed directly at exported products, it credits the theory that China's latest TCM regulation is largely a response to international pressure.

2. *Regulations Protecting TCM Quality*

The State Drug Administration works in conjunction with these national and regional TCM laws to create national legislation regulating the development, production and sale of pharmaceuticals, specifically including TCM drugs.¹⁵⁹ TCM drugs include any "man-made manufactures of traditional Chinese medicine" and "newly formulated prescription preparations made from traditional Chinese medicines."¹⁶⁰ Although the laws do specify a few areas where TCM drug regulation differs from conventional drug regulation, as a general rule, TCM drug manufacturers, distributors, and wholesalers are held to the same standards as other Chinese drug manufacturers.¹⁶¹ Under these new laws, all manufacturers, producers and wholesalers must be licensed by local and national agencies, all drug institutions are subject to investigation, and violation of the laws results in large fines and loss of license.¹⁶²

3. *New Pharmaceutical Examination and Approval Procedures*

China is subjecting TCM medications to more rigorous pharmaceutical testing.¹⁶³ Several recent laws revised the examination and approval procedures for drugs produced in China. These regulations set out

¹⁵⁸ See Circular of State Administration of Chinese Traditional Medicine, Ministry of Foreign Trade and Economic Cooperation, State Administration of Import and Export Commodity Inspection and Customs General Administration on Implementing the Quality Registration, Inspection and Releasing of Chinese Traditional Medicine, *supra* note 144.

¹⁵⁹ See New Pharmaceuticals Examination and Approval Procedures, *supra* note 57, and Administration of Pharmaceuticals Law (Revised), *supra* note 57.

¹⁶⁰ New Pharmaceuticals Examination and Approval Procedures, *supra* note 57.

¹⁶¹ Decoction (extracts obtained by boiling raw materials) TCM products are subject to separate standards to be issued by the State Council. See Administration of Pharmaceuticals Law (Revised), *supra* note 57 at art. 10.

¹⁶² *Id.* art 73-96.

¹⁶³ See New Pharmaceuticals Examination and Approval Procedures, *supra* note 57, and Administration of Pharmaceuticals Law (Revised), *supra* note 57.

discrete steps for application, clinical testing and approval.¹⁶⁴ TCM is generally considered a Category 1 pharmaceutical¹⁶⁵ and subject to State pharmaceutical standards.¹⁶⁶ The law specifically notes the additional requirements for TCM medications including sourcing, cultivation, ecological environment, collection, handling, processing, and preparation information included in the pretrial testing phase.¹⁶⁷ Only after final completion, reporting, and examination may the medicines be approved for production.¹⁶⁸ This process aims to assure the quality of the product as well as provide documented scientific backing for the product claims from both a municipal and national level.¹⁶⁹

4. *Internet Regulation*

To limit the ability of Chinese products to reach the international market without proper investigation and certification, the Chinese government restricts the sales channels of Chinese TCM suppliers. The State Drug Administration and the Ministry of Health cooperate to attack fertile ground for both domestic and international purchase of TCM medicines: the Internet.¹⁷⁰ Legislation passed in 2000 and 2001 regulating online advertising and sales of Chinese medicine.¹⁷¹ On January 1, 2000, the

¹⁶⁴ Part 3-6 New Pharmaceuticals Examination and Approval Procedures, *supra* note 57.

¹⁶⁵ Category 1 Pharmaceuticals include "(a) man-made manufactures of traditional Chinese medicinal materials, raw material medicines manufactured through synthesis or semi-synthesis, and their preparations, (b) effective monomers extracted from natural materials or extracted through fermentation, and their preparations, (c) combinations of chemicals for which research reports on their medical use exist abroad but which have not yet been approved for marketing by another country's drug administration." New Pharmaceuticals Examination and Approval Procedures, *supra* note 57, part II, art. 6.

¹⁶⁶ Some exception is made for "decoction" TCM products that are subject to separate standards to be issued by the State Council. New Pharmaceuticals Examination and Approval Procedures, *supra* note 57, part 2, art. 6. *See also* Administration of Pharmaceuticals Law (Revised), *supra* note 57.

¹⁶⁷ The pretrial testing is followed by four stages of clinical trials. New Pharmaceuticals Examination and Approval Procedures, *supra* note 57, part III.

¹⁶⁸ New Pharmaceuticals Examination and Approval Procedures, *supra* note 57, part 6, art. 44.

