

**Traditional Chinese Medicine Could Make**

**“Health for One” True**

# Contents

## Abbreviations

## Summary

|   |           |
|---|-----------|
| <b>1 The developing history and present situation of Traditional Chinese Medicine</b> .....   | <b>1</b>  |
| <b>1.1 The developing history of TCM</b> .....  | <b>1</b>  |
| 1.1.1 Origins of TCM .....  | 1         |
| 1.1.2 Developing period of TCM .....  | 2         |
| <b>1.2 The present situation of TCM</b> .....   | <b>4</b>  |
| 1.2.1 The situation of TCM in the first half of 20 century .....  | 4         |
| 1.2.2 The situation of TCM in the near 50 years .....   | 5         |
| <b>1.3 The developing prospect of TCM</b> .....   | <b>9</b>  |
| <br>  |           |
| <b>2 The Value of TCM</b> .....   | <b>11</b> |
| <b>2.1 The general viewpoints of TCM theories</b> .....   | <b>11</b> |
| 2.1.1 Both man and nature are originated from the same thing .....  | 11        |
| 2.1.2 The body is in unity with mind .....  | 12        |
| 2.1.3 Its holistic medical pattern .....  | 13        |
| <b>2.2 About the therapies of TCM</b> .....   | <b>15</b> |
| 2.2.1 The self-healing power is the key of TCM and make it possible for “health for all” .....  | 15        |
| 2.2.2 Medication therapies are developed from the non-medication therapies and only the complementary of the latter .....                     | 17        |
| 2.2.3 Prevention is primary in comparison with medication or non-medication cures and thus lowered the cost and raised the health level ..... | 20        |
| <b>2.3 The potential values of spreading TCM knowledge</b> .....  | <b>21</b> |
| 2.3.1 Changing the using ways of drugs and avoiding its side effects .....  | 22        |
| 2.3.2 More effective cure methods can be applied and invented .....   | 24        |
| 2.3.3 TCM is suitable for both the developing countries and the developed countries .....   | 25        |
| <b>2.4 The Possibility of TCM from CAM to UM (Universal Medicine)</b> .....   | <b>27</b> |
| <br>  |           |
| <b>3 The Innovation of Traditional Chinese Medicine</b> .....   | <b>30</b> |
| <b>3.1 Differences between TCM and modern medicine</b> .....  | <b>30</b> |
| 3.1.1 The differences of guidelines .....   | 30        |
| 3.1.2 The difference of sources and basement of application .....   | 31        |
| 3.1.3 The difference of methods of cooperation .....  | 31        |
| 3.1.4 The difference of toxicity, side effect and drug resistance .....   | 32        |
| <b>3.2 To research and develop new drugs</b> .....  | <b>33</b> |
| 3.2.1 Chinese patent medicine .....   | 33        |

|                                      |    |
|--------------------------------------|----|
| 3.2.2 New chemical drugs .....       | 37 |
| 3.2.3 Problems and suggestions ..... | 40 |

**4 Existing Challenges and Proposals for Conservation and Development**

|  |           |
|--|-----------|
| <b>of TCM .....</b>  | <b>42</b> |
| <b>4.1 Incorrect policies and rules made by government to administer TCM due to making little of the theory and value of TCM .....</b>                   | <b>42</b> |
| 4.1.1 TCM is gradually losing its characteristics and clinic advantages mainly from the misdirection of national policy .....                            | 42        |
| 4.1.2 Indigenous practitioners of TCM are not qualified to treat patients .....  | 47        |
| <b>4.2 Endangered causes of wild animals and plants used in TCM, and proposal of ensuring sustainable supplies of natural produce for TCM .....</b>      | <b>48</b> |
| 4.2.1 Endangered causes of Wild Animals and Plants Used in TCM .....   | 48        |
| 4.2.2 Proposal of protecting the endangered species used in TCM .....  | 50        |
| <b>4.3 No good methods have been developed to protect traditional knowledge .....</b>  | <b>54</b> |
| 4.3. 1 The existing forms of protecting intellectual property of TCM .....   | 54        |
| 4.3. 2 The situation of patent application for TCM in China .....  | 55        |
| 4.3. 3 The awareness of protecting intellectual property is weak in China .....  | 58        |
| 4.3. 4 The function of current protection of intellectual property is limitative .....   | 59        |
| 4.3. 5 The experts in intellectual property of TCM are in badly need. ....   | 60        |
| 4.3. 6 The international situation of intellectual property of TCM .....   | 60        |
| <b>4.4 The existing evidence revealed a serious flaw in the educational system of TCM ...</b>  | <b>64</b> |
| 4.4.1 The situation of current TCM education .....   | 64        |
| 4.4.2 Challenges existed of TCM education .....  | 66        |
| 4.4.3 Proposal .....   | 67        |
| <b>4.5 Some serious side effects and toxicity of Chinese medications occurred because many people haven't used TCM following the theory of TCM. ....</b> | <b>68</b> |
| <b>4.6 Existing science and technology can hardly understand TCM .....</b>   | <b>68</b> |
| <b>4.7 It is benefic for enhancing everyone's body to spread TCM all over the world .....</b>  | <b>69</b> |

## Abbreviations

|       |  |
|-------|--|
| CAM   | Complementary and Alternative Medicine   |
| CITES | The Convention of International Trade of Endangered Species of Fauna and Flora |
| GOV   | Gross Output Value   |
| HAART | Highly Active Antiretroviral Therapy   |
| KMT   | Kuomintang (government)  |
| NDA   | New Drug Application   |
| PRC   | People's Republic of China   |
| R&D   | Research & Development   |
| RMB   | Renminbi   |
| SARS  | Severe Acute Respiratory Syndrome  |
| SP    | Sulfadiazine and Pyrimethamine   |
| TM    | Traditional Medicine   |
| UM    | Universal Medicine   |
| USA   | United States of America   |
| WHO   | The World Health Organization  |
| WIPO  | The World Intellectual Property Organization                                   |

## Summary

### Traditional Chinese Medicine Could Make “Health for One” True

Traditional Chinese Medicine (TCM), which is the quintessence of the Chinese culture heritage, has a long history of 5000 years as that of the Chinese nation and has made an everlasting contribution to the Chinese Nation survival and producing offspring and prosperity.

#### 1 The developing history and present situation of Traditional Chinese Medicine

TCM has been systematized and theorized in practice and has developed many methods to keep health during thousands of years. TCM has become the academic medicine instead of experiential medicine.

TCM dated back to the period of The Huang Di. *The NeiJing (The Yellow Emperor’s Canon of Internal Medicine)* that is the greatest and the oldest Chinese medical classic is milestone, which has established the theoretical foundation for the medical system and philosophical theory.

With development of Chinese nation, the theory of TCM is also constantly improving. The Han dynasty lived Zhang Zhongjing, and others, the greatest physicians of China. The Tang dynasty lived Sun Simiao named Herbal King. There have come into being four branches of TCM for the Jin-Yuan dynasty, each one with his characteristic and thesis, which improved theory of TCM infinitely. The Ming dynasty lived Li Shizhen and Zhang Jingyue, who promoted TCM development. The Wen Bing school was founding gradually in the Qing dynasty. TCM has taken shape unique its own system and theory in practice, which develops his own way according to internal theories.

Since the beginning of the 19<sup>th</sup> century, with western medicine entering and developing rapidly in China, TCM development was affected severely, which was between the devil and the deep sea.

After the Opium Wars in China, which made Chinese to have falsity belief that TCM is unscientific, feudal. Therefore, TCM had always been in the position being investigated, examined, queried and reformed, and developed on thin ice.

After the foundation of the People’s Republic of China, the Government affirms the policy to protect TCM. Then, it developed steadily. However, in the latest 20 years, the policy of the Party Central Committee and the gist of the Constitution haven’t been carried out conscientiously, TCM has been in a difficult position.

Over the past thousands years, TCM has developed a set of both practical and advanced, universal and thorough, and systematic health care system, which is notably characterized by simplicity,

convenience, affordability, safety, efficacy and effectiveness. TCM is thriving and prosperous in future, and it could make “health for one” true!

## 2. The Value of TCM

The value of TCM is judged by its potentialities as well as its present applications, and the evaluating work should be based more on the TCM theory-based method than merely on scientific-based standard. TCM originated from the ancient times and collected various kinds of techniques under the directing of its theory. TCM theory has the character of holism, and is told mainly by concepts related to Chinese philosophy and culture. Those classic canons of Chinese culture, such as *The Book of Changes* and *Laozi* or *Taodejing*, have their deep relationships with *NeiJing* that lays a foundation of TCM theory. All these books acknowledge of that everything in the world is movable and changeable, so do the health and disease of a man. Besides of that, *Taodejing* points out that both the man and nature are originated and deep-rooted from *Tao*, and our actual world cannot keep away from *Tao* or the natural law. TCM theory does its best to make use of the natural law, and finds out that the body of a man is in unity with his mind and should not be apart from each other anytime and anywhere. To do like this, the mind must play its active role in dominating the body, and the holistic medical pattern of TCM declares the original meaning of wholeness that nature, society and man are joined together by something invisible. TCM theory has never changed its holistic character in comparison with modern Western medicine, and the knowledge about this character is the core value TCM contributes to our modern times.

TCM theory emphasizes on the self-healing power of man for curing diseases and keeping fitness, and many of its therapies are employed for enhancing this power. Without it, TCM cannot do anything for health promoting and disease curing, and the mechanism of TCM would remain a mystery to us. The cultivation of mind or spirit is the basis of those methods for flourishing self-healing power, and thus TCM theory has the character similar to that of religions that ask people depend on themselves. Being independent, TCM theory thinks of that everyone has his own potentialities for living a good life, and “health for one” is possible if everyone could be taught the knowledge about the self-healing power. This is a different idea from what WHO has proposed, and serious consideration must be taken of it because we have already lived in a knowledge-based society. The non-medication therapies and medication therapies of TCM are just the knowledge serving for the individual, and both of them are procedure-based therapies that can be manipulated by doctors and patients. In fact, the medication therapies of TCM are developed from the non-medication therapies in the TCM history of development and only the complementary of the latter, and the concerned herbals, minerals and animal parts have their properties judged by TCM theory. Seeking for the active ingredients cannot be used to replace the usage of TCM theory-based knowledge, and the present scientific-based standards are not sufficient for evaluating the values of TCM medication therapies. The reason is that TCM theory thinks of materials transformable in a time related way and thus inseparable by the prevailing research methods. Similarly, TCM theory lays the preventive work in advance, and the curing must be based on it, otherwise, TCM doctor will be looked down upon even though he is good at the curing work. TCM theory encourages doctors considering results in a holistic way, and thus the cost may be lowered and the health level may be raised at the same time. This is different from

the allopathic medicine.

After the general introduction of TCM theory and therapies, we find out that mastering its knowledge and using it actively in practical work is the most convenient and valuable way to preserve and develop TCM, and without the usage being directed by TCM theory, its characters such as being simple, convenient, cheap and effective will disappear because of the misuse of TCM therapies and products. The medication therapies of TCM have the effect of avoiding those so-called side effects theoretically, and thus have the meaning of deconstructing the industry of chemical drugs. To change TCM into the modern form will not bring about surely the progress, and making progress of TCM must follow the way what TCM theory asks for. Therefore, more effective therapies for preventing and curing can be applied to our modern society if TCM theory can play its directing role in the process of application. These therapies include Chinese herbal medicine, acupuncture, moxibustion, massage, *taiji*, *qigong* and other mind-cultivating methods. Apart from the infectious diseases, certain chronic diseases, senile diseases and psychosomatic disorders can also be cured by TCM. The most encouraging fact is that many new therapies can be invented according to TCM theory, and our modern world would not be embarrassed by those deadly diseases anymore.

Now in China, TCM accounts for around 40% of all health care delivered. Many other developing countries have learned from China the experiences of harmonizing traditional medicine and modern medicine in achieving the goal of primary health care, and TCM theory and therapies have been spread around the world. Among the therapies, acupuncture is the typical one, and *Taiji* is another. They are easy to learn but hard to perform and understand perfectly. The key problem is that TCM theory has not been studied and understood systematically. In some developed countries, TCM has been accepted widely as CAM and the non-medication therapies are classified as procedure-based therapies, but the medication therapies of TCM are unfortunately treated as scientific-based therapies. This classification results in many problems such as “safety, efficacy, quality, availability, preservation and further development of this type of health care”, and the methodology for evaluating work has kept people in developed countries from enjoying the profits of TCM. If we cannot develop a compromising method to solve this trouble in the future, both China and those developed countries would feel sorry about the applications of TCM.

TCM is old enough but is not something out of date, and it still has the power of getting rid of troubles of our modern society. How to employ its functions correctly and avoid disorders? China has learned a lesson from integrating TCM with modern Western medicine that TCM is uniquely both in theory and methodology, and the two kinds of medicine can be combined technically, but it is quite difficult to restate the two medical philosophies in terms of one another. So we must abandon the habits mixing them simply together. As a holistic medicine, TCM has its own strengths in solving those problems the allopathic medicine cannot solve, and this indicates not only the change of the knowledge, but also the change of the methodology and the philosophy. We should judge the value of TCM by its holistic philosophy and methodology and should not merely by its language. The classic Chinese is not the decisive factor preventing TCM from going forward, and the scientific language feels shy for expressing TCM theory explicitly. People may easily get excited when they think of the Wholeness, but the cultural diversity, conflict and pluralism need them keeping calm, peaceful and reasonable when they hope to live together

forever.

### **3 The Innovation of Traditional Chinese Medicine**

To develop new drugs by innovating on TCM now draws plenty of attention and interests all over the world. It is considered a convenient way to develop low-cost, more available and affordable new drugs.

TCM and modern medicine contain different ways of prevention, treatment and rehabilitation as well as health care due to their individual theories. Differences could be made out in many aspects like guidelines, sources and basement of application, methods of cooperation as well as toxicity, side effect and drug resistance.

It is one of the preponderant fields to access new chemical drugs from Chinese medications in China. A lot of research on innovation of Chinese medications has been done. There are two kinds of new drugs, namely, new Chinese patent medicine and new chemical drug. For the former, which often contains more than one Chinese medication, its development and application still base on understanding TCM syndrome.

And it is also a good and economical way to discover new chemical drugs based on active ingredients and leading compounds separating from Chinese herbal medicine and it may be an available path with less risk. Some new drugs are active ingredients such as Artemisinin, while others are compound extract from an herb including active part such as Ginko Biloba Extract.

As some disadvantages existed in innovation, some suggestions are put forward in order to improve the quality of innovative drugs.

Firstly, some well-known prescriptions are hard to develop because the characteristics of TCM are neglected during the process of examining and approving. So the national administrations should create a reasonable policy environment for the growth of the TCM industry containing real quintessence and characteristic of TCM.

Secondly, Many indications of new Chinese patent medicines now haven't explained clearly, some are even indicated by modern medicine only. So the efficacy of medicines decrease and more toxic effects happened. Therefore, the new Chinese patent medicines should be researched and developed on the basis of TCM theory and the functions and indications should be explained by more TCM terms. And further education and training on TCM is needed for both TCM and allopathic practitioners.

Thirdly, it is now serious that the research and development of TCM in new medicine markets are repeated poorly at low level. So it is important to provide scientific information and guidance for TCM industry and researchers.

Finally, it is significant for Chinese industry and government to increase the investments, emphasize the fateful diseases and expand TCM industry as well.



## **4 Existing Challenges and Proposals for Conservation and Development of TCM**

### **4.1 Incorrect policies and rules made by government to administer TCM due to making little of the theory and value of TCM.**

**TCM is gradually losing its characteristics and clinic advantages mainly from the misdirection of national policy.**

Firstly, there is lack of practical standards to evaluate the safety, efficacy of TCM.

Secondly, the accessibility and efficacy of Chinese medicine have been limited as the evaluation procedure and norm are almost the same as chemical drugs. It isn't fit for Chinese medicines to examine and ensure their quality by analyzing quantities of one or a few measurable components. Current guidelines on new Chinese medicine have resulted in the decrease of pharmaceutical efficacy and plenty of effective Chinese patent medicines couldn't obtain productive permission. Price of Chinese patent medicines is tending upward and many Chinese patent medicines are increasingly disappearing because of low price.

Thirdly, researches on TCM theories are increasingly divorced from clinic practice and the frequency of using TCM against diseases gradually decreases in clinic.

#### **Indigenous practitioners of TCM are not qualified to treat patients**

Many indigenous TCM holders who have been respectable doctors for years lost their doctor's qualifications because they haven't the required educational experience.

So it is important to promote authorities' understanding on TCM, and standards of diagnoses and treatments as well as examination and approval of new Chinese medicine should be set up.

Authorities should qualify excellent indigenous TCM holders to treat patients with traditional knowledge. And it is necessary for them to get more continuation training.

### **4.2 Endangered causes of wild animals and plants used in TCM, and proposal of ensuring sustainable supplies of natural produce for TCM**

Chinese medicines are mostly based on the natural products that come from plants and animals, which are now decreasing due to environmental damage and pollution, population explosion, overspending, illegal trade of wild animals and the other reasons. There exist challenges in ensuring TCM sustainable development.

To guarantee TCM to have enough materials resources to use, the government, local community and the medical enterprises should strengthen the endangered wild species to be farmed and cultivated and tamed, for the complement alternation of herbal materials and artificial synthetic are not effective. At the same time, they should strengthen research of the domesticated species to adapt the wild environment to recover the wild population of the species and keep TCM herbal virtue and effectiveness. Controlling growing of Chinese population and decreasing the export of

herbal materials to developed country are methods to ensure the rare and precious wildlife resources sustainable supply. Of course, the protection of environments is necessary, i.e. the natural reservation of wild species used in TCM should be established, and new medicine application should illuminate source of materials.

**4.3 No good methods have been developed to protect traditional knowledge including TCM from being used without consent. Individuals and countries that have created and kept such knowledge could not benefit from it while the “biopiracy” frequently occurred in the developing areas.**

It is now hard to effectively protect the intellectual property of TCM that would affirmatively disturb the normal manufacture and markets of TCM industry, weaken the potential advantages and the possibilities of enrichment offered by traditional knowledge. So it is therefore very important and urgent to develop effective regulation to protect intellectual property of TCM in more effective ways.

There are more than 10 forms for protecting intellectual property of TCM like trade secret, national secret, trademark, geographical indication, patent, protection and inspection of new medicine and so on.

In recent years Items of patent applications examined as well as certified of TCM rose fast. The rise of patent applications examined as well as certified of big and medium enterprises is stable. Patent applications examined of state-owned enterprises are greatly going up too.

But the awareness of protecting intellectual property is still weak in China, and the function of current protection of intellectual property is limitative. The experts in intellectual property of TCM are badly needed.

So effective forms of protecting intellectual property of TCM should be developed like generalization movements, aiming at raising the general public awareness and abilities of protecting intellectual property of TCM, should be carried out.

It is suggested to establish an independent national commission of intellectual property of TCM that would improve and execute correlative laws.

Governments should attach importance to the experts of both TCM and intellectual property, and establish specific policy and regulatory issues for traditional medicines all over the world as well.

It is necessary to encourage innovations in TCM as the initial traditional knowledge is hard to be protected now.