¹⁶⁹ *See* New Pharmaceuticals Examination and Approval Procedures, *supra* note 57, part 1, art. 1.

¹⁷⁰ *See* Ministry of Health, Administration of Internet-based Medical and Health Information Services Procedures, (Jan. 01, 2001), and State Drug Administration, Administration of Internet-based Pharmaceutical Information Services Tentative Provisions, (Jan. 11, 2001).

¹⁷¹ *See* China Economic Information Network, *Green Light for Online Medicine Purchases*, Economic News, at http://ce.cei.gov.cn/new/new_e2/eb2h0j39.htm (Nov. 19, 2000). *See also* China Economic Information Network, *The Supervision of Medicine Ads to be Strengthened*, at http://ce.cei.gov.cn/new/new_fl/pg00fc68htm (Mar. 24, 2001), and China Economic Information Network, *State Drug Board Cracks down on Pharmaceutical Web Sites*, Economic News (Dec. 5, 2000), at <http://ce.cei.gov.cn/new/new-e2/eb2h0114.htm> [hereinafter *State Drug Board Cracks Down on Pharmaceutical Web Sites*].

Ministry of Health outlawed online diagnosis and treatment services.¹⁷² Websites touting medical information must receive approval from the appropriate medical and health authorities and display the seal of approval on the home page.¹⁷³ The Ministry of Health also agreed to designate a special task force to periodically inspect health and medicine websites for violations.¹⁷⁴ The State Drug Administration independently screens and regulates providers and traders of online pharmaceutical information.¹⁷⁵ The concern of both agencies indicates it is receiving support from various government camps. In the short term, enforcement is likely as Internet regulation is currently a popular campaign in China.¹⁷⁶ The long-term enforceability of this law, particularly given the tremendous progress made in Internet sales, remains questionable.

China hosts a rapidly growing online medicinal market.¹⁷⁷ In contrast to the expected response to online sales within China, Chinese authorities are encouraging medicinal websites.¹⁷⁸ However, the goal is the creation and support of truthful, professional websites, preferably correlated with established, legal pharmaceutical companies.¹⁷⁹ China is greatly concerned with the potential for false advertising and the repercussions in the international community.¹⁸⁰ Truthfulness in advertising will create the image that China is capable and willing to produce quality medical products. Prolific international online medical traders ensure stiff competition for their Chinese counterparts. China's regulation indicates that it understands the ongoing importance of reliable online medical resources. If China ignored this potential market, its continuing attempts to establish quality medicine and international markets would be severely hindered by efficient, quick, and private online providers.

¹⁷² Ministry of Health, Administration of Internet-Based Medical and Health Information Services Procedures (Jan. 01, 2001).

¹⁷³ *Id.*

¹⁷⁴ Ministry of Health, Administration of Internet-based Medical and Health Information Services Procedures, *supra* note 172, art. 12.

¹⁷⁵ State Drug Administration, Administration of Internet-based Pharmaceutical Information Services Tentative Provisions (Jan. 11, 2001).

¹⁷⁶ State Drug Administration, The Provisional Regulations concerning Drug Information Service on the Internet, Decree No. 26 (Jan. 11, 2001). See also State Drug Administration, *supra* note 175, and Ministry of Health, *supra* note 172.

¹⁷⁷ In 2000, statistics indicated the existence of over 200 pharmaceutical and healthcare websites as well as forty illegal pharmaceutical websites. See State Drug Board Cracks down on Pharmaceutical Web Sites, *supra* note 171.

¹⁷⁸ See *Green Light for Online Medicine Purchases*, *supra* note 171.

¹⁷⁹ *Id.*

¹⁸⁰ See State Drug Administration, The Provisional Regulations Concerning Drug Information Service on Internet, Decree No. 26, (Jan. 11, 2001), art. 1.

5. *Modern Education and Certification of TCM Professionals*

In addition to increasing regulation and standardization of the TCM drugs, the Chinese government recently issued new legislation regarding the certification of healthcare professionals.¹⁸¹ Domestic users of both Western and traditional medicine will benefit from the increased training and uniform certification of medical professionals. Furthermore, as growing numbers of international students study in China, the regulations assure the international community that doctors trained in China are competent.