It is also a practical measure to establish “Database of TCM knowledge”, service agencies of intellectual property of TCM and self-discipline organizations.

**4.4 The existing evidence revealed a serious flaw in the educational system of TCM including textbooks, curriculum and faculty and so on because many graduates from TCM academies**

**couldn't master the essentials of TCM and employ TCM to treat patients.**

TCM education has changed from apprentices-master training into academic education since 1956. The existing education run lack of TCM character and make educational mode humdrum.

So authorities should emphasize the insistent use of TCM and improve the efficacy of TCM by reforming the current TCM educational system.

**4.5 Some serious side effects and toxicity of Chinese medications occurred because many people including most doctors who don't understood TCM enough haven't used TCM following the theory of TCM.**

It is considerable reasonable to say that herbal toxicity has something to do with the users instead of the herbs themselves. We don't think it would resolve the toxicity of Chinese medication by only strengthening the herbal toxicological studies.

The important way to avoid toxicity of Chinese medication is to understand TCM theory as well as characteristics of Chinese herbs. The government should encourage mastering appropriate use of TCM by training and additional education.

**4.6 Existing science and technology can hardly understand TCM because most of TCM knowledge exceeds the scope which modern science studies.** But TCM is provided with characteristic and advantage to be used by modern society. And TCM would be understood and accepted better only after the modern science and technology develop further.

**4.7 It is benefic for enhancing everyone's health to spread TCM all over the world.**

It is necessary to popularize TCM knowledge in order to let more and more people know the advantages and gradually accept it, and TCM will play a more important role to achieve the goal of WHO 'Health for one' all over the world'.

## **CHAPTER 1**

### **The developing history**

#### **and present situation of Traditional Chinese Medicine**

Traditional Chinese Medicine (TCM), which is the quintessence of the Chinese culture heritage, has a long history of 5000 years as that of China and has made an everlasting contribution to the Chinese Nation survival and producing offspring and prosperity. And it has played the great historic role and the practical significance shown, which is the objective reality.

With modern science developing increasingly, though TCM developed rapidly, which played crucial parts in primacy health care once in China, and is still in national health care system, but TCM develops slowly, its situation is inferior and secondary position at present.

#### **1.1 The developing history of TCM**

TCM has been systematized and theorized in practice and has developed many methods to keep health during thousands of years. TCM has become the academic medicine instead of experiential medicine.

##### **1.1.1 Origins of TCM**

TCM has been in existence for at least thousands years. It includes Han medicine and the theories and practices of the various national minorities, such as the Miao, Dai, Mongolian, and Tibetan nationalities, each with their own unique systems as that of Han medicine.

TCM dated back to the era of Huangdi, the Yellow Emperor (2698-2598 B.C). The duties of doctors were defined in the early Zhou dynasty (traditionally dated 1122-221B.C.), which was characterized by great intellectual achievements, including the rise of Confucianism and Taoism and the writing of the oldest known Chinese literature. The dynasty was one of the most outstanding phases in Chinese history, literature, art, religion, philosophy, and all that is usually included in the term civilization flourished and reached a high degree of development.

Initially, medicine was an applied, practical and effective art, which was based upon observation and experience, adopted the philosophical speculations of the time that practiced today such as the theories of Yin and Yang, the wu-xing (five evolutions or elements) concept. It was thought that health was a question of the body maintaining a relative balance, not only internally but also with

the external environment.<sup>1</sup> Thus, diagnosis (such as inspection, listening and smelling examination, inquiring, and pulse-taking and palpitation) and treatment (such as herbal remedies, acupuncture, moxibustion, cupping, breathing exercise therapy, systematic exercise, massage, hydrotherapy, etc.) were aimed at identifying the type of imbalances present and then restoring it to normal, a very scientific concept for all its antiquity. From the various theories about, which formed the basis of the whole of TCM for over three thousand years, up to today.

Bian Que also named Qin Yueren from Renqiu (today) in Hebei province, who was the most ancient of the physicians from the historical period (ca. 500 B.C.). He was reputed to be an excellent diagnostician, excelling in pulse-taking and acupuncture therapy. He is ascribed the authorship of *Bian Que Neijing (Internal Classic of Bian Que)*. Han dynasty physicians claimed to have studied his works, which have since been lost. After his death and because of his abnormal skill of medicine, people have named him as the spiritual doctor Bian Que.<sup>2</sup>

Publication of *The NeiJing (The Yellow Emperor's Canon of Internal Medicine)* that is the greatest and the oldest Chinese medical classic is milestone, which has established the theoretical foundation for the medical system and philosophical theory. Tradition ascribes it to Huangdi, but without clear historical evidence, being a compilation by various writers. *The NeiJing* was completed gradually until the Spring-Autumn and the Warring States Periods of China (about 770-221 B.C.), which is the grandfather of TCM theory, the first encyclopedia in China. It includes astronomy, geography, human being, and medicine, science, culture, and philosophy.

The *NeiJing* sums up the clinical, physiological and theoretical knowledge of all the centuries, which preceded it, and is the earliest attempt to systematize the medical thought of these ancient times. The work consists of two distinct and separate books: *the Su Wen* and *the Ling Shu*. The former covers the general principles of health and the standard methods of diagnosis and treatment, the latter is more or less a special treatise on the art of acupuncture and moxibustion that are peculiarly Chinese because of never mentioned in the medical history of any other nation.<sup>1</sup>

### 1.1.2 Developing period of TCM

With development of the Chinese Nation, the theory of TCM is also constantly improving.

The Han dynasty (206 B. C. – A. D.220), which is considered the most glorious epoch in Chinese medical history, was rendered especially memorable by the fact that during this period there lived Zhang Zhongjing, Hua Tuo and others, the greatest physicians of China. Much stress was laid upon direct observation, thus placing medicine on a more scientific basis.

Hua Tuo, who was born in Bo County in Anhui province, was one of the famous ancient physicians and the first famous Chinese surgeon. He is the first in the world to develop the use of

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<sup>1</sup> Tian Jingfu, Traditional Chinese Medicine: Past, Present and Future, The Role of Traditional Medicine in Primary Health care in China

<sup>2</sup> <http://www.taijichinesemedicine.com/bienque.htm>

<sup>1</sup> Tian Jingfu, Traditional Chinese Medicine: Past, Present and Future, The Role of Traditional Medicine in Primary Health Care in China

anesthesia, and further the Chinese knowledge of anatomy. When using acupuncture and herbs, he preferred simple methods, using a small number of acupuncture points and formulas comprised of only a few herbs. He practiced Qi Gong and taught the “frolics of the five animals,” a practice still used today. The five animals are tiger, deer, Bear, ape and crane.

Zhang Zhongjing, who is the most famous of China’s ancient physicians, often spoken of as the Chinese “saint of medicine”, is especially known to later generations for his *Shang Han Za Bing Lun*(*Treatise on Febrile Diseases and Miscellaneous Diseases*), which contains over 100 effective formulas (many of them still used today), and implies a theoretical framework that led to hundreds of books analyzing, explaining, and reforming it, ranks with *the NeiJing* in importance and deals with febrile diseases and other non-febrile diseases such as asthma and jaundice.

With the advent of Zhang Zhongjing a new era was created. Diseases were studied by a clinical system of “treating the patient according to syndrome differentiation” that was established for the first time, which is still widely used nowadays.<sup>1</sup>

Theory of TCM is more perfect than that of the past.

Sun Simiao of Yuncheng County in Shaanxi province, who was a famous doctor of the Tang dynasty, was named Herbal King by the offspring. He gave much energy to the virtue of medicine and said: “Human life is worth a thousand gold bars, with a virtue of one prescription you can fix it”. He wrote the famous works *Qian Jin Yao Fang* and *Qian Jin Yi Fang*, which contain from the theoretical foundation of TCM to clinical diagnosis and treatment, medicine utilization and folk remedies.

In his theory the virtue of medicine came into play as well as thorough understanding of obstetrics and gynecology. In addition, he contributed greatly to malnutrition illnesses, such as recommending seaweed to people living in the mountain regions who suffered from goiter, and recommending liver of ox and sheep for person suffering from night blindness. His thoughts still have far-reaching meanings to the development of TCM even to this day.

There have come into being four branches of TCM in the Jin-Yuan dynasty, each one with his characteristic and thesis, which improved the theory of TCM infinitely. For example, Liu Wansu, who established “cooling school”, promoted the idea of using herbs of cooling nature to treat these conditions, which was the opposite direction of many of his predecessors using warming herbs; Zhang Zhihe is known as the father of the “attacking school” of TCM, emphasizing the use of diaphoretics, emetics, and purgatives to attack the pathogen and drive it out of the body; Li Dongyuan established his famous thesis that most diseases were due to injury to the stomach/spleen system, which occurred as the result of intemperance in eating and drinking, overwork, and the seven excessive emotions; Zhu Danxi was good at temperance and use of tonic formulas, especially those that nourished the kidney and liver, for he believed that people suffered from chronic disease mainly due to overindulgence in pleasurable things and activities, resulting in debility of the *yin* essence.

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<sup>1</sup> Tian Jingfu, *Traditional Chinese Medicine: Past, Present and Future, The Role of Traditional Medicine in Primary Health Care in China*

TCM was further improved in the Ming dynasty (A.D.1368-1644) largely. On the one hand, the most outstanding contribution was the publication of *the Compendium of Material Medica* by Li Shizhen, which improved theory and enlarged the scope of medical materials. Li Shizhen devoted about 30 years to it, listed 1094 drugs from plants, 443 from animals, and 354 from minerals and other substances on his works. Under each drug, the proper and popular names, source, form and general history all are given, together with information from the literature and critical remarks, with details concerning collection, preparation, dosage and presentation, and a description of the nature and properties of each drug, with recipes and indications for use by the author. As early as the seventeenth century, it was translated successively into Latin, Russian, Japanese, English, German and French, and it spread all over the world.<sup>1</sup>

On the other hand, Zhang Jingyue, who wrote many works on gynecology, pediatrics, surgery, pulse diagnosis, and an analysis of *the NeiJing* called *the Lei Jing*, was one of the most famous doctors on Chinese history, which perfected theory of TCM and made TCM develop rapidly.

The Wen Bing(infectious febrile diseases) school was founding gradually in the Qing dynasty(A.D.1644-1911), which could make people further understand Wen Bing, whose head doctors were Wu Youke, Ye Tianshi, and Wu Jutong, and famous works was monographs on *The Wen Bing Tiao Bian*.

In all, TCM has taken shape unique system and theory in practice for thousands years, which develops his own way according to internal theories.

## **1.2 The present situation of TCM**

Since the beginning of the 19<sup>th</sup> century, with western medicine entering and developing rapidly in China, TCM development was affected severely.

### **1.2.1The situation of TCM in the first half of 20 century**

In 1840s, China was defeated in Opium War. After seeing the western strong warships and artilleries and the power of Western science and technology, many Chinese wanted to go all out to make the country strong.

At the same time, western medicine had been developed rapidly after the Opium Wars in China, its remarkable and universal effect has reached common understanding, so some elite of China only set eyes on its comparative advantages, but seldom studied the virtue of TCM, often criticized the shortcoming of TCM with western medicine strongpoint.

In political revolutionary times, to negate the old drastically, some revolutionist discarded TCM as feudal culture, made the academic debate between TCM and western medicine take on the political odor that made use of administrative, juristic methods to discriminate and annul TCM, and retard TCM development.

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<sup>1</sup> Tian Jingfu, *Traditional Chinese Medicine: Past, Present and Future*, *The Role of Traditional Medicine in Primary Health Care in China*

For instance, in Japan, *Meiji* Reform affirmed Western medicine to be the only legal health care system. Han medicine (TCM) has been interrupted since the reform, up to this day, there never reappears TCM. This is the wicked example that the countries all over the world eliminate TCM, the Kuomintang (KMT) government followed that of Japan.

Early in the end of Qing dynasty, when the “Chinese learning as the fundamental frame, Western learning for practical use” was advocated in the Constitutional Reform and Modernization, there were many people who began to depreciate and negate TCM. During KMT period, under the influence of “total Westernization”, it was tried twice to annul TCM. In 1914, education minister Wang Daxie proposed: “From now on, I have determined to annul and abolish TCM”<sup>3</sup>. In 1929, the Ministry of Health of the KMT government adopted also an Act Annul Chinese medicine to remove obstacles for medical and health affairs, which was proposed by Yu Yunxiu<sup>4</sup>.

But both resolutions have not been really implemented due to the opposition of the people. So, those authorities that despised TCM again suggested to thoroughly reforming TCM with Western medicine, and this thinking has deeply influenced the Chinese medical circles from beginning to end.

On the other hand, since the 20<sup>th</sup> century, the Chinese educational circles have to a great extent regarded “Western learning” and “traditional Chinese culture” as two aspects respectively, which are opposite and contradictory to each other. From Liang Qichao and Sun Zhongshan to Chen Duxiu and Lu Xun, they all believed that TCM can cure the diseases and do not deny its curative effect. But they also held that Chinese medicine was not scientific, with their central argument being “Though Chinese medicine can cure diseases, but nobody can explain the logic principles of curing diseases to the people”.

The wrong knowledge of elite of the nation makes TCM academic circles neglect and look nonchalantly at the traditional culture and despise and distort the theory of TCM. Therefore, traditional Chinese medicine practitioners and TCM have always been in the position being investigated, examined, queried and reformed.<sup>5</sup>

So, TCM developed on thin ice in the period.

### **1.2.2 The situation of TCM in the near 50 years**

At the beginning of the foundation of the People’s Republic of China (PRC), all various political movements were “to eradicate the old and foster the new”, but still regarded TCM as “obstinate” and “non-scientific”. In the 1950s, Wang Bin, who accepted Yu Yunxiu’s opinion, the vice-Minister of the Public Health put forward that TCM was feudal and should be annulled along with the feudalism. However, the government criticized this. President Mao Zedong put forward

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<sup>3</sup> Deng Tietao, *The Future of Traditional Chinese Medicine*. <http://vip.6to23.com/nztcn/wrtings>

<sup>4</sup> Yu Yunxiu, *Abolish Old Medicine to Remove Obstacles for Medical and Health Affairs*, The Central Public Health Conference, 1929.2.27

<sup>5</sup> Jia Qian, etc. *The Great Significance of Establishing Strategic Status of Traditional Chinese Medicine*, Engineering Science, Vol.6.No.7, 2004.



that “traditional Chinese medicine is a great treasury”<sup>6</sup>, affirming the policy to protect TCM. Then, TCM developed steadily.

Therefore, early in the 1950s the Party Central Committee of China has clearly defined the way of development of medicine by “laying equal stress both on TCM and western medicine” and enacted the correct policy that TCM and western medicine should be of “long-term coexistence and joint development”. And in 1982, “To develop TCM” was written in the Chapter 21 of *The Constitution of the People’s Republic of China*. From then on, TCM development stepped out, by the end of 2003, there have been established 32 TCM universities and 2868 TCM hospitals, etc.<sup>7</sup>

With developing rapidly, TCM played important roles in primary health care in China, especially in rural areas. Chinese government resolved the question of people’s healthcare with TCM by and large in the 1970s, the health service of coverage of Chinese population is about 90%.

However, in the latest 20 years, the policy of the Party Central Committee and the gist of the Constitution haven’t been carried out conscientiously. In aspects of the law and policy, administration and state investment, scientific research and medical practices etc., stress was laid, in general, on the western medicine; the status of TCM is increasingly coming down. At present, TCM is in a difficult position. TCM plays partial roles in nation health care.

For example, there were 276,000 TCM doctors in China in 1949. In 2001, there were 334,000 doctors, an increase of only 21% than in 1949. While there were 87,000 Western medicine doctors in 1949, and the figure has been increasing year by year. In 2001 there were 1,751,000 doctors, increasing by 20 times, with an increase speed of 95 times as that of TCM (Figure 1- 1).<sup>8</sup>

### **Figure 1-1**

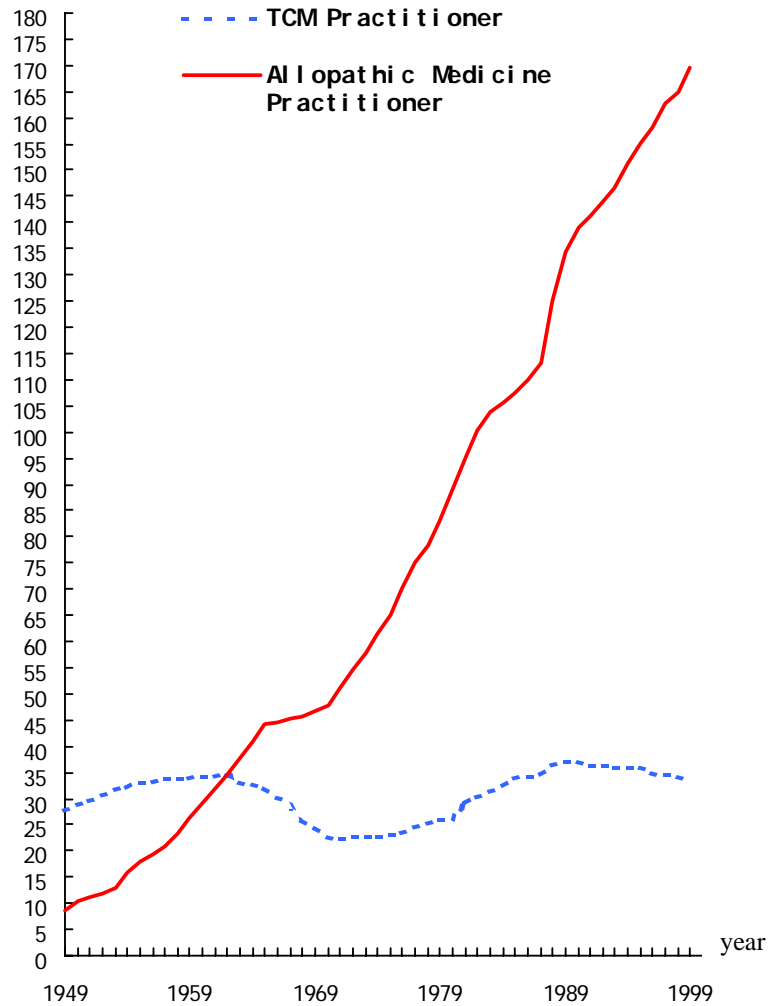
Growth of TCM Practitioner And Allopathic Medicine Practitioner From 1949 to 2001

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<sup>6</sup> Mao Zedong. *Traditional Chinese Medicine Is A Great Treasury*. Collected Works of Mao Zedong, Vol. VII, Beijing, The Central Documents Research Institute, 1993

<sup>7</sup> National Bureau of Statistics of China, *China Statistical Yearbook 2004*, China Statistics Press, Beijing, China

<sup>8</sup> National Bureau of Statistics of China, *China Statistical Yearbook 2002*, China Statistics Press, Beijing, China



Source: China Statistical Yearbook 2002

Another example is TCM administrative systems. TCM has its own theory and characteristic, whose administration must conform to its own theory and laws. But TCM is supervised according to the administrative patterns of western medicine, which could hamper TCM development and reform TCM theory to adopt western medicine standard.

Moreover, TCM spread all over the world rapidly in the latest 50 years. Chinese TCM export increases gradually (Table1-1~1-5).