In 1998, the Ninth People's Congress adopted the Law on Licensed Doctors of the People's Republic of China.¹⁸² This regulation covers both doctors, and assistant doctors.¹⁸³ The law requires uniform examinations for all doctors and assistant doctors formulated by the administrative department for public health under the State Council.¹⁸⁴ As a prerequisite to taking the exam, all doctors are required

- (i) to graduate from a faculty of medicine of a university and practice under the guidance of a licensed doctor that works in a healthcare institution, or
- (ii) obtain license as an assistant doctor and graduate from medical school, and work for two years in medical treatment, or
- (iii) graduate from a specialty of medicine at polytechnic school and work for five years in medical treatment, disease prevention or healthcare institution.¹⁸⁵

Assistant doctors are subject to similar requirements, requiring graduation from a faculty of medicine of a university or polytechnic school and having worked for at least one year in medical treatment, disease-prevention or healthcare under the guidance of a licensed doctor.¹⁸⁶ Alternatively, doctors may study TCM for three years via apprenticeship or field practice, prove mastery of a specialized field, pass TCM exams (exams are administered by organizations specializing in TCM, disease prevention or healthcare institution recognized by the Administration for Public Health at or above the county level), and be recommended by such organization for

¹⁸¹ Law on Licensed Doctors of the People's Republic of China adopted at 3rd Meeting of the Standing Committee of the Ninth National People's Congress (June 26, 1998).

¹⁸² *Id.*

¹⁸³ NPC, *supra* note 181.

¹⁸⁴ *Id.* at chap. II art. 8.

¹⁸⁵ *Id.* at chap. II art. 9 (1-2).

¹⁸⁶ *Id.* at chap. II art. 10.

license either as a doctor or assistant doctor.¹⁸⁷ The State Council separately determines contents of exams under this alternative system.¹⁸⁸

Doctors and assistant doctors are also subject to ongoing obligations to report to the appropriate authorities any problems that occur during the course of their work, and these problems are subject to state investigation.¹⁸⁹ However, compliance with this requirement is questionable. Certainly, malpractice claims in China are seldom successful.¹⁹⁰ As a Chinese malpractice lawyer stated, “[Y]ou take a chance any time you receive medical treatment. It’s unrealistic to expect a hospital visit to be a complete risk-free experience.”¹⁹¹ In general, urban Chinese doctors are underpaid and overworked, seeing fifty to sixty patients in a single day.¹⁹² However, because of greater regulation at the local level, rural areas theoretically face fewer problems.¹⁹³

There are thirty institutions of TCM higher learning in China, three of which are supervised by SATCM.¹⁹⁴ There are approximately 42,000 students enrolled in the three institutions of higher learning, and 14,000 undergraduates enroll annually. There are 52,000 students studying in the fifty-one secondary schools and 18,600 enroll annually.¹⁹⁵ All TCM education encourages practicable TCM by working in rural areas, supplemented by continuing education and further specialization.¹⁹⁶ There is also a strong focus on integration of TCM and Western medicine.¹⁹⁷

Directly resulting from the increased emphasis on TCM and integration with Western medicine, 22% of outpatients visiting hospitals and 5-10% of hospital patients use TCM departments.¹⁹⁸ There are 170,000 TCM professionals working in the cities, and of the 970,000 rural doctors, almost all utilize TCM.¹⁹⁹ The number of hospitals using TCM quadrupled

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.* at chap. III art. 29.

¹⁹⁰ Ching-Ching Ni, *Maladies of China's Medical System*. SEATTLE TIMES. Feb. 3, 2002 at A12.

¹⁹¹ *Id.*

¹⁹² *Id.*

¹⁹³ NPC, *supra* note 181, at chap. IV art. 31.

¹⁹⁴ Twenty colleges of TCM enroll foreign students and twenty-seven offer correspondence courses. There are five undergraduate TCM specializations, three post-graduate specialties, fifteen second-class disciplines and fourteen specialties for secondary schools. See State Administration of Traditional Chinese Medicine People's Republic of China, Education, at <http://www.satcm.gov.cn/english/satcm/jiaoyu.htm> (last visited Apr. 29, 2002).

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ See The State Administration of Traditional Chinese Medicine of People's Republic of China, Medical Administration, at <http://www.satcm.gov.cn/english/satcm/jiaoyu.htm> (last visited Apr. 29, 2002).