Table 1-1

### Japan imports quantity of TCM from China

from 2000 to 2002

| Year | Import quantity (10 <sup>4</sup> tons) | Import expense (10 <sup>4</sup> \$) |
|------|--|-------------------------------------|
| 2000 | 8.44                                   | 12551                               |
| 2001 | 9.23                                   | 13653                               |
| 2002 | 6.56                                   | 14194                               |

Source: Customs Administration People's Republic of China 2002

Table 1-2

### Korea imports quantity of TCM from China from 2000 to 2002

| Year | Import quantity (10 <sup>4</sup> tons) | Import expense (10 <sup>4</sup> \$) |
|------|--|-------------------------------------|
| 2000 | 4.2                                    | 4374                                |
| 2001 | 4.1                                    | 4454                                |
| 2002 | 4.3                                    | 4759                                |

Source: Customs Administration People's Republic of China 2002

Table 1-3

### Vietnam imports quantity of TCM from China from 2000 to 2002

| Year | Import quantity (10 <sup>4</sup> tons) | Import expense (10 <sup>4</sup> \$) |
|------|--|-------------------------------------|
| 2000 | 0.81                                   | 721                                 |
| 2001 | 0.40                                   | 452                                 |
| 2002 | 1.1                                    | 2011                                |

Source: Customs Administration People's Republic of China 2002

Table 1-4

### The United States imports quantity of TCM from China from 2000 to 2002

| Year | Import quantity (10 <sup>4</sup> tons) | Import expense (10 <sup>4</sup> \$) |
|------|--|-------------------------------------|
| 2000 | 0.81                                   | 721                                 |
| 2001 | 0.40                                   | 452                                 |

|      |     |      |
|------|-----|------|
| 2002 | 1.1 | 2011 |
|------|-----|------|

Source: Customs Administration People's Republic of China 2002

Table 1-5

**European Union imports quantity of TCM from China from 2000 to 2001 (10<sup>4</sup> \$)**

| Year | Germany | the U.K. | France | Spain | Italy |
|------|---------|----------|--------|-------|-------|
| 2000 | 2770    | 1291     | 837    | 1020  | 700   |
| 2001 | 3156    | 1101     | 951    | 1242  | 702   |
| 2002 | 2046    | 554      | 1026   | 488   | 719   |

Source: Customs Administration People's Republic of China 2002

Many international universities, colleges, and institutes of TCM have been established in the world, i.e. there are 80 colleges of TCM in United States since 1980s. At the same time, Chinese university and academy of TCM have trained numerous acupuncturist and students for 130 countries and regions since 1970s.

Now, Traditional Medicine (TM) including TCM is accepted gradually, and is becoming more and more popular in the developed countries. The percentage of the population which has used TM at least once is 48% in Australia, 70% in Canada, 42% in USA, 38% in Belgium, and 75% in France.<sup>9</sup>

**1.3 The developing prospect of TCM**

TCM and western (modern) medicine should be equal and complementary each other. They are two human health care systems, which shouldn't replace each other.

TCM has the characteristic of the direction thinking, which shapes a medical theory that is integrated, systemical, and advanced, developing for thousands years. Under the theory, TCM has made indelible contribution to the reproduction and prosperity of the Chinese nation, and under the countless attacks of pestilence has never made its people die in millions such as once occurred in Europe.

TCM attaches importance to the time structure of human body, and emphasizes analysis on pathogeny and pathogenesis, and integrates cognitions that come from biology, psychology, society, and physical nature. It is an original science, whose scopes of research are beyond that of western medicine.

TCM calls for prevention no less than cure and focus should be on health preserving. The most

<sup>9</sup> World Health Organization, Key points: WHO Traditional Medicine Strategy 2002 - 2005, WHO Traditional Medicine Strategy 2002 - 2005.

important methods of disease preventing and health preserving are to keep mental health and manage to keep heart in a good condition. This is just what western medicine has neglected in the past and begun to lay stress on at present.

TCM emphasizes that the most important thing is to prevent disease and treat ailment in time so as not to let it become a serious one. And this is also just what is required by the modern preventive medicine. TCM supports mental healing and holds that to cure a disease, the heart should be cured the first, laying stress on the harmony between mind and body, man and society, as well as man and nature. These are all what future medicine energetically advocates.

TCM is accessible, affordable, safe and effective. TCM makes health preserving by a whole set of its theory that has been taken shape from *Taiji* to sitting in meditation so as to ease heart, should they be exercised once in the morning or at night, people will have a calm and peaceful mind and glow with energy all day long, and build up body strength. They all are fit for both the young and the old. This is just the way that modern mind-psychology and the combination between medicine and sports are to explore.

TCM prevents disease in four seasons from food nourishment and diet treatments to cupping therapy and cutaneous scraping therapy, many people have all learned a set of skills to prevent and cure minor diseases from TCM.

TCM practitioners prevent and cure diseases with an accessible, affordable and effective way which is a whole set of methods from Chinese medical herbs treatment to acupuncture, moxibustion and massage, etc. They can also have many unique methods to prevent and cure some difficult and complicated cases with significant results in the world; there is a way to keep in good health that will play a more significant role in preventing and curing many so-called modern diseases, such as all kinds of sub-health state and diseases with which the patients need long-time rest and nourishing.

Over the past thousands years, TCM has developed a set of both practical and advanced, universal and thorough, and systematic health care system, which is notably characterized by simplicity, convenience, affordability, safety, efficacy and effectiveness. To make use of excellency of TCM to resolve the problem of Chinese people's health care, especially farmers, it should be established that healthcare system is laying equal stress both on TCM and western medicine. This may provides the brand-new mode of healthcare for the other countries.

Meanwhile, medicine scientific researches should study human being health other than diseases in the 21<sup>st</sup> century. Therefore, TCM should be one of the main bodies, and can guide leading direction of medical research.

## CHAPTER 2 The Value of TCM

### 2.1 The general viewpoints of TCM theories

Like many other types of traditional medicines, TCM has its own unique cultural and philosophical background, and its basic theories are told by some related concepts and ideas. People who accept modern scientific and cultural education perhaps find it difficult to understand those seemingly ancient and remote civilizations, and thus the value of TCM remains undiscovered. It had been the case until WHO worked hard to achieve the goal of health care for all, TM emerged to be a technical resource probably meeting the needs of people or countries who could not afford. Although TCM has been appreciated by WHO as a powerful one, it still has a long way to go. Some introductions below about TCM maybe helpful for getting rid of bias and misunderstandings upon it, and enable people to follow the suitable way to integrate TCM with modern medicine.

#### 2.1.1 Both man and nature are originated from the same thing

It has been a general accepted viewpoint that holism is a key element of all TM. Therefore, when reviewing the literature on TM (both herbal medicines and traditional procedure-based therapies), the theories and concepts of the individual practice of TM, as well as the cultural background of those involved, must be taken into account (<sup>10</sup>). Nevertheless, TCM is not an exception of this basic principle.

During the Spring and Autumn and Warring States Periods (770-221 B.C.) in the Chinese history, there existed so-called a hundred schools of thought contending about what the true knowledge should be, the school of medicine was one of them. When *Neijing*, the basic classic of TCM was given to birth, those knowledge accumulated generation by generation, including experiences, practice skills and theories all were organically integrated into one whole system. In addition to this system was a collection of knowledge, it also had its own theories that guided people collecting and classifying those different types of knowledge. In the following times, although TCM had developed a lot on the skills and technologies of disease treatment, its basic theories still kept unchanged and effective. A latest example was shown during the spring time of 2003 when SARS, an infectious disease prevailing in China and other countries or districts, the theories of TCM were used by Chinese doctors as guidelines directing them finding out ways letting this

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<sup>10</sup> World Health Organization. General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine. Geneva, World Health Organization, 2000. ( document reference WHO/EDM/TRM/2000.1).

disease gone. So the theories of TCM are no doubt valuable in modern times, and its basic ideas should be learned, studied and applied to solve modern problems.

The theories of TCM consist of concepts about the Heaven, the Earth and the man itself which all of them are movable and changeable, and this is why scholars also think *the Book of Changes* is another elementary canon of TCM. Knowing really and directly the changes of one's health and disease are not only associated with oneself, but also with the conditions surrounding him which includes time, place, society, etc. Why these factors can influence upon an individual person is explained philosophically as follows: all of them, no matter what they are at the moment, are originated from the same thing that exists materially or spiritually. The idea above was expressed by another book of Taoism, *Laozi* or *Daodejing*, the supreme value to TCM because it possesses that both man and nature are evolved from the primary thing called *Tao*. So the natural law guided by *Tao* should be followed and should not be broken in any way. The insight into the relationship among these classic books could help doctors and researchers understand TCM quite well. Only when they have a holistic viewpoint and thus find the wisdom of harmony and co-existing, they can be called qualified personnel. *Neijing* once tells exactly the truth: "Man is related with heaven and earth, and corresponds with the sun and moon." ("Discussion on Exopathic Wind and Rain", Chapter 79 of *Miraculous Pivot*)<sup>11</sup> Believing in it and then using it with confidence in their practical works, TCM doctors never lose its value and effect.

### 2.1.2 The body is in unity with mind

Just as man is in unity with nature, TCM theories also link the living body with mind in a perpetual way, and that is to say, they are inseparable. Particularly, TCM theories look the body as a system which is composed of *zang*-organs and *fu*-organs, channels and collaterals, essence, *qi*, blood, body fluid, five sense organs and nine orifices, limbs as well as tendon, vessel, muscle, skin and bone. Although all these parts are different in names and functions, they are dominated by the same mind that also means vitality. TCM theories especially emphasize the functions of mind, and many other words, such as spirit, mentality, consciousness, thinking, emotion, thought, character, even the external manifestation of life, they together reflect the sophisticated meanings of it. In a word, TCM theory is the theory about mind or vitality, and this is testified by *Neijing*, which says "patients with vitality will be cured; otherwise, they will die." ("Discussion on Treating Diseases with Grafting Spirit and Altering *Qi* in Witchcraft", Chapter 13 of *Plain Questions*) Another sentence in the canon conveys this meaning in a more concise way that says "Life process ends off as soon as vitality dies away." ("Discussion on Conventions of the Five Evolutive Phases", Chapter 70 of *Plain Questions*)

Four aspects including physical, mental, spiritual and body-mind are considered by modern medicine step by step, doctors also are accustomed to the classification above. TCM theories classify these four aspects on the basis of mind, and this shows a different holistic way people observe the health and disease. This character of mind and its domination over the body is the key as well as the most mysterious manner of TCM, and its relationship with heart is the core theory in TCM. *Neijing* thinks the heart is "the master of the five *zang*-organs and the six *fu*-organs and the

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<sup>11</sup> The Book of *Neijing* consists of two books: One is named *Plain Questions*, the other is named *Miraculous Pivot*.

house of mind.” (“On Invasion of Pathogens”, Chapter 71 of *Miraculous Pivot*) Additionally, “The heart is the sovereign organ, where mental activities originate ... if the sovereign is sound, all the subordinate organs will faithfully attend to their own duties ... If the sovereign is unsound, there will occur disorder in *qi* and dysfunction among the twelve internal organs, thus severely damaging the body”. (“Discussion on the Functions of the *Zang-Fu*-Organs”, Chapter 8 of *Plain Questions*) Those scientists who want to find the micro-fundamental material of herbal medicines and always meet to failures lacks the knowledge of mind and heart of TCM, and without it, the mechanism of TCM could not be explained at all. From this point of view, the abilities about how to know the mind are more basic than those knowing the body. For example, why the channels remain scientifically unsolved, the main reason is that the character of mind has been overlooked during the test. People should pay more attention to the mind in stead of to the body if they intend to reserve the true value of TCM.

### 2.1.3 Its holistic medical pattern

As for the mainstream medicine, its medical pattern has changed greatly nowadays in comparison with the biomedical times. Doctors are well aware of that they should consider the physical, psychological, social and even ethical conditions when they try to help their patients. From the changes people may think easily of that modern medicine has achieved obvious progresses in order to keep pace with the transformation of lifestyle. So many problems, as the by-products of lifestyle must be solved because they make people suffer on their health as a whole. TM also can be used to solve these problems, and the strengths and weaknesses of it, and its indications for use and its limitations might be summarized as follows<sup>(12)</sup>:

|                                    |                                     |
|------------------------------------|-------------------------------------|
| <b>Strengths</b>                   | <b>Weakness</b>                     |
| Absence of side effects            | No standardization                  |
| Use of holistic approach           | No scientific basis                 |
| Self-sufficiency (local materials) | Not investigated by modern research |
| A form of appropriate technology   | Shortages in supply of medicinal    |
| Effectiveness proven by time       | Substances, where demand is heavy   |
| Low toxicity                       |                                     |
| <b>Indications</b>                 | <b>Limitations</b>                  |
| Chronic degenerative diseases      | Unsuitable for emergencies          |
| Psychosomatic disorders            | Little used for diagnosis           |
| Geriatric patients                 |                                     |
| Treatment of pain                  |                                     |

The summaries above have concluded that TM has its own values to the modern society.

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<sup>12</sup> World Health Organization. The Role of Traditional Medicine in Primary Health Care in China. (Based on an Inter-Regional Seminar Sponsored by the WHO in Association with the Ministry of Public Health of the People’s Republic of China, 9-21 October 1985). Geneva, World Health Organization, 1986



Nevertheless, these values still are mixed with weaknesses and limitations. This phenomenon has puzzled many people who possess scientific research methods and it has reminded people that TM is rooted in respective cultures and traditions, so there are many issues and perspectives that need to be examined aside from the basic science and clinical aspects. As a typical one of TM, TCM is rooted in Chinese cultures, and just as having said above, it has a deep relationship with Chinese philosophies. We must say now that TCM explains the world not only in a philosophically way, but also in a holistic way. The “use of holistic approach” has given TCM a profound influence that people can not understand and practice it well if they misuse its holistic medical pattern.

TCM theory thinks an individual as a whole, and this characteristic of thinking endows its holistic medical pattern. Of course, those people lived thousands of years ago had no microscopes to use, and so they certainly can not find virus under it. But the wisdom accompanied by birth enable them to treat those disadvantages through a comparatively active way. Thus TCM theory especially put emphasis on the mind or vitality of man and by it the thought of becoming and creating the dwelling of the center of the theory. While the natural sciences separate themselves from the religions, philosophies and other cultural disciplines in western histories, TCM theories still integrate them as a whole, and further more it may be said as that TCM still remains the core values of religions and philosophies. It is the wholeness that lies beyond the scope of natural sciences, and it is hard to say explicitly what the wholeness idea or the mind is if people lack the experiences of it, so TCM remains a very difficult system to cope with in comparison with mainstream medicine. Therefore, its basic principles can not be proven eventually by scientific-based means or by evidence-based medicine at present time.

Fortunately, attitudes towards TCM have changed in spite of that solid scientific evidence is still emphasized. It has been realized that the effects of TCM have been “field-tested” by tens of thousands of people for hundreds of years. <sup>(13)</sup> In fact, learning from the history can give people more confidence in terms of “evidence of practice” than any single methodologically rigorous clinical trial, and it is the “evidence of practice” that gives birth to the holism philosophically than scientifically. The knowledge that is correct scientifically is not always useful to the practical therapies of TCM, and thus careful attentions must be put on its holistic medical pattern.

The difference in the holistic aspect between TCM and mainstream medicine make the former a very valuable category of knowledge. It can lead us to find out what the freedom of life is and what the justice of nature is. From the supreme values of freedom and justice, people should link the TCM with social sciences instead of only with the natural sciences, and the relationship between science and humanity also should be considered as an important factor when the values of TCM can be judged upon. Of course, these viewpoints about TCM can not be understood easily if people have not studied the elementary knowledge about it. So many problems such as what its scientific mechanism is and whether or not it can be developed by scientific methods have been given rise to it when people just look it as ancient medical resources. WHO has found out its values in meeting the need of health for all, but when the health care is delivered to individuals, medical knowledge has already changed into a holistic knowledge and concerns with politics, policy, economics, society, organization, science and so on. How to integrate these factors as a

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<sup>13</sup> World Health Organization. General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine.

whole? Much should be learned from the holistic pattern of TCM, and maybe that is the true value of TCM.

## **2.2 About the therapies of TCM**

TCM has its history as long as Chinese culture, and when its theories had been founded and systematized through *Neijing* thousands of years ago, various types of techniques for prevention and treatment had been collected and developed according to it. These techniques can be classified as medication therapies called the traditional Chinese materia medica and non-medication therapies such as acupuncture, moxibustion, massage, acupression, heat, *taiji*, *qigong* and so on. The latter are also regarded as procedure-based therapies which have been spread around the world. Generally speaking, these techniques are able to offer certain advantages such as simplicity, efficacy, economy and acceptability which make it worth serious examination by anyone responsible for the provision of medical care, and aside from it, more interesting functions of it should be studied further if health for all can come true.

### **2.2.1 The self-healing power is the key of TCM and make it possible for “health for all”**

Primary health care became a core policy for WHO in 1978, with the adoption of the Declaration of Alma-Ata and the strategy of “health for all by the year 2000.” Much progress has been achieved from that time, and challenges are yet more to be confronted. Just as the specialists have pointed out, the following four principles should be discussed for further development in achieving the goal:<sup>(14)</sup>

universal access to care and coverage on the basis of need;

commitment to health equity as part of development oriented to social justice;

community participation in defining and implementing health agendas;

intersectoral approach to health.

From the four aspects mentioned above as well as other factors concerning health, it is generally the truth that the deficiency in resources is the principal obstacle for fulfilling the goal. “Health for all” needs the perfect distribution of all kinds of health resources. But actual policies, scientific technologies, economical supplies, and social structures more or less can not keep their paces with the growing health needs. TM has already played a very important role in those developing countries for ensuring primary health care, and self-sufficiency is the chief strength of it. Although self-sufficiency regards mainly for the local materials, this concept can be employed to serve the TM theories, and especially the TCM theories. From the core principle of TCM, a different way should be shown theoretically and perhaps should be followed to achieve the goal.

Guided by the concept of holism of relevant adaptation of man to nature, TCM theory holds that

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<sup>14</sup> World Health Organization. The World Health Report 2003. Shipping the Future. Geneva, World Health Organization, 2003.

all the life activities of the human body must comply with the changes of nature, otherwise, diseases will occur and may even endanger man's life. Therefore, *Neijing* suggests that, to preserve his health, "the wise man will surely conform himself to the changes of the four seasons, adapt himself to the cold of winter and the heat of summer, control joy and anger and live a regular life."("On Spirit", Chapter 8 of *Miraculous Pivot*) Why man should do like this? TCM declares philosophically that the universal law has the power to sprout in spring, to grow in summer, to harvest in autumn and to store in winter, and if it is not conformed to, there will be no law and discipline to be followed. It is just the natural law that man must conform to, the active power dominated and cultivated by mind is based on, and so the self-healing power is based on. Without well aware of the self-healing power, the performances and effects of TCM could not be understood and put into use properly. Instead of suppressing individual symptoms, TCM looks the disease as a holistic result and addresses the whole person. By utilizing self-healing power and rebuilding immunity, health is naturally restored and disease disappears. If health and immunity are thereafter conscientiously maintained, the individual is no longer vulnerable to disease, and thus "health for all" will be possible theoretically.

We all know well that the mainstream medicine is allopathic medicine, and its adverse effects showed out that TM/TCM has its own values in the modern society. In some developed countries, TM/TCM is gradually thought as CAM and is used to treat some diseases, and this alternative is more practical than scientific meaningful. The research into the self-healing power shows that it is somewhat belief-linked, and this can be used to explain the diversities of TM as that of religions and cultures. From the past we learn that TM had been developed based on the religious culture, and if people can not believe in doctors, there will be no effect even though doctors have done their best to their patient. For example, *Neijing* once says that: "When treating a patient, a doctor must collect the comprehensive conditions of his patient which includes what he has looked about and touched about, whether or not the patient is in sound mind and what the disease has developed. If the patient believes in supernatural beings and can not treat it wisely, the doctor should not tell him the virtual truth. If the patient dislikes needles and stones, the doctors should not apply the concerned techniques to him. The patient who refuses to the treatment will die absolutely, and the reason is that there will be no effect if the patient does not believe in the doctor and his techniques."(The Remained Discussion on Five *Zang*-organs", Chapter 11 of *Plain Questions*)

We know now that religion and science are two different disciplines, and can not explain one by another. Although religion once had been doubted skeptical by science, it still possesses its own values and ways in the modern society. We can not deny that those various new types of religions have developed all over the world, and the rediscoveries of TM/TCM can be compared with that of religions. What people have learned from the religions can be used to explain the self-healing power similarly, and a man can not be helped if he does not believe in himself. If people do acknowledge that everyone is born equal and all of them have their own self-healing power, the problems remained will be that what kinds of knowledge and techniques can help people cultivate and enhance their self-healing power. This is another unique way for "health for all", and TCM is good at doing these things. If people have not realized this character of TCM, it will be impossible to use its theories and techniques correctly and properly, and TCM would be restricted by unsuitable ways.

Speaking theoretically, the principle of self-healing power encourages people treating diseases by themselves, and emphasizes on the full play of one's subjective initiative. It tells people that one's health is depended only upon and is controlled by oneself, anyone else can only play the role of a helper. This is seemingly different from the way that medical treatment is performed by a doctor. But as for TCM, the way of self-therapy and self-care is the same in principle with the way of cure by a doctor. Thus we may conclude that if someone takes part in the training class of TCM and educated well, and has been managed to use correctly the TCM knowledge, he will be a doctor of his own and serves for himself. Only a man is independent on others, he can be called self-sufficient and has the ability to help others. This concept comes from the Chinese culture and roots deeply in religions such as Taoism, Buddhism, and Confucianism, and in order to achieve the goal of health for all, it should be considered as the most valuable concept. Therefore, the most difficult work lies in that how can people know really the value of self-saving and self-healing power.

TCM has practiced this way for thousands of years, and has accumulated rich experiences. On one hand, TCM doctors apply the therapies such as acupuncture, moxibustion, massage, herbal medicines, emotion-interchecking to cure their patients, and in the other hand, they also direct the patients practicing those kinds of do-it-yourself activities such as mind cultivating, *taiji*, *qigong*, meditation as well as the rational way of life for enhancing the treating effects. In some cases, the therapies used by doctors can be gradually transformed into self care techniques, and to be accepted by more and more people as their daily routine. When these therapies became popular and publicly conscious, some folk costumes were formed and played the role of promoting public health. In a word, TCM has evolved a whole set of therapies for prevention, health promotion and health education, and the modern society may learn a lot from it if we can give the deserved respect to it. But the fact is that it has been found easier to break with the past than trying to live with it. Fortunately, profound changes have taken place in the fields of science, politics, culture and society, and people have learned well to respect each other and live peacefully together. So TCM will be studied and applied as a whole system in stead of merely some parts of it.

### **2.2.2 Medication therapies are developed from the non-medication therapies and only the complementary of the latter**

TCM therapies are generally divided into two categories: non-medication therapies and medication therapies. The difference between them is mainly that the latter involves the use of herbal medicines, animal parts and minerals and the former does not use them. Because of these visible materials, many researchers have been absorbed in finding out their active ingredients in order to explain the therapeutic activities. Although some active results have been discovered and already have their practical effects in clinical use, those experienced specialists in traditional Chinese materia medica still insist that the functions of TCM medication therapies are underestimated greatly. What attention should be paid to in the research and evaluation of traditional Chinese materia medica? How can we give them a mostly proper application? The well-documented history of TCM will supply us the theories and methods for realizing the know-how.

A man can not know exactly the animals in a zoo if he keeps staying outside of it. Similarly the

concerned literatures of TCM must be studied systematically or holistically for understanding what TCM is. While *Neijing* had laid the foundation of TCM theories and collected many kinds of non-medication therapies before the Eastern Han dynasty, the book *Treatise on Febrile Diseases Caused by Cold* written by Zhang Zhongjing developed systematically the medication therapy afterwards. The two books above give us a clue to study carefully the therapies of TCM, and the information in them do have the value to judge certainly what kind of therapy should be more fundamental.

Now the question is that by what criterion can people discover and invent these therapies and ensure their curing effects. Of course we can not subscribe them to the active ingredients just like the scientists have done nowadays. People living in modern times are always accustomed to use tools to live, study, and create, and they have forgotten or can not imagine how could the ancestors do if they had not invented those tools. Anthropologists have investigated these themes and are shocked by the abilities of man's instinct. For the ancestors, the most valuable kind of tool was their wisdom, and they could not depend on anything but themselves. We can say now that TCM theories, therapies and the holistic idea alike were generated from the wisdom of instinct. The naturalist declares the values of nature now and pursues the freedom as the ultimate goal of development, and it is just the natural law that TCM is based on. Conformity to nature and following the changes of nature to act are the supreme principles of TCM theory and Taoism. So TCM theories judge everything by the criteria of their natural characters and make use of those characters serving the therapies.

It is generally the principal and most important idea of TCM that people lived in ancient times were innocent and had not lost their natural characters, so very few diseases occurred during that times, and people were in "a state of peace and tranquility without avarice and wild fancy" ("Discussion on How to Keep Innate Vitality", Chapter 1 of *Plain Questions*) and enjoyed their healthy lives. This idea can be told by the name of Chapter 1 and Chapter 2 of *Neijing* which are respectively the 'Discussion on How to Keep Innate Vitality' and the 'Discussion on Regulating Mental Activities in Accordance with the Changes of Four Seasons'. Unfortunately, people could not keep their natural characters because of the gradual evolving of the civilization, and diseases occurred when people were not to be what they were naturally. So TCM theories and therapies pay all of the attention to preserve and restore one's natural character, and ask the society to change towards the freedom and justice so as to let people undisturbed and keep their health.

From the idea mentioned above we learn that TCM theories think the disease caused by the losing of one's natural character, or by being not holding in a whole condition of the mind. The therapies would have their effects and disease would disappear as long as the whole condition is restored. Many different kinds of therapies can be used to reach this effect, and the selecting of therapies depends on the concrete condition of a patient. According to what have been described in *Neijing*, the therapies were invented one after another and from the kinds of mind cultivating to that of needing tools. For example, the preventive measures are thought to be the most powerful therapies in TCM for their mind cultivating effects, and the concept of "curing the disease not coming about yet" is the highest criterion for appraising a doctor. Another example taken in *Neijing* is the therapy called "*Zhuyou*" that just like the praying, and it can be used in such conditions as the patient being just in a spiritual simplicity and the disease being in its primary stage. The

mechanism of this therapy is that spirit has the ability to remove the “evil *qi*” by employing the power of confidence, and the power is enough until the other non-medication therapies as acupuncture and medication therapies are used for curing the more complicated diseases.

As the representative of non-medication therapies, acupuncture had been developed fully two thousands years ago, and its theories about channels and collaterals in *Neijing* still have practical values as well as scientific values. Traditionally, metal-made needles are used for puncturing at the acupoints selected for the disease concerned, and the form of treatment has spread to many other countries around the world. Although several new types of acupuncture techniques such as electro-acupuncture, acupoint injection, thread embedment at acupoints, acupoint magneto-therapy, and acupoint laser irradiation have been used as substitutions for traditional needles, we must acknowledge that the traditional therapy is the most important and fundamental method. When a TCM doctor manipulates a needle by lifting and thrusting, twisting and twirling, his patient should feel local soreness, numbness, distension and heaviness as the needling sensation. Now the problem is when the needling sensation is also felt during *qigong* exercise and meditation, can these methods be used to replace acupuncture for the treatment? Speaking theoretically, the answer is yes. Similarly, can the non-medication therapies be used to replace the medication therapies? We should say that the answer is the same either. Generally we can say that all the therapies of TCM have the same fundamental theories, and a particular therapy is unique and different from others because it is convenient and applicable for some certain circumstances. TCM theories oppose to the simple use of it, and advocate the wisdom than merely the knowledge of the theories. So *Neijing* says that “the saint uses all the capable therapies to dispose of the disease”, (“Discussion on Different methods from Different Places”, Chapter 12 of *Plain Questions*) and this means that only a man integrates his wisdom with the various kinds of techniques can he make a correct decision and leave no damage on the health of a patient.

Therefore, the question will be that what is the standard a TCM doctor should follow when he selects the therapies to treat his patient? This question may also be described as what is the most suitable therapy for a disease? To answer it, a well-trained TCM doctor will think the process of treatment just as the restoring process of the health. For the rebuilding of the health, two main factors should be considered completely before taking any action. The first factor is the differentiation of syndrome, and this refers to the specific nature of the disease. By observing and analyzing the patient’s reactive state and taking into full account the individual constitutional differences, the collective condition of the patient would be determined and on it the relevant therapies would be selected. The second factor is the patient’s condition of mind, and it is active or passive. If the patient feels unhappy and can not keep it in a peaceful state, the most basic principle in TCM that man should take his initiative to conform with the law of nature and make use of it so as to promote the health would find no place in the therapies. So for the selecting of the therapies, the first and the most powerful one is that keeping the patient in a natural, peaceful, and active state, and this is primarily the non-medication therapy. Only on the basis of the primarily non-medication therapy, the other kinds of non-medication therapies and the medication therapies can play their roles in the disease treatment. The medication therapy that is only composed of herbs or medical materials has not been invented yet in the TCM history, and the medication therapies are inseparably with the non-medication therapies in clinical practices.

In fact, the invention of the TCM herbal medicines was promoted by the infectious diseases and other miscellaneous diseases, and the use of those prescriptions can supply what a man lacks for restoring his health as soon as possible. These therapies can shorten the process the non-medication therapies needed naturally but never break the natural law. They have the meaning of “procedure-based therapy” and should not be thought as the chemical or biochemical drugs. When a TCM doctor makes use of the materials such as herbs in the traditional Chinese materia medica, he should think the herbs as a whole which is always indicated as the Four Natures (or properties) – cold, hot, warm and cool and the Five Flavours - sour, bitter, sweet, pungent and salty. These Natures and Flavours have the character of holism, and can not be observed under the microscope. In a word, they can be felt but can not be seen, and they also have the character of Channel Attribution, in which the five flavours are specifically related to the five viscera and also the five elements. Furthermore, the prescription is composed of components selected according to the principle of “monarch, minister, assistant and guide”, in which the monarch is the main drug, while the others have an adjuvant role. From the names and roles given to the herbs in a prescription, we should be impressed by the imagination of that all the herbs have their own living lives, and these herbs are used to serve the living man who has been out of the healthy condition. So we can make out the difference between the non-medication therapies and the medication therapies in TCM as follows:

Both of them play their roles in employing the patient’s self-healing power to restoring the health, but the non-medication therapies are in a direct manner and the medication therapies are in a manner of somewhat indirect;

The non-medication therapies are comparatively simple and convenient than the medication therapies, and the latter should need the process of baking, roasting, simmering, steaming and boiling before being used. So the medication therapies are always used as the substitution and complementary method of the non-medication therapies;

It is hard to say that there exists a rigid standard except for the natural law directing a TCM doctor to select the suitable therapy, especially when the patient has the conscious of self-healing and self-care. The difference between the TCM therapies is superficial, and the valuation of them should use the same kind of methodology as the procedure-based therapy. Otherwise, many side effects would come about because of the reductive method.

### **2.2.3 Prevention is primary in comparison with medication or non-medication cures and thus lowered the cost and raised the health level**

The mainstream medicine has turned its effort to the preventive work for a long period, and health is thought as the more basic concept than the disease. This variation of instructing idea has already brought about enormous active effects economically as well as socially, and has played its leading role in the progress of our times. As a sign of the changes, WHO has finished several yearly reports named “World Health Reports” since 1996, and everlastingly advocates the importance of prevention. Similarly, TCM has the solid tradition of emphasizing the preventive work, and can be observed easily in the daily lives of Chinese people today. From this special point of view, TCM has successfully lived into the life style of common people, and has decreased the unfair

distribution of health resources.

Taking the consideration of benefits in a long run, the importance of prevention is proposed in *Neijing* and has been emphasized through the TCM history. Doctors believe in the fact after their practical work that prevention in advance can get twice the result with half the effort, and modern health economics has proved it to be true and the effect is even larger than that to be believed. The theories and methods of prevention in TCM are just that used for curing diseases, and the difference is only that they are practiced before the disease attacks and for the promoting of health. People may ask curiously the question that why TCM treats the prevention as the curing, and advises doctors should be a man of doing their best to prevent diseases from affecting upon their patients. We should go further before we let the doubt solved. The question certainly concerns with the viewpoints of what TCM defines to health and disease, and combines them as a holistic manifestation of one's health level.

The concept of the vital-*qi* may help people to understand the meaning of health in TCM, and it refers to the capacity a man has to live and to be used for self-defence. Immunity may have the similar meaning of it but can not confer its core meaning of mind-dominated condition. TCM thinks highly of the vital-*qi* of the human body and defines it as the decisive factor in the onset, development of and the recovery from a disease. *Neijing* once says in one side: "The existence of vital-*qi* within the body prevents the attack of pathogenic factors." ("Discussion on Needling Methods", Chapter 72 Of *Plain Questions*) And in the other side it says: "Wherever there is a success of pathogenic factors, there must be a deficiency of vital-*qi*." ("Discussion on Febrile Diseases", Chapter 33 of *Plain Questions*) Thus the key factor of health preservation in TCM is to preserve and cultivate the vital-*qi* by the various kinds of non-medication and medication methods that include mind cultivating, proper diet, enlivening daily life, *taiji*, massage, acupuncture, herbal medicines, etc. During the practicing activities of these methods, keeping conformity with the natural law is still the highlight, and any carelessness of it would lessen the preventing power.

Although people could benefit from the prevention so much, those who have not accepted the related education and can not practice these methods well would not believe easily in that the knowledge is power. As the result, they will spend more on the medicines, surgical operations and the medical nursing. This tendency was noticed in *Neijing* two thousands years ago, and the unhealthy life style as "addict to drinking and do things recklessly" (Chapter 1 of *Plain Questions*) was told to be given up. By taking many measures in TCM form to ensure the health, Chinese people have lived through numerous adversities and calamities, infirmities and diseases, and the rich experiences and lessons taught by the long history have found out their values in the modern society. WHO had held a seminar to discuss "the role of traditional medicine in primary health care in China" in 1985 and the participants had learned that China could do well to the public health. Nevertheless, the preventing power of TCM had not been paid to attention thoroughly at that time, and when almost thirty years have past, the social-cultural context of TCM is misunderstood and so is despised by the scientists and doctors of the mainstream medicine who are not open-minded in China. This abnormal phenomenon should be changed as soon as possible, and it should be the greatest challenge before Health for All comes true in the future.

### **2.3 The potential values of spreading TCM knowledge**



By being originated from the ancient times and having the history of more than two thousands years, it is called traditional Chinese medicine(TCM). Someone may have the idea that TCM is old enough to confront the fast changing paces of new world, and thus it could be looked only as the knowledge of cultural appreciation. In fact, WHO has never looked down upon those indigenous medicines, and has made out the “WHO Traditional Medicine Strategy 2002-2005” for promoting the use of TM. We now cite the first paragraph of the Strategy as the proof for the problems of TM:

“Traditional, complementary and alternative medicine attract the full spectrum of reactions – from uncritical enthusiasm to uniformed scepticism. Yet use of traditional medicine (TM) remains widespread in developing countries, while use of complementary and alternative medicine (CAM) is increasing rapidly in developed countries. In many parts of the world, policy-makers, health professionals and the public are wrestling with questions about the safety, efficacy, quality, availability, preservation and further development of this type of health care.”<sup>(15)</sup>

The “safety, efficacy, quality, availability, preservation and further development” of TCM are questioned often because of the seemingly under developed type of scientific knowledge. Now we have no time to discuss whether it is scientifically or not before its practical values can be discussed, and we hope that things would be changed after its values are proved to be true practically as well as theoretically.

### **2.3.1 Changing the using ways of drugs and avoiding its side effects**

TCM has its theory based on the holism, and many principles are evolved from it for avoiding the side effects of therapies. For example, herbs are usually classified by their characters into three ranks: high, moderate and low, and the higher the rank, the smaller the toxicity. When they are used in a prescription, doctors should do in the light of protecting the vital-*qi*. And the principle is told in *Neijing* as follows:

“Curing with herbals of greater toxicity, removes away the force of disease six of its ten; and with that of moderate toxicity, then seven of its ten; for the smaller one, the eight of its ten; Even using the herb of no toxicity, removes away nine of its ten. For removing the remaining force of disease, grains, meals, fruits and vegetables are used as herbs. Keeping from over curing and hurting the vital-*qi* is the reason of doing like above. If the disease has not been cured fully, then do like thus again is needed. The following principles must be obeyed during the performing: considers first of the character of *qi* of the year in order to make full use of it, and can not do any harm to the natural vital-*qi* of one’s own, neither enhance the evil-*qi* nor weaken the vital-*qi*, otherwise the patient will be punished by natural law. All the advent of the evil-*qi* and the loss of the vital-*qi* can shorten the life span of the patient.” (“On the Five Commonly Dominating Elements”, Chapter 70 of *Plain Questions*)

When a TCM doctor uses the herb in single form or in mixed form, he will certainly make use of the natural condition and combine it carefully with the vital-*qi* of the patient. Even if for the taking

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<sup>15</sup> World Health Organization. Traditional Medicine Strategy 2002-2005. Geneva, World Health Organization, 2002. (document reference WHO/EDM/TRM/2002.1).

of prepared medicines, the patient must be instructed by the experienced doctor to ensure the correct usage of it. So we conclude that two types of knowledge must be controlled correctly by TCM doctors: one type is the characters and usages of herbs and prepared medicines, another type is the individual condition including the vital-*qi* as well as the concerned natural conditions. Both of them are important for the curing, and the latter is more basic because the vital-*qi* is individually unique and decides the use of the former. If people intend to research how the herbs are used in TCM, they would research first what the vital-*qi* is, and the character of holism in TCM is represented practically by the knowledge of vital-*qi*. It is the theory and principle of vital-*qi* in TCM that the side effects can be avoided effectively, and the quoted paragraph above is typically the guide to actions.