¹⁹⁹ *Id.*

since 1980, and patient costs in TCM hospitals are almost one-quarter less than the cost of Western-based hospital stays.²⁰⁰ Domestic benefits of TCM weigh toward government regulation attempting to capitalize on this national resource.

C. *Effects of TCM Regulation*

1. *Domestic Improvements*

The primary domestic impediment to Chinese entry into the world market is enforcement of existing laws. Although the Chinese economy functions without the rigid legal standards of the West, international consumers desire the guarantees provided by enforceable laws.²⁰¹ Lack of enforcement and legal uncertainties impair market transparency.²⁰² Market transparency is a major issue, particularly in light of the China's accession to the WTO.²⁰³ Market transparency generally requires the publication of relevant legislation, dismantling of economic barriers, and a mode of administration for "tradeable services."²⁰⁴ Lack of enforcement of administrative actions greatly limits the confidence of foreign investors and consumers in China.²⁰⁵

The Chinese State Drug Administration found that 6.8% of TCM medicines and 19.2% of TCM medical materials tested during medicine inspections were substandard, while 21.4% of TCM medicines used in Chinese hospitals were substandard.²⁰⁶ This investigation of local usage indicates concern over the risks to domestic users. However, quality control issues touch upon both the international and national markets for TCM products. Widespread knowledge of the results of the State Drug

²⁰⁰ *Id.*

²⁰¹ This desire is recognized by the Chinese Minister of Foreign Trade and Economic Cooperation who said a major concern of China post-WTO accession is to "intensify the revisions of policies and regulation on foreign investment in a step-by-step and planned manner to improve the transparency of policies and regulations, and further perfect the legal system for foreign investment." Wang Fanfan et al, *Shi Guangsheng Says China to Speed Up Marketization According to WTO Rules*, BEIJING XINHUA HONG KONG SERVICE IN CHINESE, available at <http://wnc.fedworld.gov/cgi-bin/retrieve.cgi> (Sept. 8, 2000).

²⁰² "Transparency now requires publication of laws, regulations, and the mode of administration in tradable services or, to a more limited extent investment regimes." Sylvia Ostry, *China and the WTO: The Transparency Issue*, 3 UCLA J. Int'l L. & Foreign Aff. 1, at 9 (1998) (according to this definition, legal uncertainty due to unpublished law and the lack of enforcement of laws as is the case in much of China would hinder transparency).

²⁰³ *Id.*

²⁰⁴ *Id.* at 9.

²⁰⁵ *Id.*

²⁰⁶ See Chinatopnews.com, *China Cracks Down on Fake Medicine Sales*, at http://www.chinatopnews.com/Politics/Mon_Jan_17_23_39_35_2000.html (Jan. 18, 2000).

Administration's investigations could further undercut the international community's faith in Chinese manufactured medicines.²⁰⁷ However, some recent case law from China indicates a willingness to investigate and prosecute violations of the product guarantee laws.²⁰⁸

International investments in China are increasing, and relevant legislation in areas of medicine may become the basis for considerable profit.²⁰⁹ However, uncertainty regarding enforcement of both foreign investment regulation and TCM regulation discourages investment. Nations of the WTO rely heavily upon transparency to determine trade expectations and the effectiveness of the legalization of international trade.²¹⁰ China's multi-faceted legal system creates confusion for investors over the existence and interpretation of applicable law.²¹¹ Moreover, lack of enforcement of foreign arbitration awards, as well as the critical estimations of the success of dispute resolution within the WTO relating to Chinese international trade, further inhibits investors.²¹² Unfortunately, difficulties with regulatory enforcement in China, as well as the general disregard for acceptable relief (particularly for foreigners) indicate that investment and reliance on official channels remains a dangerous enterprise.

Arguably, any enforcement of TCM law currently is simply a reaction to the popular propaganda movement advocating TCM as a "Chinese export." As is commonly the case with Chinese propaganda movements, they exist in a single moment in time and are quickly forgotten.²¹³ Without assurance of longevity, TCM regulation is nothing more than a passing fad.

The sheer quantity of TCM regulation alone cannot dismiss the real fear of TCM as a popular, but fast-fading movement. Copious regulation often indicates a fleeting interest of the Chinese government. However, TCM regulation has occurred since the 1982 Chinese Constitution made

²⁰⁷ See EFE News Service File, *China-WTO-Drugs Low Standards, Pirated Brands Threaten Chinese Drug Industry*, Mar. 12, 2002, LEXIS. See also EFE News Service and BBC Summary of World Broadcasts, *Law and Order: Hebei Illegal Pharmacy*, May 7, 1980, LEXIS.