Now in China and around the world, people have been accustomed to taking pills for curing diseases and injecting vaccines for preventing. These measures are very essential to the health of people, and much progress will be made surely in the future. But people can not deny at the same time that the side effects of these measures have brought plenty of pains to patients. We need not to take related concrete examples here for the demonstrating of the facts, what we really need is that by what kind of way these side effects can be avoided and eliminated. If there existed a way meeting the need, then it would dedicate itself to modern society a lot of values.

TCM has the value of avoiding and eliminating the side effects of the modern medicine, and the way has been practiced for more than two thousand years. Unfortunately, both of the ways and its values are forgotten gradually by people as well as the specialists living in modern society. The reason is that the modern industry of pharmacy is based on the reductive principle instead of holistic principle, and drugs are made in the constructive way instead of the way of becoming. In a word, the modern industry of pharmacy has the character of separating from the nature and thus can not return to the condition of holism. The side effects of the drugs are just the result of the principle, and in order to keep it from appearing, the principle of holism must be applied to practice. So we should say that TCM has the value of deconstructing the modern industry of pharmacy. For example, due to the drug hormone and the like is widely and heavily used, one third or more SARS patients treated by western medicine have contracted lung-fibrosis and osteonecrosis. No special squeals have so far been found in SARS patients treated by TCM.

The meaning of deconstructing is that the herbs are not definitely made completely into modern drugs, the way of using herbs in TCM has its value for avoiding the side effects. And for those thousands of types of prepared Chinese medicines, taking them in the traditional way is essential to keep from bad effects. For example, a clinic in Belgium wrote a prescription of Chinese medicine “diet pill” for banting use in 1992. Half of those who have taken the pills for 1~3 years suffered from serious kidney illness, and research found that this is caused by aristolochine contained in the medicine. As a matter of fact, the result due to the composition of Chinese medicine, the rejection of diagnosis and treatment based on an overall analysis of the illness and the patients conditions, to give medicine not according to the differentiation of diseases or to use medicine as food taken excessively for a long time. To blindly revise the prescription of Longdan Xiegan Wan in “Pharmacopoeia”, inevitably makes a very bad effect. So TCM idea insists on that “the harm of medicine lies in the man who use it but not in medicine itself.” Thus the education of the TCM theory is important for the human resources, and without the qualified personnel, there

will be no qualified medicines. TCM is good at teaching a man to be whole hearted and with natural manner, and maybe this is really the value TCM devotes to the modern society.

### **2.3.2 More effective cure methods can be applied and invented**

The developing history of TCM has shown that new theories and therapies could be invented on the ground of the past, and by applying the new one, those special kinds of diseases of the time could be cured effectively. For example, during the Eastern Han Jian'an period (196-220 A.D.), typhoid fever was raging in many places. On the basis of *Neijing*, Zhang Zhongjing promoted the theory of six channels and wrote *Treatise on Febrile Diseases Caused by Cold* and effectively stopped the spread of the disease, laying the foundation of the theoretic base of TCM diagnosis and treatment. Following what Zhang Zhongjing did, the prescription named Baihutang was used to cure epidemic encephalitis B raged in Shijiazhuang, HeBei Province in 1956, and the good curative effects surpassed the world standard. Since the end of 2002, SARS has spread through 32 countries and regions. By July 2003, the SARS case totaled 8,422 the world over, of which 5,327 were in Chinese mainland, and 1,755 in Hong Kong. The world average mortality of SARS was 11%, Chinese mainland 7%, Chinese Taiwan 12.5%, and Hong Kong and Singapore 17%. The mortality of SARS in Chinese mainland was much lower than those in other countries and regions. One important reason is, under the appeal from TCM circles and the support from the leadership of the State Council, TCM has been involved in the SARS therapeutic process, bringing about a special effect by laying equal stress on TCM and western medicine.

The examples above show the fact that the basic theories of TCM founded by *Neijing* has assured by its curing values in different times including the modern times. Apart from the infectious diseases, certain chronic diseases, senile diseases and psychosomatic disorders can also be cured by TCM. And the modern society should not always blame what TCM can not do because of its traditional character, the right attitude to TCM should be that people ought to know completely what potential abilities TCM has. Only by studying TCM knowledge, then we are able to make use of it. That knowledge is power and it is suitable to both TCM and the mainstream medicine. Of course, the policies can play its role in encouraging or depressing the development of TCM, but whether a suitable policy can be made depends on the policy makers' knowledge about it. The saint always tells to people to be modest when they learn new knowledge, and this kind of virtue is not always to be followed in action. The reason may probably be that some people believe in science more than in life, and thus forget the beginning where science comes from. Despite of the negligence mentioned above, the non-medication therapies and medication therapies of TCM can serve them to relieve the sufferings and solve some kinds of problems in our modern time.

It is difficult to provide examples one by one for commenting on every therapy of TCM, we can only give a brief summary to them now. Generally speaking, TCM advocates that prevention is more important than cure and emphasis should be laid on health preserving, and correspondingly it emphasizes keeping mental health and taking good care of mind. This is just what Western medicine has neglected in the past and begun to lay stress on at present. TCM also insists on "superior doctors value preventive treatment" just as the modern preventive medicine has declared, and thus a minor illness can be cured in time and be prevented from becoming a serious one. TCM favors mental healing and holds that to cure a disease is first to cure the mind, laying stress on the

harmony between mind and body, man and society, as well as man and nature. These are all what future medicine energetically advocates. TCM promotes health preserving and a whole set of its theory has been taken shape, and has discovered the way that modern mind-psychology is to explore.

In summary, we will say that the whole set of therapies of TCM from Chinese herbal medicine to acupuncture, moxibustion, massage, *taiji*, *qigong* and etc. have their values of helping us to prevent and cure diseases. On the basis of them, doctors and scientists can also find out ways to cope with some difficult and complicated cases with significant results unrivalled in the world. The so-called modern diseases, such as all kinds of hypo-health state and kinds of “diseases of the rich and the privileged”, can certainly be prevented and cured by keeping in good health in advance. In a word, to realize these possibilities lies in giving up the doubts and should not hesitate to learn and to practice.

### **2.3.3 TCM is suitable for both the developing countries and the developed countries**

The global strategy for health for all has brought its great influence on the development of TM/CAM, and since 1991, WHO has promoted the integration of traditional medicine into national health care systems and the proper use of traditional medicine through the development of technical guidelines and international standards, particularly in the field of herbal medicines and acupuncture<sup>(16)</sup>. As the representative therapies of TCM, Chinese herbal medicine and acupuncture are both the practical, socially acceptable, primarily scientific-evidenced methods, and have the potential of universally accessible to individuals and families, at the cost they can afford. Now in China, TCM accounts for around 40% of all health care delivered<sup>(17)</sup>.

China is typically a developing country in the world, and its population is almost beyond 1.3 billion and most of them live in rural areas. At present, 0.9 billion of peasants still have not enjoyed the most basic medical and health guarantees, and only 0.2 billion people are qualified to enjoy fuller public health services. For providing promotive, preventive, curative and rehabilitative services for such an amount of populations, the following factors as economic conditions, technical resources and policies must be considered carefully. By integrating these factors together, TCM appears to be the kind of “appropriate technology” in China. Experience of the past 50 years shows that TCM can help China to establish its own medical and health guarantee system with Chinese characteristics, and its “simplicity, convenience, inexpensiveness and effectiveness” have contributed a lot to Chinese people. For example, in the 1970s, China has solved the medical and health care of its population (22% people of the world) with a comparatively small input (1% of world expenses), and its public health system makes the coverage of cared population high up to 85%, creating a miracle in developing countries and obtaining high praise from WHO. One basic reason is that the system of rural cooperative medical care has played an important role and taken TCM therapies and doctors as the dominant factor and employed both TCM and Western medicine.

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<sup>16</sup> World Health Organization. The World Health Report 1998. Life in the 21<sup>st</sup> Century: a Vision for All, Geneva, World Health Organization, 1998.

<sup>17</sup> World Health Organization. Traditional Medicine Strategy 2002-2005.

Experience of the past also shows that governance is one of the decisive factors in securing the implementation of health care goals. In 1970s, China has established the three level network of the health care system which governed respectively by county people's government, township people's government and village people's committee. At county level, medical and health institutions and services are mainly financed by government. Health services at district and township levels are supported about two-thirds by the community and one-third by government, while for those at village level, costs are entirely met by the community. <sup>(18)</sup> Since 1980's, China has changed this centrally-planned normative distribution of government budget funds, and the three level network of health care can not play its role in new circumstance. Nowadays, a central issue for China is improved coordination and management of multiple funding sources, and many health systems struggle to keep up with rising costs or are affected by national decisions to reduce expenditure on health. <sup>(19)</sup> Although the exploration of market mechanism to meet health service needs has resulted in healthy competition between medical institutions for improving efficiency and reducing costs, the fact is that TCM has not taken advantage of the policies. In last 20 or more years, the medical undertakings, in particular, the western medicine has made an unprecedented development, the beneficiaries is those living in city and towns, particularly, part of those who enjoy the public health service guarantee system, but around 80% of peasants and urban and rural residents with low-income have not been included. So the urgent task for China now is to establish a health system serving universally the whole people with Chinese character, and re-establish the important strategic position of TCM. <sup>(20)</sup> It has been suggested that China should intend actively to enhance the research on fundamental theories, to save the clinic knowledge of elder TCM doctors, to reform the TCM higher educational patterns, to train new generation of "bare-foot doctors" for rural areas, to popularize TCM culture and education, and to carry out practical and effective policies and measure to strengthen the construction of TCM institutions.

By accompanying the cultural, technological, scientific, and economical exchanges of the past, TCM has spread to Korea, Viet-Nam, the Philippines, Singapore, Malaysia, South Africa, etc. Learning from China the experience and the technologies concerned, TCM has the possibility of being developed and integrated with national health care systems in other developing countries. Before TCM can be accepted partly or completely as a health promoting resource, the chief problem will be the efficacy of TCM. As long as this problem is solved in an appropriate way, its safety, quality, availability can be ensured by corresponding suitable policies, and its high cost-effective character will make it accessible and affordable in developing countries as well as developed countries. In fact, TCM has not been thought as an outdate medicine in China, and this depends mainly on its efficacy. The other problems are generated inevitably from the idea that TCM is not as effective as western medicine, and so great efforts must be made to prove its efficacy in the way of not coherent wholly with TCM theories. WHO has proposed in its strategy of traditional medicine the methods to solve this problem by developing and providing international standards, technical guidelines and methodologies for research into TM/CAM therapies and products, and for use during manufacture of TM/CAM products, but these measures

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<sup>18</sup> World Health Organization. The Role of Traditional Medicine in Primary Health Care in China.

<sup>19</sup> World Health Organization. The World Health Report 1998. Life in the 21<sup>st</sup> Century: a Vision for All.

<sup>20</sup> Jia Qian, Cheng Yongjie, Cheng Guangman, Yang Juping, Ying Guangrong, The Great Significance of Establishing Strategic Status of Traditional Chinese Medicine (TCM), Engineering Science of China, Jul. 2004, Vol. 6 No. 7.

are all scientific-based and evidence-based manner instead of TCM theory-based manner. That is to say that the efficacy of TCM must be testified and confirmed by another kind of method which is different from TCM method. Unfortunately, these two kinds of methods can not be interpreted each other well at the present time, and this lead to the change of the conventional way to the non-conventional way in which people accept the efficacy. In countries where the dominant health care system is based on allopathic medicine, or where TM has not been incorporated into the national health care system, TM is often termed “complementary” or “alternative” medicine, and TCM becomes one kind of CAM. For example, the Chinese herbal medicines become a kind of diet complementary in USA, and many Chinese TCM factories make their great efforts to acquire the qualified certification of drugs from FDA for their products. If the efficacy of these products were accepted by TCM theory-based standard in USA, then much time and resources could be saved before these products were integrated into the national health system, and TCM would certainly do good to people living in the country. So the problem lies in the knowledge of that how the efficacy of TCM is promised to be claimed in principle, and as soon as this problem is solved, TCM can be employed well in both developing countries and developed countries.

Due to the plural cultural background and social context in different countries, the efficacy of TCM is not simply a technical problem, and WHO has done its best to break the communicating barrier of cultures and religions. Thinking the world as a whole, WHO wants the Health For All to be realized in all of its member states, and TCM appeared to be one of the technological resources. However, TCM is also a resource of thought, and the trend of returning to nature around the world is just what TCM theory asks for people to do. But whether this thought can be expressed in scientific form is a question people must face to, and it has already brought about great contends in China as well as in the developed countries. Before people can reach to a common conclusion, we can not wait anymore to meet the needs of the real world. We should notice that TCM is perhaps suitable for the developing countries technologically if compared with China, and is suitable for the developed countries theoretically compared TCM theory with that of the allopathic medicine. Of course, this is just a chance for the countries concerned, and whether TCM can serve to them depends on the governments and their people.

#### **2.4 The Possibility of TCM from CAM to UM (Universal Medicine)**

More than two thousand years have past since *Neijing* was written and we have ushered into 21 century now when the globalization has brought the world together gradually. During the communicating process of one civilization with another of the past, people have learned how to live together peacefully from the cruel war, and WHO has made great efforts for promoting the harmonization between TM and modern medicine. The policy-makers and researchers in China are seemingly having their passions for integrating TCM and modern medicine into one, and the fact turn out to be that TCM can not employ its values completely in national health system.

After the study with scientific methods and technology of many years, the researchers of TCM has found out that TCM is still a living medicine and its theory is quite different from Western medicine, and it is useful and yields good results in clinical practice in spite of the difficulty of mastering. Because TCM Still “contains” so much of value, so it is essential to study it with

modern methods, to sift the grain from the chaff.<sup>(21)</sup> If people do like this, a modernized TCM will appear as the form of integrating traditional and Western medicine as one. In fact, China has practiced this way for more than half a century, and the development of TCM has departed from its correct line followed in the history. Those people educated and trained by scientific method and other so-called modern methods lack the ability of using correctly the non-medication therapies and medication therapies of TCM, and thus the clinical and preventive value of TCM in national health system is lessened by a regretful manner.

This result has turned out contrary to the expectations of the researchers and the policy-makers in China, and is called a paradox during the modernizing process of TCM. The goal of studying with modern methods is to enhance the value of TCM and to keep TCM from extinction, but in a long run TCM is reformed to be another kind of medicine. Many experienced and thoughtful TCM doctors in China have proposed that the reason lies in the neglect of TCM theory, and the theory has the power enabling the therapies and products to be their TCM characters. If the research method is not TCM theory-based method, then the research result will certainly be not with the TCM character. About the possibility of integrating TCM with Western medicine, Dr. Joseph Needham once said:

In an abstract of a discourse prepared for the XVIIth International Congress of Internal Medicine, held at Kyoto towards the end of 1984, we wrote “We have got to discuss the merits and demerits of both Chinese traditional and modern Western systems, the former organicistic, psychosomatic, perhaps inexact, certainly based on theories characteristic of ancient and medieval science; the latter atomistic and analytical, based on reductionist biological science and chemistry, but perhaps dangerous in the side-effects of its drugs, and liable to treat symptoms as such, rather than inquiring into the health and welfare of the entire human being.” At that time I said that it is relatively easy today to combine Chinese with Western techniques, but it is quite difficult to restate the two medical philosophies in terms of one another.<sup>(22)</sup>

It is sure what Dr. Joseph Needham said about the exploration of integrating TCM with the modern Western medicine, and so far the results of the exploration is technical only, we have not seen scientifically as well as philosophically the successful restate of one kind in terms of another. The differentiation between them is philosophical firstly, and thus methodological and scientific at last. We all know that modern science has not been developed to the level being able to tackle fully the holistic problem, and TCM is typically the holistic medicine. Those past explorations are just the exploring works trying to combining TCM with modern medicine, but we can not make sure that we are able to restate TCM by this way. Being not restated asks for harmonizing the traditional and the modern medicines, so WHO advocates with great enthusiasm the co-exist one with another and the practical functions they are playing in the health systems. It is cooperation and not the interference that can bring about the best effect, and thus TCM should be respected as an independent one can it be used to serve people practically.

Now it is the time for discussing the possibility TCM as Universal Medicine. We must say that this

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<sup>21</sup> World Health Organization. The Role of Traditional Medicine in Primary Health Care in China.

<sup>22</sup> Luo Xiwen, Treatise on Febrile Diseases Caused by Cold with 500 Cases, New World Press, Beijing, China.1993.

possibility is beyond the scientific scope and is accepted only by those open hearted man. Compared with modern medicine, TCM is still in a condition to be studied mainly with scientific method and to be treated as CAM, speaking strictly, to be an alternative and complementary medicine in terms of the allopathic medicine. That is to say TCM as a holistic medicine has its own strengths in solving those problems the allopathic medicine can not solve, and this indicates not only the change of the knowledge, but also the change of the methodology and the philosophy. Among the present methods, most of them are developed from the separating works scientists engage in, and many kinds of knowledge can be expressed by them but the holistic knowledge because the whole can not be separated. The TCM knowledge is just the holistic one with TCM theory-based character and is the alternative of the allopathic knowledge. The lack of holistic knowledge makes the scientists find out an unsuitable way to study TCM, and this factor combined with other factors have lead to the great underestimation of TCM values. So TCM is called passively the CAM in those developed countries, and this reflects the difference more methodologically between the holistic medicine and the allopathic medicine than timely between the traditional and the modern. Making out the difference is essential and helpful to develop a holistic medicine called UM in future by TCM or by other holistic method or knowledge, and the concerned research is seemingly beyond the scope of WHO.

WHO is playing its role actively to harmonize the TM and the modern medicine, and this is important to TCM living through the difficulty of misunderstanding. The meaning of harmonization can teach us more than we expected, and the United Nations has accumulated the common experiences in disposing of such problems as cultural diversity, conflict and pluralism. From the past we learned that TCM may be changed in form, its holistic value will remain forever.



## CHAPTER 3

### The Innovation of Traditional Chinese Medicine

To develop new drugs by innovating on traditional Chinese medicine (TCM) now draws plenty of attention and interests all over the world. It is considerably easy to make good and it is also considered fitted for developing countries.

The spectrum of disease, which has changed remarkably in developed countries, doesn't alter obviously in many poor countries and regions yet. The experiences and theories relevant to the most prevalent diseases such as malaria and tuberculosis are still practical.

At the same time, new drugs got from it certainly are cheaper, more available and affordable for developing countries as the research & development (R&D) expenses are comparatively lower.

Of course, people from developed countries also turn to non-chemical drug therapy because of the changes of medical mode from simple treatment against diseases to combination of prevention, health care, treatment and recovery.

Based on the differences between TCM and modern medicine, those new drugs could be mainly divided to two types according to the innovative methods and applications of new drugs, i.e. Chinese patent medicine and new chemical drugs.

#### 3.1 Differences between TCM and modern medicine

TCM and modern medicine are two distinct kinds of medical systems. They contain different ways of prevention, treatment and rehabilitation as well as health care due to their individual theories.

##### 3.1.1 The differences of guidelines

TCM and modern medicine have significant different view on illness and the relation between illness, man and his environment.

**Modern medicine**, which is almost equal to allopathic medicine, regards diseases as the research objects and it generally tries to find the various causes of diseases and then gets rid of those such as bacteria and viruses mainly by chemical drugs.

Practice of the modern medicine is now especially exhibiting an increased predilection toward the wholesale eradication (rather than control) of microbial organisms, which is truly harmful to the balance of nature, and it surely results in multiple antibiotic resistance and increased virulence and

tolerance<sup>23</sup>.

**TCM**, which is a sort of harmonic medicine, always researches into lives of human being instead of diseases and it emphasizes on the concept of relevant adaptation of man to nature.

In the opinion of TCM, man should coexist peacefully with everything in the world including microbial organisms and try to stimulate and enhance human's ability of recovery by medication therapies (such as drugs of herbs, animals and minerals) and non-medication therapies (such as Qigong) in order to keep the harmful factors away.

It is the most distinguished characteristics of TCM that diagnosis and treatment is based on the overall analysis about the symptoms, signs and conditions of patients and the whole environment (e.g. syndrome of TCM) instead of disease.

### **3.1.2 The difference of sources and basement of application**

**Chemical drugs** are nearly all monomer and produced by synthesization so that it is important to analyze the structure and ingredient of drugs which needn't be processed.

**Traditional Chinese medications**, derived from natural plants, animals and minerals, are generally made of compounds and contain lots of ingredients what are now hard to understand entirely.

It is so significant to find out the special characteristics of Chinese drugs on the basis of TCM theory and clinic practice such as four natures (cold, cool, hot and warm), five flavours (pungent, sweet, sour, bitter and salty), directions of actions of Chinese drugs in human body when being taken (rising, lowering, floating and sinking) and meridian tropism [e.g. selective concentration and effect of Chinese drugs on some meridians and viscera. for example, Chaihu (Radix Bupleuri), could be mostly carried into liver meridian and treat hepatic diseases].

Since most Chinese drugs come from the crude materials, it is necessary for them to be processed so as to meet therapeutic requirements, reduce the toxicity, ensure safety and produce satisfactory therapeutic effect according to their specific properties.

### **3.1.3 The difference of methods of cooperation**

**Chemical Drugs:** Cooperative use among chemical drugs are tolerable unless their chemical structures are contradictive or one part would react with the others resulted in less effect, toxicity or adverse effects.

In general, chemical drugs are almost in the same state in a prescription and each aims chiefly at various causes of diseases or different pathologic changes.

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<sup>23</sup> Jennifer Brower, Peter Chalk. The Global Threat of New and Reemerging Infectious Diseases: Reconciling U.S National Security and Public Health Policy. Rand Science and Technology, 2003,5

**Chinese drugs:** It seems to be more complicated and systematized to make a TCM prescription. In general, a single drug could not fulfil its therapeutic purpose when the disease is complicated.

Compatibility of Chinese drugs refers to combination of more than two drugs according to the clinical requirement and principles of medicinal application so as to increase and reinforce the effects of these drugs, or to decrease and correct the adverse effects.

There are two major sorts of methods of cooperative use among Chinese drugs. One is the cooperation within two drugs, which contains seven aspects, namely, using a single drug, mutual reinforcing, assisting, restraint of toxicity, being detoxified, mutual inhibition and incompatibility.

The other method of cooperation of Chinese drugs is based on the different function of medication in the whole prescription, which is described as drugs as monarch, minister, assistant and guide. This is the most important basis of developing a TCM prescription and it will show how to start analyzing a TCM prescription handily. Though it is considered unscientific to describe TCM like these rather than drugs' structures, many agree that the TCM prescriptions guided by traditional concepts are more effective in clinic practice.

### **3.1.4 The difference of toxicity, side effect and drug resistance**

**Chemical drugs:** Overuse of antibiotics and other drugs to “treat” viruses together with failure to finish prescriptions and the use of antibiotics in animals have dramatically hurt the effectiveness of these medications and led to the rapid rise of highly resistant “supergerms”<sup>24</sup>.

Meanwhile, the toxicity and side effect of chemical drugs can't be ignored too. For example, the incidence of avascular necrosis of femoral head was much higher in convalescent SARS patients than in general population<sup>25</sup>. But there are no obvious sequelae shown in the patients treated with TCM<sup>26</sup>.

**Chinese drugs** used properly are believed to be safety because TCM is generally a compound prescription in which toxicity is limited by drugs' cooperation.

**Meanwhile, Chinese drugs are almost harmless after special process. For example, the toxicity of raw Fuzi (Aconitum carmichaeli Debx.) is 200 times than that of the processed drug<sup>27</sup>.**

**At the same time, it isn't easy to bring toxicity, side effect and resistance for TCM if the practitioners insist on treating patients according to TCM syndrome based on**

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<sup>24</sup> S. B. Levy, *The Antibiotic Paradox: How the Misuse of Antibiotics Destroys Their Curative Powers*, 2nd edition, Cambridge, Mass.: Perseus Publishing, 2002

<sup>25</sup> Li Yu-ming, Wang Shi-xin, Gao Hong-sheng, et al. Factors of Avascular Necrosis of Femoral Head and Osteoporosis in SARS Patients' Convalescence. *Natl Med J China*, 2004, 84(16): 1348-53

<sup>26</sup> Zhong Jiayi, Zhu Min, Wu Zhibing, et al. Effect of Traditional Medicine on Severe Acute Respiratory Syndrome: An Observation of 61 Cases. *Journal of GuangZhou University of Traditional Chinese Medicine*, 2004, 21(1): 1-5

<sup>27</sup> Xu Tingsheng, Liang Xiulang. The Analyses and Countermeasures against Toxicity of Aconite. *China Pharmacist*, 2003, 6(8): 518

**understanding of integrated concept. That is why Chinese drugs have developed little resistance after thousands of years.**

### **3.2 To research and develop new drugs**

In later half of the 20th century, researches on innovation of Chinese medications have been done in China in order to encourage the improvement of clinic therapeutic effect, applications of convenient ways as well as the novel means of managing new diseases, stubborn diseases or chronic diseases.

#### **3.2.1 Chinese patent medicine**

New Chinese patent medicine is a sort of Chinese drug that is used on the basis of understanding TCM syndrome of patients and is guided by TCM theory. It usually contains more than one Chinese medication.

It incorporates following objectives to develop new Chinese patent medicines: safety, efficacy, stability of pharmaceutical techniques as well as quality, prompt, persistence, less dosage, convenience of taking as well as traveling and at low cost.

Innovation of Chinese patent medicine now mainly includes four methods: innovation of those ancient famous and effective prescriptions; summarizing new clinic experience according to the needs of consumers and changes of diseases; innovation of effective prescriptions descended through family; reform of the traditional dosage form.

It is rather prominent to change the dosage form of Chinese drugs in all research fields of innovation, as it is increasingly important for TCM to innovate its appearance, taste and dose in such a modern society.

In recent years, TCM industry supported by modern sciences and technology has got a quite considerable progress. There had been about 1,175 enterprises of TCM, which accounts for 12.23% of the total pharmaceutical enterprises in China by the end of 2001.

The proportion of gross output value (GOV) completed by big enterprises of Chinese patent medicine, accounted for 9.6% of the total enterprises of Chinese patent medicine, is more than 40% in all GOV of Chinese patent medicine (Shown as table 3-1<sup>28</sup> and figure 3-1, 3-2<sup>29</sup>).

At present, about 5,000 kinds of Chinese patent medicine are produced and about 673 new Chinese patent medicines were examined and allowed to produce from 1999 to 2002 since the implement of “*Measures for Examining and Approving New Drugs*”.

At present, however, the research and produce of Chinese patent medicine haven't developed adequately to meet the national and international needs. Export of Chinese herb that would

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<sup>28</sup> Annual Report of State Economic and Trade Commission (1998-2001)

<sup>29</sup> Analysis of the Competition of Famous Listed TCM Companies. China Medicine Economic Information Net of State Food and Drug Administration.

consume natural resources farthest and bring the lowest value is still the mainbody of the export of Chinese medicine (see the figure 3-3<sup>30</sup>)

**Table 3-1**

**The Statistics of Composition of China's Medical Enterprises in 1998-2001 (10,000 RMB)**

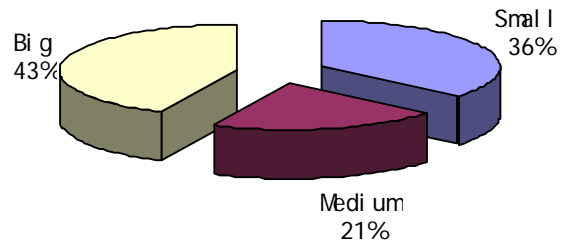
| Item                                    | Year | Enterprises (units) | Gross Output Value | Sale value |
|---|------|---------------------|--------------------|------------|
| Chemical<br>Medicine                    | 1998 | 1,583               | 11,875,621         | 8,018,618  |
|   | 1999 | 1,600               | 13,756,400         | 9,155,731  |
|   | 2000 | 1,662               | 17,252,151         | 10,551,448 |
|   | 2001 | 1,530               | 19,630,176         | 11,772,119 |
| Biological<br>Preparation               | 1998 | ----                | ----               | ----       |
|   | 1999 | ----                | ----               | ----       |
|   | 2000 | ----                | ----               | ----       |
|   | 2001 | 206                 | 1,400,483          | 1,082,877  |
| Chinese<br>patent<br>medicine           | 1998 | 1,042               | 3,349,149          | 3,109,308  |
|   | 1999 | 1,052               | 3,808,061          | 3,511,688  |
|   | 2000 | 1,107               | 4,801,188          | 4,468,305  |
|   | 2001 | 1,127               | 5,432,734          | 4,985,166  |
| Chinese<br>prepared<br>herbal<br>slices | 1998 | 66                  | 40,712             | 46,820     |
|   | 1999 | 69                  | 37,592             | 44,542     |
|   | 2000 | 67                  | 49,215             | 106,956    |
|   | 2001 | 48                  | 40,399             | 47,623     |

*Source: Annual Report of State Economic and Trade Commission (1998-2001)*

<sup>30</sup> Customs General Administration of People's Republic of China

Figure 3-1

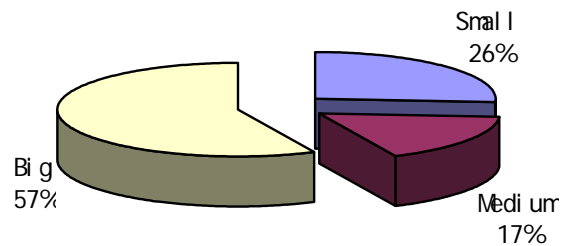
**The Composition of Gross Output Value (53900 Million RMB) of Industry of Chinese Patent Medicine (Grouped by Size of Enterprises) in 2001**



*Source: China Medicine Economic Information Net of State Food and Drug Administration*

Figure 3-2

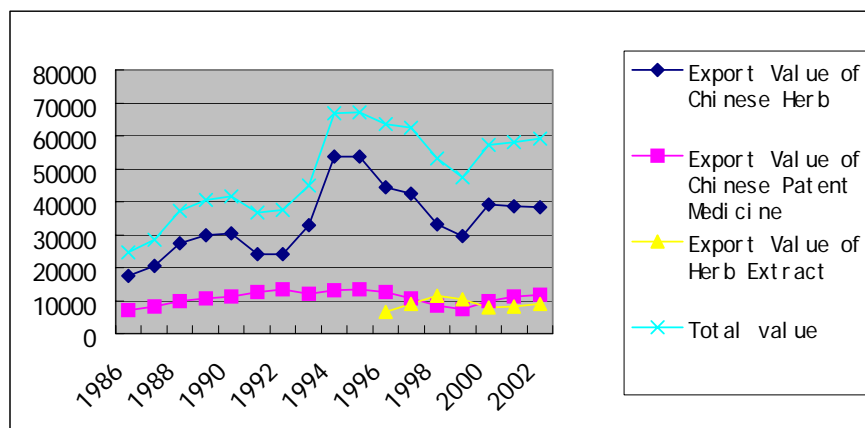
**The Composition of Total Profits (5471 Million RMB) of Industry of Chinese Patent Medicine (Grouped by Size of Enterprises) in 2001 total**



*Source: China Medicine Economic Information Net of State Food and Drug Administration*

Figure 3-3

**The Changes of Export Market of Traditional Chinese Medicine in 1986-2002 (1,000 \$)**

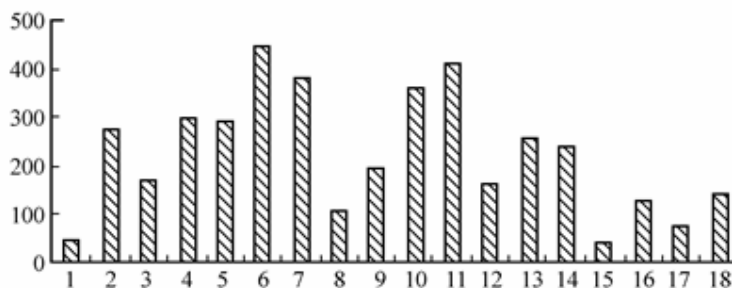


Source: Customs General Administration of People's Republic of China

The drugs used in the department of internal medicine account for 73% among those 4,089 Chinese patent medicines (shown as figure 3-4)<sup>31</sup>.

Figure 3-4

**The Distributions of Application of Chinese Patent Medicines**



1: Emergency; 2: Cold; 3: Interior heat syndrome; 4: Heart system diseases; 5: Liver and gallbladder system diseases; 6: Spleen and stomach system diseases; 7: Lung system disease; 8: Kidney system diseases; 9: Disease of vital energy (Qi), blood and body fluid; 10: Meridian disorders; 11: Deficient syndrome; 12: Surgical diseases; 13: Gynecology; 14: Pediatric diseases; 15: Ophthalmic diseases; 16: Disease of five sensory organs; 17: Dermatology; 18: Diseases of skeleton system

<sup>31</sup> Shi Xinde. Analysis and Thought of the Situation of Chinese Traditional Patent Medicine in the Late 15 Years. Traditional Patent Medicine. 2002, 24(3): 213-215

But what deserves to pay more attention to is that the innovation of Chinese patent medicine including the reform of dosage form has caused constant rise of price during the past decade. It is obviously opposite to the original objectives of innovation<sup>32</sup>.

### 3.2.2 New chemical drugs

It is a good and economical way to discover new drugs based on active ingredients and leading compounds separating from Chinese herbal medicine and it is also an available path with less risk, which may promote the development of new drugs.

Though they come from herbs, they are almost the same with chemical drugs as their main structures are nearly clear and most of them are monomer or the compounds of some monomers. On the other hand, they are used to treat patients by aiming straightly at diseases according to modern medicine.

There are two kinds of new chemical drugs from Chinese herbs. One is an active ingredient that is always a monomer like Artemisinin. The other kind is compound extract from herbs including active part such as Ginko Biloba Extract.

There are now over 200 enterprises specializing in the processing of herb extracts except some Chinese patent medicine companies and fine chemical companies whose produces include herb extracts too.

But the business scale of their market is generally small and the biggest one hasn't reached 10 million U.S dollars. There are now over 80 kinds of produces made in China<sup>33</sup>.

At present, the Chinese herb extracts mainly export to the U.S., Asia and European Union regions, especially to the U.S. and Japan<sup>34</sup> (shown in table 3-2).

**Table 3-2**

The Export Value of Herb Extracts and the Proportion to the Total  
Export Value of TCM

| Year   | 1996  | 1997  | 1998   | 1999   | 2000 | 2001 | 2002 |
|--|-------|-------|--------|--------|------|------|------|
| Export Value of Herb Extracts (1,000\$)      | 6,667 | 9,137 | 11,592 | 10,400 | 8024 | 8232 | 8927 |
| The Proportion to the Total Export Value (%) | 10.5  | 14.7  | 21.8   | 22.0   | 14.0 | 14.2 | 15.1 |

<sup>32</sup> China Association of Traditional Chinese Medicine. Adjustment of Price of Chinese Patent Medicine in Catalogue of Health Care Is Essential. Research & Information of Traditional Chinese Medicine.2001, 3 (3):14-17

<sup>33</sup> Development Research Center (DRC) of The State Council of P. R. China. The Strategic Study on the Internationalization and Industrialization of Chinese Medicine.2003.11

<sup>34</sup> Qian Jia, Zhixiang Shen, Junying Fu, et al. The Environmental Analysis of Internationalization of TCM Industry. 2003,11



### 3.2.2.1 The possibility of access new chemical drugs from Chinese medications

Firstly, there are various landforms and climates in China. Chinese herbs resource is greatly developed there so that the good chance is endowed with expanding TCM industry.

In accordance with the national census, there are 12,807 Chinese medications recorded (shown as table 3-3)<sup>35</sup>.

**Table 3-3**

**The Classified Statistic of Chinese Medications Resource**

| Class                              | Sorts                | Volume         |
|------------------------------------|----------------------|----------------|
| According to sources               | Medical plants       | 11146          |
|                                    | Medical animals      | 1581           |
|                                    | Medical minerals     | 80             |
| According to status of application | Chinese herbs        | More than 1200 |
|                                    | Minority medicines   | More than 4000 |
|                                    | Indigenous medicines | More than 7000 |

*source: National Chinese Medications Resource*

Secondly, TCM, practiced through thousands of years have a good clinic basis and the safety of Chinese medications is rather stable.

Thirdly, a great many classical books are reserved and the characteristics and functions of medications have been detailed described. The information would give a cheaper, faster and more effective path to discover new drugs.

Finally, there are some highly qualified personnel who master the theories and practice of TCM as well as the modern scientific and technical knowledge. It would meet the need for human resources.

Nearly 50 kinds of new drugs come out around the world yearly. The average cost of R&D for a new drug that comes into the market is about \$120 millions and it would generally cover more than 10 years<sup>36</sup>. For example, with a 2003 Pfizer budget of \$7.1 billion in R&D, Pfizer now holds one of the industry's largest pharmaceutical R&D organizations<sup>37</sup>.

In China, however, the cost of R&D to get a new drug is usually lower than 10 millions RMB, which may be attributable to the researchers' preceding work based on the theory and practice of

<sup>35</sup> HuiYuan Zhang, ChangQi Yuan. National Chinese Medicine Resource. Beijing: Science Press.1995,3

<sup>36</sup> HaDa. Artemisinin and Innovation of New Drugs. Chinese Journal of TCM Administration.1994,13(4): 57-58

<sup>37</sup><http://www.chinweb.com.cn/cgi-bin/chemport/getfiler.cgi?ID=xHqgi6Tms6FYhvAJKu75eCQroRGQe4ynnuYPNzI0ATs9JxoEyfRJGf1DjaqjZQT0h&VER=C>

TCM.

### 3.2.2.2 The methods of accession of new chemical drugs from Chinese medications

**One method** to access new drugs is to find new active ingredients or effective parts in accordance with the information that one Chinese medication could treat some diseases or symptoms. Resembling the so-called “reverse pharmacology”, it is the same process that begins with a useful natural product and works backward to identify the active materials.

The process of finding Artemisinin is the sample of forementioned method<sup>38</sup>. Hundreds of herbs and their extracts were screened by malaria models of mouse or monkey from 1967 in China. The notification of Qinghao (*Artemisia annua* L) was benefited from the medical reference, *The Handbook of Prescriptions for Emergencies* written by Hong Ge in the 3rd century, in which the plant was used to treat diseases with alternative fever and chill. The pharmacological evaluation showed positive result for the extract of this herb in October 1971. The Chinese researchers isolated and purified the effective compound in 1972 and named it as Artemisinin which is effective especially against the subtertian malaria and the drug-resistant malaria.