²⁰⁸ See Pub. Health Bureau of Haungchuan County v. Med. Co. of Huangchuan County, 3 China L. Rep. 196, 1991 (Intermediate People's Court of Xinyang Prefecture, Oct. 5, 1991).

²⁰⁹ MOFTEC, *The Statistics About Utilization of Foreign Capital in 2000*, available at http://www.moftec.gov.cn/moftec_en/tjsj/wazi_01_en.html (last visited April 29, 2002).

²¹⁰ Ostry, *supra* note 202, at 11.

²¹¹ "The problem of securing reliable information has created severe problems for effective resolution of commercial disputes in China." *Id.* at 15 (note also discussion at 13-16 of the multiple tiers of legislation, interpretation, enforcement and adjudication).

²¹² *Id.* at 19.

²¹³ See generally STANLEY LUBMAN, *BIRD IN A CAGE: LEGAL REFORM IN CHINA AFTER MAO* (Stanford University Press, 1999) at 133-37 (general discussion of the use and effectiveness of modern campaigns in China).

explicit mention of it.²¹⁴ The Chinese Constitution does not stand as a formal document of rights and beliefs in the same manner as the U.S. Constitution,²¹⁵ but mention of TCM in the document is nonetheless relevant. Moreover, TCM regulation seems to have only increased since that time. Arguably, this simply indicates a cresting of the movement; however, criminalizing aspects of TCM law indicates a real willingness to actively partake in the regulation of TCM

2. *WTO Accession*

The Chinese government indicates that it expects the domestic TCM market to benefit from accession to the WTO. A seminar on April 23, 2000, presented by a conglomerate of Chinese government ministries,²¹⁶ was dedicated to examining the effects of WTO membership on TCM.²¹⁷ The seminar focused on the influence on Chinese TCM of joining the WTO, as well as the global market and foreign countries' policies on TCM.²¹⁸ This seminar demonstrated the interest of several Chinese government branches in identifying potential new markets for TCM products resulting from WTO membership.

However, it is questionable whether WTO membership will create new markets. China already held Most Favored Nation²¹⁹ (MFN) status with most of the primary importers of TCM products prior to its entry into the WTO. Moreover, China never maintained truly unreasonable tariffs on traditional medicines.²²⁰ It is unlikely the purely political benefits of WTO

²¹⁴ *Id.* at 6.

²¹⁵ For a general discussion of the function, purpose and scope of the Constitution of the PRC and its interpretation of personal rights, see William Jones, *The Constitution of the People's Republic of China*, 63 Wash. U.L.Q 707 (1988), and Andrew Nathan, *Chinese Democracy*, 111-13 (1986).

²¹⁶ The Ministry of Health, Ministry of Foreign Economy and Trade, State Administration of Traditional Chinese Medicine, Pharmaceutical Department of State Economic, and Trade Administration of Drug Inspection and Supervision of China.

²¹⁷ See The 7th Branch Meeting of the International Congress on Traditional Medicine, Seminar on WTO and Development of Traditional Chinese Medicine in the 21st Century, available at http://www.satcm.gov.cn/english_satcm/chuantongyixue/di7huichang.htm (last visited April 29, 2002).

²¹⁸ *Id.*

²¹⁹ "With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports . . . any advantage, favour, privilege or immunity granted by any contracting party shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties." The General Agreement on Tariffs and Trade, Oct. 30, 1947, part I art. I [hereinafter GATT] (see art. I for complete definition of MFN).

²²⁰ According to China's WTO accession tariff schedule, old tariffs for TCM items averaged 6%, and post-accession tariffs average 3%. See China Accession Documents, Goods Schedule HS # 3001 & 30049020-9059 available at http://www.wto.org/english/thewto_e/acc_e/protocols_acc_membership_e.htm (last visited April 29, 2002). Although the decrease is significant proportionally, the actual monetary value

membership that motivated passage of the vast array of TCM legislation. The WTO political benefits of increased TCM legislation appear negligible. However, other TCM providers were already WTO members; and China did rely on its discretionary MFN status to stay in the market. Understandably, WTO accession reduced worries of worldwide investors and traders of TCM products that global TCM markets would become economically unprofitable if China lost MFN status with its primary importers of TCM products.

China may feel that WTO membership will smooth its entry into the global TCM market.²²¹ GATT²²² nondiscriminatory import and export requirements forced China to examine its discriminatory pharmaceutical related laws.²²³ Theoretically, WTO membership should break down protective tariffs and non-tariff barriers inhibiting the trade and development of TCM products. Despite the revolutionary TCM related legislation passed in China, some medical organizations already express concerns with regulations that encourage import substitution and, de facto, violate sections of GATT.²²⁴

Intellectual property protection also remains a crucial issue for the Chinese, largely because of WTO requirements²²⁵. SATCM has supported increased intellectual property protection within China.²²⁶ Better protection

is negotiable and the tariff reduction was effective immediately indicating a lack of perceived need for protection of the domestic TCM market. *Id.*

²²¹ *Health Minister Vows Support for Traditional Chinese Medicine*, *supra* note 9. See also World Economic Forum, *Health: China's Next High Growth Industry*, at <http://www.weforum.org>

²²² GATT, *supra* note 219 (amended 1994). See <http://www.wto.org> (English translation of GATT 1994 available online as well as China's WTO accession agreements) (last visited Mar. 26, 2002).

²²³ Sec. II Economic Policies, Part 23:

The representative of China confirmed that measures would be taken at national and sub-national level, including repeal or modification of legislation, to provide full GATT national treatment in respect of laws, regulations and other measures applying to internal sale, offering for sale, purchase, transportation, distribution or use of the following. . . . Pharmaceutical products, including regulations, notices and measures which subjected imported pharmaceuticals to distinct procedures and formulas for pricing and classification, or which set limits on profit margins attainable and imports, or which created any other conditions regarding price or local content which could result in less favourable treatment of imported products.

While the working party and the Chinese representative both recognized the potential problem in pharmaceutical, including TCM, the eventual success of this agreement is still unpredictable. WTO Ministerial Conference, Fourth Session Doha, 9-13 November 2001 Report of the Working Party on the Accession of China 4 (Nov. 10, 2001).

²²⁴ Pharmaceutical Research and Manufacturers of America, *Barriers to Market Access for Patented Pharmaceutical Products, Issues Around the World, Watch Country: China*, available at <http://www.phrma.org/policy/aroundworld/special301/china.phtml> (last visited April 18, 2002).

²²⁵ Thomas T. Moga, *China Changes Patent Law to Comply with TRIPS*, NAT'L L.J., July 23, 2001 at C15.

²²⁶ *Experts Call for Protection of Traditional Chinese Medicine*, *supra* note 125.

for patentees will not only reward Chinese creation of TCM products, it will also encourage foreign investment. Enforcing patent rights could also encourage standardization in the final products. Only products complying with accepted patents are protected, which motivates producers to standardize medicines. Product quality issues could then be avoided both internally and externally.²²⁷

It is reasonable to think that regulation and enforcement, even in the short-term, will result in a change in the perception and attitudes of the Chinese people, manufacturers, and foreign investors. There is reason for cautious enthusiasm for the domestic and global future of TCM products from China.²²⁸

V. EXPECTATIONS

The growing popularity of TCM in the international community is unquestioned. Increased faith in TCM treatments is evidenced by the willingness of insurance companies to cover TCM treatments and increased use of TCM in international hospitals. Moreover, the United States, U.K. and Australia have opened their own TCM schools. Largely focusing on acupuncture, massage therapy and herbal tonics, these institutes turn out medical assistants capable of aiding patients in relief of pain and symptoms. Furthermore, TCM offers hope AIDS and cancer patients. TCM also offers comfort without continual worries about side effects. Consequently, it appears that the global popularity of TCM will continue to increase.

Clearly, China holds the home advantage for the research and development of TCM products. Documentation of traditional remedies known in isolated areas of China is encouraged. Urban TCM institutes are also actively researching little known TCM treatments. Isolated territories are encouraged to legitimize practice of local TCM therapy. Regional laws on TCM production indicate that local areas are increasingly recognizing their potential for profit from their local heritage. Hopefully, as more local attention is paid to this valuable national resource, self-regulation, and genuine scientific interests will flourish.

²²⁷ *Id.*

²²⁸ Moga, *supra* note 225.