Meanwhile, Artemisinin is available in forms of tablets and it could be taken orally. They are the most advantages such as application convenient as well as quick work, remarkable effect and less toxicity.

In Kwazulu Natal province of South African, people who suffered from malaria decreased from 41,786 to 9,443 and the mortality from malaria reduced by 87% as well as the carry rate of gametocyte, which was 74% treated with SP, was only 2% after Artemether Tablet which belongs to Artemisinin family was used as the first line therapy against malaria from February to end of the year in 2001<sup>39</sup>.

Scientists have pointed out that Artemisinin is made up of a novel structure different from the traditional antimalarial drugs like quinin so that it shows a new way to discover unknown chemical structures.

**The other method** to access new drugs is proven practical too, namely, to find the effective pharmacological ingredient from the Chinese medication that has the correlative function recorded.

For example, Chinese experts have found that Hongqu (Red Yeast Rice), which is believed to have the function of invigorating peptic to promote digestion, consists in the natural ingredient like Lovastatin, and then developed a new health care product against cardiovascular and cerebrovascular diseases. Many believe it better than chemical Lovastatin as it comes from nature.

### 3.2.2.3 The disadvantages to access new chemical drugs from Chinese medications

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<sup>38</sup> ChunChao Liu, YuChun Wang, Fan OuYang. The Progress of Artemisinin. Progress in Chemistry. 1999,11(1):41-48

<sup>39</sup> TianWei Liu, LingBo Qu, BingRen Xiang. The Progress of Antimalarial of Artemisinin Family. Chinese Journal of medicinal guide. 2003, 5(6): 399-401

It is important to distinguish such new chemical drugs from Chinese medications though they come from Chinese medications. After extracting, it is generally a monomer and has to aim directly at diseases rather than harmonizing the condition of body.

As it is, the new chemical drugs come from Chinese medications are inevitably provided with the disadvantages of chemical drugs. For example, their toxicities and side effects are accordingly increased and drug resistance is considerably easy to induce too.

At the same time, to the experts' disappointment, extract compounds seldom brought out the improvement of clinical therapeutic effect comparing with traditional Chinese decoction. Sometimes it would even decrease the effect.

It shows that some advantages of TCM, which are resulted from cooperation of various structures and herbs restrained or reinforced one another have disappeared by simplifying and refining the herbs to some extent.

So it should not become the mainstream research on TCM for TCM experts. It will certainly do harm to conservation and development of TCM if we regard it as the only way to research TCM.

### **3.2.3 Problems and suggestions**

According to the disadvantages existed in innovation, some suggestions are put forward in order to improve the quality of innovative drugs.

#### **3.2.3.1 Some well-known prescriptions is hard to develop**

To develop a new Chinese patent medicine from well-known prescriptions now has great difficulties because the characteristics of TCM are neglected during the process of examining and approving. At present, it is becoming more prevalent to limit indications of Chinese patent medicine in a disease defined by modern medicine, so that some good prescriptions fitting TCM syndromes, which could treat more than one disease, are restricted conversely.

The national administrations should adopt powerful measures which could embody real quintessence and characteristic of TCM to create a loose policy environment for the growth of the TCM industry.

#### **3.2.3.2 The indication of new Chinese medicine is not specific**

Many indications of new Chinese patent medicines now haven't explained clearly, some are even indicated by modern medicine. For example, some medicines against cold hasn't explained that it suits what kinds of TCM syndromes, and then doctors can't give indications to the patients properly. As a result, the efficacy of medicines decrease and more toxic effects happened.

Therefore, the new Chinese patent medicines should be researched and developed on the basis of TCM theory and the functions and indications should be explained by using the TCM terms since there are no good means to have TCM syndromes equalized to disease of modern medicine.

At the same time, further education and training on TCM is needed for both TCM and allopathic practitioners, even the popularization on TCM should be carried on to the consumers.

### 3.2.3.3 To provide scientific information and guidance for the industry and researchers

At present, it is serious that the research and development of TCM in new medicine markets are repeated poorly at low level. It indicates that the sustaining functions of the information service have not shown enough.

The databases existed have many questions such as less volume, content repeated and the information are compiled simply instead of systematization. Effective evaluation is badly needed.

So it is important to cognize the essential function of traditional knowledge and make full use of the resource of Chinese medications. National authoritative databases should be built and it should exert a profound influence on traditional medical industry as well.

### 3.2.3.4 To improve the investment of R&D

Tsumura & Co, one of the largest pharmaceutical companies in Japan, produces Chinese medicines that account for 70-80% of its total products. Its cost of R&D reached to highest level (15,785 millions yens) in 1993. It is keeping at the level of 1998 (8,792 millions yens, which accounted for 8.8% of the total sale value) for recent years that is much higher than the total of entire Chinese invests in TCM. And their priorities for research is outstanding too (see table 3-4).

It is significant for Chinese industry and government to increase the investments, and emphasize the fateful diseases and expand the TCM industry step by step.

Table 3-4

#### The distributing of patent applied by Tsumura & Co in recent decade

| The diseases treated           | The numbers of patents | Proportions to all (%) |
|--------------------------------|------------------------|------------------------|
| Tumor and cancer               | 14                     | 10.9                   |
| Infectious diseases            | 14                     | 10.9                   |
| Cardiovascular Disease         | 10                     | 7.8                    |
| Virosis                        | 10                     | 7.8                    |
| Analgesis                      | 8                      | 6.3                    |
| Improvement of mental capacity | 8                      | 6.3                    |
| Enhancement of immunity        | 8                      | 6.3                    |
| Urinary diseases               | 6                      | 4.7                    |
| Digestive diseases             | 2                      | 1.6                    |
| Endocrine diseases             | 1                      | 0.7                    |
| Skin diseases                  | 1                      | 0.7                    |
| Mental diseases                | 1                      | 0.7                    |
| Others                         | 45                     | 35.1                   |

## CHAPTER 4

### **Existing Challenges and Proposals for Conservation and Development of TCM**

Traditional Chinese medicine (TCM), accumulated and developed through thousands of years, has ensured the descent of Chinese nation and it has contributed a valuable medicine to the world people as well.

However, it is a fact that TCM has made little progress and its application is increasingly shrinking in later decades of the last century. Hence, it is necessary to explore all the challenges that face TCM and consider the possibilities for the solution of these problems in order to find a great breakthrough in its practice and theories.

#### **4.1 Incorrect policies and rules made by government to administer TCM due to making little of the theory and value of TCM.**

The authorities and many scientists generally consider TCM to be out of date for it is old and traditional. TCM is also considered unscientific because it isn't compatible well with modern science and many TCM theories couldn't be explained by the modern scientific measures now.

As a result, the authorities are inclined to administer TCM according to the experience adopted from the modern medicine and encourage to research and develop TCM by employing the mode of thinking and study methods of modern medicine directly. To a large extent, the intrinsic characteristic and regulation of TCM are neglected and some policy and rules have been developed resulting in the restriction of TCM.

##### **4.1.1 TCM is gradually losing its characteristics and clinic advantages mainly from the misdirection of national policy.**

For many years, the directions and emphases of TCM researches mostly lie with the evaluation standards of government and the favoritism of a few authorities.

###### **4.1.1.1 It is rather difficult to estimate value of TCM because of lack of practical standards fitted to the characteristics of TCM to evaluate the safety, efficacy of TCM. Modern medicine has become the "gold standard" to evaluate TCM and decides its developmental direction.**

For a long time, we haven't provided the norms and standards for research into safety and efficacy

of TCM. And we are used to abiding by the rules of modern medicine. The regulatory issues raised by modern medicine are shaping the development of TCM.

**Firstly, the existing statistic evidences and evaluation methods could do little to show the value of TCM.**

Many individual cases, recorded in TCM books, seemed impossible to be approved and repeated. And describable regulations of using TCM properly and assured evidences of efficacy of TCM are not found by general modern medical statistics.

In the opinion of some experts of TCM, however, these results are inevitable because TCM always exhibits its repetitions by repeating its application according to the TCM syndromes instead of diseases.

The principles of treatment based on TCM syndromes could be repeated entirely though a prescription or a medication maybe difficult to be repeated. Patients who share the same major TCM syndromes could be treated by the almost same prescription even they suffer from completely different diseases like hypertension and arthritis.

That is also the reason why TCM could be descended from generation to generation. Otherwise, TCM wouldn't have come down and spread widely, and it couldn't have been mastered by posterity.

**Furthermore, TCM runs short of its own standards of efficacy.**

Except employing examinations of modern science to testify the efficacy of TCM, we should emphasize and collect the evidence based on the TCM theories such as the changes of tongue and pulse.

Now more and more diseases fail to show observable changes except for various discomforts complained about. But TCM has plenty of detailed descriptions about it and lots of treatments against those diseases caused by reasons like stress. So it is valuable to collect those evidences and summarize the efficacy of TCM according to its own theory.

**4.1.1.2 It has limited the accessibility and efficacy of Chinese medicine as the evaluation procedure and norm are almost the same as chemical drugs.**

**Firstly, it isn't fit for Chinese medicines to examine and ensure their quality by analyzing quantities of one or a few measurable components, which aren't surely the effective parts.**

It is difficult for TCM prescriptions to illuminate their efficacy by analyzing a few chemical components because Chinese medications treat diseases by mutual function of every compound.

It is also hard to control the quality of Chinese medicines by examining the quantities of one or a few components because the same materials measured would exist in many herbs as the major ingredients. Meanwhile, some Chinese herbs that belong to same species and contain the almost

same ingredients have considerably different functions if they are harvested in different places or time.

So there is a long way to go to ensure the quality of Chinese medicine, especially to that of Chinese patent medicine.

**Secondly, plenty of effective Chinese patent medicines could not obtain national productive permission.**

On the one hand, according to *the Drug Administration Law of P.R.C*, all Chinese patent medicines, including the prescriptions which are made up of nontoxic Chinese medications proved by modern technology and has used in practice for years, have to do plenty of animal and clinic studies. Chinese medicine, however, which is considered harmonic medicine, is not often effective on viruses and bacteria out of body as well as animals that are greatly different from human being.

On the other hand, it is very difficult for TCM practitioners especially the indigenous providers who hold effective prescriptions to provide required data that is based on expensive experiments. Many pharmaceutical manufactures would rather produce old and profitable Chinese patent medicines than investing a lot of money and exploring a new one because it is very hard to succeed in approving a new drug in China.

Conversely, foreign countries have been always taking active attitudes towards developing new Chinese medicines. A new Chinese patent medicine against AIDS/HIV developed by Kunming Institute of Botany is going to come into the market in Thailand next year because Thailand has cooperated with the Institute and supported the researches since 1999<sup>40</sup>.

**Thirdly, many cases show that the current guidelines on new Chinese medicine have resulted in the decrease of pharmaceutical efficacy.**

The new Chinese patent medicines, which are designed and examined according to *the Drug Administration Law*, seldom show remarkable effect as they aren't instructed by TCM theory. As a result, few have been used for a comparative long time<sup>41</sup>.

**Fourthly, price of Chinese patent medicines is tending upward as a result of lack of active national instructions.**

Increasing price certainly connects to many aspects, like expends for new drug application (NDA) becomes more expensive and the examining duration lasts longer, and some species of Chinese medications become rare as well.

But the possibility shouldn't be excluded for some enterprises have raised the price just for the sake of higher profits because some of them only changed Chinese medicines to a new dosage

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<sup>40</sup>Clinic Study on Prescription against AIDS Developed by Kunming Institute Of Botany Was Carried Out in Thailand. YunNan Daily. <http://www.zaobao.com.sg/special/newspapers/2000/pages4/yndaily130700.html>

<sup>41</sup>Industrialization of Choiceness of Chinese medication.

<http://www.yy2000.com/xinyaodongtai/youliangpinzhongchanyehua.htm>

form or only changed the name. The administrators have failed to develop strong policy to control the market and prevent enterprises from such situations in order to protect the benefits of consumers.

**Fifthly, a lot of effective and simple Chinese patent medicines are increasingly disappearing because the price was so low that no pharmaceutical enterprise would like to produce.**

In recent years more than 50 kinds of Chinese patent medicines have been suspended manufacturing and selling because of other reasons but its poor therapeutic effect.

**4.1.1.3 Researches on TCM theories are increasingly divorced from clinic practice and TCM would no longer be an active science if it couldn't be changed.**

TCM, which was accumulated, abstracted and systematized during the long term of practice has the most important feature that its formation and development were all founded on the practice and its focus is on the careful observation on human beings.

But now most of TCM researches, which are usually carried out in the laboratory and instructed under the theories of modern medicine, entirely sacrifice TCM's own characteristics and advantages for nothing but the "scientific evidence", which is now difficult to truly melt into the TCM system and instruct the TCM clinic practice. It would result potentially in the possibility of decreasing efficacy as the practitioners seldom exercise on the accuracy of TCM syndromes.

**The frequency of using TCM against diseases gradually decreases in clinic.**

Nowadays, most hospitals of TCM in China have turned into the attachments of modern medicine in fact as many effective and affordable TCM treatments aren't used any longer such as the manual manipulation to put back a fracture<sup>42</sup>.

**The status of Chinese medications is more serious in hospitals of TCM.**

Now, Chinese prepared herbal slices, Chinese patent medicine and Chemical drugs used in the provincial hospitals of TCM is 30 : 30 : 40, and in the district hospitals of TCM it is 20 : 30 : 50 as well as 18 : 30 : 62 in the county's hospitals of TCM, while it should follow the rational proportion of 49 : 21 : 30.

Before 1990's, the ratio of them was 60 : 12 : 28. It implied that TCM hasn't been the major therapeutic method for TCM practitioners<sup>43</sup>.

**Why the TCM practitioners in hospitals of TCM are reluctant to use TCM?**

Firstly, the current TCM practitioners especially those younger frequently strive for less risk and

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<sup>42</sup> Junying Fu, Qian Jia, Ruimeng Bai. The Challenge, Prospect and Developing Strategy in the Field of TCM in Rural Area. Chinese Journal of Information on Traditional Chinese Medicine. 2005, 12(1)

<sup>43</sup> Gyzy. Analyze the Westernization of TCM from the Usage Rate of Chinese Herbal Slices. China News of TCM.



more convenience so that they prefer to chemical drugs rather than TCM as they could treat patients directly according to the diseases based on various examinations.

Further more, the price of chemical drugs is much higher so that it has become the major economic sources of hospitals and doctors.

And finally, less use of Chinese herbal slices also has something to do with the difficulty in decocting slices and taking the decoctions as well as the instable efficacy in accordance with the different degree of identifying the TCM syndromes accurately of TCM practitioners.

**Meanwhile, it is disturbing to discover that the prospect of TCM is becoming worse in wide rural areas where are referred as the base of TCM.**

According to a recent investigation<sup>44</sup>, the percentage of the rural population which expects to be treated by TCM has decreased from 21.20% to 10.20% and the percentage of rural population which trusts TCM has decreased from 76.64% to 47.08%. In village clinic only 10.20% of the doctors mainly use TCM to meet the health care needs of villagers and the number is the half as many as it used to be in 1988.

## **Proposal**

**To promote authorities' understanding on TCM, and change their concept and attitude as well. Standards of diagnoses and treatments which adapt to the particularity of TCM should be set up. TCM syndrome should be regarded as the center of such evaluation system and the base of collecting evidences of efficacy.**

On the one hand, retrospective studies should be carried out in order to collect enough evidences for efficacy and repetition of TCM on the basis of detailed documents and statistic analysis of valuable cases. On the other hand, prospective studies should be done as well. Both studies should contribute to developing safe, effective and practical norms of TCM together.

We suggest that the hard jobs should be performed by a new independent Ministry of TCM which ought to depart from the Ministry of Health as the latter is lack of profound understanding and appreciation of TCM. The new Ministry of TCM should consult with experts of all aspects, including the indigenous TCM providers.

Meanwhile, some good therapeutic methods of TCM including non-medication therapies should be encouraged to use again in both countryside and urban areas.

**To put forward feasible and rational standards of examination and approval of new Chinese medicine.**

Special favorable policy should be made to administer those Chinese medicines that have been used for years and shown remarkable efficacy in order to provide consumers access to TCM

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<sup>44</sup> LuoJia Chen. The Survey of TCM Requirement and Service in 10 Provinces and Cities. 2003

therapies.

The produce and application of some effective and low-cost Chinese patent medicines should be recovered in order to offer affordable treatment for the poor and broaden the using of TCM.

**4.1.2 Indigenous practitioners of TCM who haven't received education in the colleges of TCM are not qualified to treat patients even though they have followed an excellent TCM practitioner or have taught themselves and have been treating patients for years as well.**

The conservation and development of TCM are entirely dependent on the traditional pattern that apprentices learned about TCM from their masters in thousands of years. This kind of educational form, which has proved its advantages such as earlier and enough practice, should not be abolished entirely.

Some rules which are different from the requirement of formal education should be developed to appropiate the doctor's qualifications for indigenous TCM holders.

It is a real challenge for Chinese government that how to identify the prominent indigenous TCM holders and provide increased-recognition and support for their field in order to make best use of their capacity to meet the health care needs for the rural population as they often practise medicine in countryside.

**Now, however, many indigenous TCM holders who have been respectable doctors for years lost their doctor's qualifications.**

According to the conservative estimation of Prof. Deng Tietao, who is one of the most eminent senior TCM doctors in China of Guanzhou University of TCM, there are at least 50,000 indigenous genuine TCM practitioners who can not practise medicine any longer though they have doctored in the countryside for ten or twenty years. It is a heavy loss to the vulnerable group and community in both city and countryside<sup>45</sup>.

**Why those indigenous practitioners could not practise TCM any longer?**

Firstly, they are lack of required educational experience which results in limitations of taking the doctor's qualifying licensing examination.

Furthermore, most of them would fail in the examinations developed for the prentices who specialize in certain subjects for over 20% examinations relate to modern medicine though they treat patients with TCM only. On the contrary, allopathic medicine professionals needn't any train for TCM before their employing TCM.

Moreover, according to our investigation, many provinces in China have never held any examinations for the prentices so that it is impossible for them to be qualified as legal TCM

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<sup>45</sup> Report of the 219<sup>th</sup> Xiangshan Scientific Conference.2003, 11.  
<http://www.xssc.ac.cn/Web/ListConfs/ConfBrief.asp?mo=607>

practitioners. Some of them are forced to change their profession and some are still “practising medicine illegally” in extensive countryside.

## **Proposal**

Authorities should qualify excellent indigenous TCM holders to treat patients with traditional knowledge, some feasible and rational policy should be developed to mainly exam their abilities in using TCM in place of modern medicine.

However, it is also a fact that average level of indigenous TCM providers is usually low and most of them are lack of comprehensive knowledge. So it is necessary for them to get more continuation training rather than abrogating their qualification as a doctor because what they are doing is significant for a great many peasants who are badly in need of health care in China.

### **4.2 Endangered causes of wild animals and plants used in TCM, and proposal of ensuring sustainable supplies of natural produce for TCM**

Chinese medicines are mostly based on the natural products that come from plants and animals, which are now decreasing due to environmental damage and pollution, population explosion, overspending and the other reasons. There exist challenges in ensuring TCM sustainable development. In order to ensure sustainable supplies of natural produce, planting and farming endangered species of wildlife are encouraged by the government, community, and the international organization.

#### **4.2.1 Endangered causes of Wild Animals and Plants Used in TCM**

##### **Environmental damage and pollution**

For a long time, because of lacking the knowledge of the relation between the ecological environment and human activities, people didn't recognize the importance of protecting wildlife resources and ecological environment, so they cut down forest, and enclosed lake to build up cultivated land. When they recognize the importance of environment, they find it too late to regret.

People often thought that China is a vast land with abundant resources that are not exhausting, so they cultivated the grassland and wasteland desperately to produce more grain to support more population. Many people thought that jackal, wolf, tiger, leopard, and Asia bear were all pests. In order to protect the security of people's lives and properties, hunters were encouraged to kill them. Animals formed a part of the biological chain, but this was not realized at all.

Because of reduction of the forest reserves, destruction of the habitat of wild animals and plants, the environmental pollution due to large-scale use of agricultural pesticide, chemical fertilizer, many animals and plants in China are endangered, or even extinct.

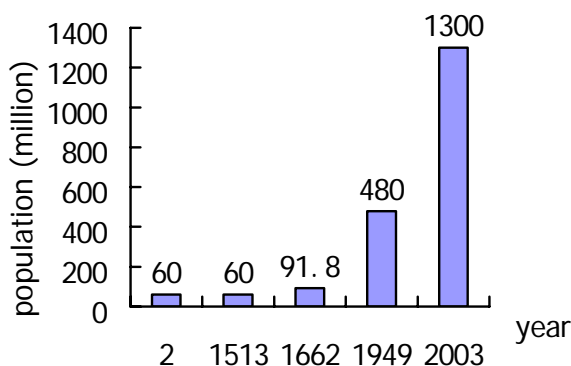
Many people don't often know that human activities destroy the environment and ecological balance, but only know to make use of science and technology to create the wealth desperately. So

the environment is more and more exasperated, the varieties and amounts of wild species used in TCM are becoming less and less.

### Population explosion

China is a developing country with the largest population in the world. It is the fundamental realities of the country that population is large, cultivated land is little; per capita natural resources are relatively insufficient. With population explosion (figure 4-1) and raising the level of human consumption, the human demand for the land resources is becoming larger and larger.

Figure 1: Growth of Chinese population



Source: Almanac of China's Population 2004<sup>46</sup>

However, the capacity of the land resources is limited, this must cause resources of wild animals and plants with economic value to reduce in a large amount, or even to die out. Especially, when population increases sharply, and people's scope of activities is becoming wider and wider, it causes the wild animals and plants lose their living environment, and they become endangered and even extinct.

### Overspending the wildlife resources

With modern science and technology developing constantly, some medical enterprises developed their new products blindly, they only paid attention to the immediate interest and ignored the long-term ecological and social benefit.

Stimulated by the high price in market, those medical materials which use widely and have higher economic value are often excessively excavated (hunted unlawfully), which destroyed the recycling ability of resources seriously and caused some wild species to become endangered and

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<sup>46</sup>Committee of Almanac of China's Population, Almanac of China's Population 2004, The Institute of Population and Labor Economics of Chinese Academy of Social Sciences, Beijing, China.

even die out.

To protect the national ecological environment and wildlife resources, some developed countries offer a high price to developing countries to purchase their wild animals and plants resources to meet their requests of such products. To gain economic benefit for the time being, some developing countries have to exchange for some foreign currency by sacrificing the wildlife resources, resulting in the ecological imbalance of some areas seriously, which is one of the elementary causes that make the wildlife resources endangered and extinguishing.

### **Illegal trade of wild animals**

At present, the scale that the global wild animal smuggled illegally has already reached a surprising degree and has become the third largest illegal trade (table 4-1) second only to the munitions and drug smuggling. It is huge interest that the profit can be up to U.S.D 11000 million per year. Total amount of smuggling the endangered animals among them is up to U.S.D 2000~3 000 million at least per year.

**Table 4-1**

#### **Illegal animal-smuggling in the world in 2000**

| Kinds            | Quantity                  |
|------------------|---------------------------|
| Primate          | $5 \times 10^4$ heads     |
| African ivory    | $14 \times 10^4$ sticks   |
| Reptile's skin   | $1000 \times 10^4$ pieces |
| Mammal's skin    | $1500 \times 10^4$ pieces |
| Tropical fish    | $3.5 \times 10^8$ heads   |
| Rhinoceros' horn | $1 \times 10^4$ kg        |

*Source: Journal of Dadi of People's Daily, PRC* <sup>47</sup>

### **4.2.2 Proposal of protecting the endangered species used in TCM**

To guarantee TCM to have enough materials resources to use, the government, local community and the medical enterprises should strengthen the endangered wild species to be farmed and cultivated and tamed, for the complement alternation of herbal materials and artificial synthetic are not effective. At the same time, they should strengthen research of the domesticated species to adapt the wild environment to recover the wild population of the species. Of course, the protection of environments is necessary.

### **Farming the endangered animals used in TCM**

To protect biodiversity in the world, to ensure the good ecological environments in our country, and to guarantee the reserves and supply of the strategic medical materials like rhinoceros horn, the government and community, etc. had put forward the policy that wild medical materials be

<sup>47</sup> Yu Ge, Huang Hongzhang, The Wild Animal-smuggling Increasing, Dadi of People's Daily, April, 2000 No.4

changed into breeding and planting early in 1958<sup>4</sup>. This had encouraged the enterprises to farm domestic existing endangered animals, and funded some enterprises to breed, tame and do research on some endangered animals. This is so far successful and prosperous.

For example, the success of farming bear is the case. Bear bile is a kind of rare and valuable medical materials as rhinoceros horn. To meet the requirements of people, bear farming and bile extracting has been practiced in 1980s. With developing technology of bear farming and bile extracting, bear farming does not depend on wild population completely and has realized sustainable supply of bear bile. The practice is bile extracting of breeding bear, which can not only meet man's medical need but also protect the wild bear and the environment.

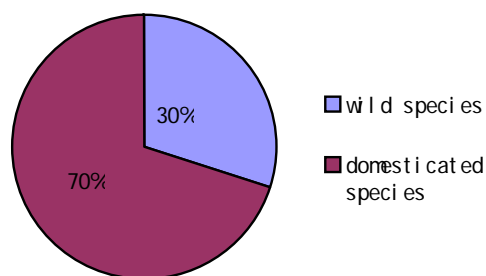
Moreover, the species of some animals on extinction should be introduced from foreign countries as soon as possible and its population should be multiplied to meet the medical use of TCM.

### **Cultivating the endangered plants used in TCM**

To protect the resources of the endangered medical wild plant, and to meet people's medical requirements, some plant materials used widely in TCM must be cultivated. At present, the portion of purchasing quantity of medical plants used widely in TCM coming from the wild species and domestication species is 30% for the wild species and is 70% for domesticated species. (Figure 4-2).

Figure 4-2

### **Quantity of Medical Material**



*Source: proceeding of symposium on the strategy of conserving and utilizing endangered species used in TCM, Kunming, China, 2000* <sup>48</sup>

Cultivating the endangered plants used in TCM is successful in meeting the medical requirements of people in China. Some medical plants that were rare and endangered in the past now can sustainably supply the need of mankind. Such species include ginseng, eucommia, gastrodia,

<sup>48</sup> Proceeding of Symposium on the Strategy of Conserving and Utilizing Endangered Species Used in TCM, Kunming, China, 2000, Research Information On Traditional Chinese Medicine, Supplement, 2000

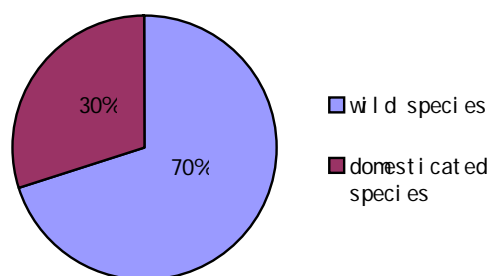
ginkgo, and so on.

To make wild species turning into domesticated species by farming and cultivating is the best way to protect in history, which is today.

Though farming and cultivating the wild species succeeds in China, but the portion of purchasing kinds of medical plants used widely in TCM coming from the wild species and domesticated species, the wild of which is 70%, the domestication is 30% (Figure 4-3). In order to make more wildlife medical species domesticated, the government, the community and the international organization must strengthen the domestication research of the wildlife to meet people's requirements increasing.

Figure 4-3

### **Kinds of Medical Material**



*Source: Proceeding of Symposium on the Strategy of Conserving and Utilizing Endangered Species Used in TCM, Kunming, China, 2000*

So the government needs funding the scientific research to domesticate the wildlife species. Not only can the research institute alleviate the pressure to wild resources, but also protect the wildlife never to be endangered by using the domestication. In fact, the protection after species being endangered is no less than mending the fold after the sheep have been already stolen.

In fact, farming and planting the wildlife accords with the national and international laws and regulations, such as the Convention of International Trade of Endangered Species of Fauna and Flora (CITES).

### **Strengthening research of the domesticated species to adapt the wild environment**

To make wild species turning into domestic species by farming and cultivating can ensure that industry of TCM develop sustainably and protect the wild resources. However, the research of the domesticated species adapting the wild environment can increase and reproduce the wild

population, and maintain the nature biodiversity. This can keep TCM herbal virtue and effectiveness.

In the case of *Elaphurus davidianus*, it was extinct in China, then immigrated from England in 1985. Today, the population breeding is over 2000 and some of them was put to nature. The other endangered wild species should learn from the practices of *Elaphurus davidianus* breeding.

### **Establishing the natural reservation of wild species used in TCM**

The government should set up the gregarious protective reservation of the medical rare endangered species. The rare wild species used in TCM have themselves special conditions and habitats. So the reservations can protect more medical rare endangered species effectively to set up all kinds of natural reserves, which can develop deposited technology of the medical rare endangered species. The researcher can study systemically the characteristic of germ plasm of the medical rare endangered species that could be collected in the reservation and construct the assessment system that can evaluate the characteristic of germ plasm. The gene database of one kind of qualities of rare endangered medical plant can be set up by the reservation.

### **Controlling growing of Chinese population and decreasing the export of herbal materials to developed country**

Today, the family planning that is the fundamental policy has been done quite well in China since 1970s, which has controlled the speed of Chinese population growth effectively. But the base of population is very large. So the policy must be kept complied with it. Thus, this can leave room for the wild animals and plants a living space, which can make the wild animals and plants reproduce themselves to meet material requirements of TCM development.

In order to meet the requirements of the Chinese People, the precious wild medical resources should be protected well for continuous utilization other than exporting for more foreign currencies.

Of course, in the sake of not destroying wild species especially the rare animals, illegal wildlife-smuggling trade must be prohibited in the world.

### **New medicine application should illuminate source of materials**

On the proceedings of symposium on strategy of conserving and utilizing endangered species used in TCM was held in Kunming in October 2000. In order to guarantee TCM production not to destroy resources and not to make some species endangered, the representations advised that declaring new medicine in every case must illuminate the source of materials which come from the wildlife or the domestication, must provide evidences to show that the resources to be abundant, prove the new medicine not to destroy resources after it goes into operation. If the new production causes destroying of resources, the medicine won't be allowed to put into production, but it should be encouraged to use the domestic.



**4.3 No good methods have been developed to protect traditional knowledge including TCM from being used without consent. Individuals and countries that have created and kept such knowledge could not benefit from it while the “biopiracy” frequently occurred in the developing areas.**

It is, so far, hard to effectively protect the intellectual property of traditional knowledge like TCM theories, trueborn medicinal herbs as well as the innovative TCM products.

As a result, it would affirmatively disturb the normal manufacture and markets of TCM industry, weaken the potential advantages and the possibilities of enrichment offered by traditional knowledge. Contrarily, the original holder may not be using such knowledge freely if foreign individuals and countries grab the patent rights earlier.

For example, the patent of Ginseng Royal Jelly has been granted to someone in the U.S. though it was initially developed by an enterprise in Jilin Province, China. So it is considered as illegal actions for the Chinese companies to sell Ginseng Royal Jelly in the U.S. markets without consent<sup>49</sup>.

**It is therefore very important and urgent to develop effective regulation and policy to protect intellectual property of TCM in more effective ways. At present, there are more than 10 types of protection measures of intellectual property concerning TCM in China.**

The general public's awareness of protecting intellectual property of TCM is considerably feeble and it is rather serious that traditional and innovative Chinese medicinal knowledge is used and even patented by foreign corporations without consent from the Chinese side. Meanwhile, it isn't rare that TCM products are imitated by foreign corporations illegally from Chinese products too.

**4.3. 1 The existing forms of protecting intellectual property of TCM**

**Trade secret:** It has a long history of thousands of years in China and it is one of the important protective methods.

**National secret:** It is one of the most effective methods of all protections now that only finite TCM products enjoy such protection like Yunnan Baiyao capsule.

**Trademark protection:** It is the weak link which TCM industry is liable to be trespassed on. For example, trademark of the Beijing Tongrentang Co. Ltd, which is one of the oldest and well-known corporations of TCM, was even enrolled by a Japanese company in 1983<sup>50</sup>.

**The geographical indication:** It is a kind of protection aimed mainly at trueborn medicinal herbs or the products made from them.

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<sup>49</sup> The Patent Protection of Chinese Medications. <http://www.chinapip.net/analy/5.htm>

<sup>50</sup> Ye Li, Di Wang. The Protective Strategy of Medical Products. <http://health.511511.com/news/2004/07-27/130548.htm>

**Patent protection:** It is the strongest methods to protect inventions. But patent system isn't considered suitable for traditional medicine except those innovative products.

**Protection and inspection of new medicine:** In 2002, administrative protection of new medicine was abolished and inspective duration for new medicine of 5 years, in which the same produces can't be manufactured as well as imported by other corporations was set up.

**Protection of Chinese medicines:** There novelty is not required and the protective limit is from 30 to 7 years. The protective species have reached to 1668 in which 12 kinds of species belong to the first class of protection<sup>51</sup>.

**Copyright system:** It contains books, articles, prescriptions and instructions.

**New herb species:** It is often developed by cultivation or domesticated from wild species which are newly found.

**Frontier protection of the intellectual property:** It could be applied to the customhouse through which the tortious products export or import.

#### 4.3. 2 The situation of patent application for TCM in China<sup>52</sup>

**Firstly, patent applications examined are increasingly up in recent years.**

Items of patent applications examined of TCM rose fast in recent years but the increase was relative slower than that of Chemical and biological products in 2002. The situation of patent applications certified was almost the same (see the table 4-2~4-3).

Table 4-2

**The statistics of patent applications examined in medical field from 1995 to 2002 (item)**

| Year                             | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 |
|----------------------------------|------|------|------|------|------|------|------|------|
| Chemical pharmaceutical products | 203  | 53   | 87   | 63   | 137  | 215  | 214  | 999  |
| Processing of TCM                | 65   | 113  | 156  | 197  | 124  | 286  | 480  | 491  |
| Biology products                 | 5    |      | 14   | 13   | 18   | 43   | 18   | 391  |
| Total                            | 273  | 166  | 257  | 273  | 279  | 544  | 712  | 1881 |

Table 4-3

**The Statistics of patent applications certified in medical field from 1995 to 2002 (item)**

| Year | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 |
|------|------|------|------|------|------|------|------|------|
|------|------|------|------|------|------|------|------|------|

<sup>51</sup> Hui Xu. It Is Urgent for Patent Protection of Chinese Medicine. Beijing Business Today, 2004/11/25/. <http://chanye.finance.sina.com.cn/yy/2004-11-25/232251.shtml>

<sup>52</sup> Annual Statistic of Chinese High Technologic Industry. 2003.1

|                                  |     |     |     |     |     |     |     |     |
|----------------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Chemical pharmaceutical products | 136 | 27  | 68  | 51  | 99  | 165 | 138 | 484 |
| Processing of TCM                | 46  | 84  | 63  | 169 | 123 | 211 | 146 | 273 |
| Biology products                 | 1   |     | 3   | 3   | 6   | 37  | 24  | 165 |
| Total                            | 183 | 111 | 134 | 223 | 228 | 413 | 308 | 922 |

**Secondly, the patent applications examined of big enterprises are increasingly raising.**

The rise of patent applications examined as well as certified of big enterprises is stable, so does it of medium enterprises after some fluctuation (shown in table 4-4~4-7).

Table 4-4

**The statistics of patent applications examined of big enterprises from 1995 to 2002 (item)**

| Year                             | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 |
|----------------------------------|------|------|------|------|------|------|------|------|
| Chemical pharmaceutical products | 135  | 32   | 55   | 27   | 109  | 169  | 160  | 775  |
| Processing of TCM                | 24   | 78   | 62   | 77   | 67   | 200  | 263  | 405  |
| Biology products                 | 5    |      | 13   | 10   | 10   | 32   |      | 291  |
| Total                            | 164  | 110  | 130  | 114  | 186  | 401  | 423  | 1471 |

Table 4-5

**The statistics of patent applications certified of big enterprises from 1995 to 2002 (item)**

| Year                             | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 |
|----------------------------------|------|------|------|------|------|------|------|------|
| Chemical pharmaceutical products | 96   | 14   | 42   | 33   | 78   | 141  | 126  | 379  |
| Processing of TCM                | 13   | 63   | 22   | 72   | 79   | 163  | 107  | 249  |
| Biology products                 | 1    |      | 3    | 2    | 4    | 32   | 12   | 106  |
| Total                            | 110  | 77   | 67   | 107  | 161  | 336  | 245  | 734  |

Table 4-6

**The statistics of patent applications examined of medium enterprises from 1995 to 2002 (item)**

| Year                             | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 |
|----------------------------------|------|------|------|------|------|------|------|------|
| Chemical pharmaceutical products | 68   | 21   | 32   | 36   | 28   | 46   | 54   | 224  |
| Processing of TCM                | 41   | 35   | 94   | 120  | 57   | 86   | 217  | 86   |
| Biology products                 |      |      | 1    | 3    | 8    | 11   | 15   | 100  |

|       |     |    |     |     |    |     |     |     |
|-------|-----|----|-----|-----|----|-----|-----|-----|
| Total | 109 | 56 | 127 | 159 | 93 | 143 | 286 | 410 |
|-------|-----|----|-----|-----|----|-----|-----|-----|

Table 4-7

**The statistics of patent applications certified of medium enterprises from 1995 to 2002 (item)**

| Year                             | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 |
|----------------------------------|------|------|------|------|------|------|------|------|
| Chemical pharmaceutical products | 40   | 13   | 26   | 18   | 21   | 24   | 12   | 105  |
| Processing of TCM                | 33   | 21   | 41   | 97   | 44   | 48   | 39   | 24   |
| Biology products                 |      |      | 1    | 1    | 2    | 5    | 12   | 59   |
| Total                            | 73   | 34   | 68   | 116  | 67   | 77   | 63   | 188  |

**Thirdly, patent applications examined of state-owned enterprises are greatly going up**

It showed that the awareness of protecting intellectual property of TCM in state-owned enterprises is stronger than before. However, the patent applications certified decreased conversely, implying that the state-owned enterprises have to improve their abilities and skills of protecting intellectual property.

On the contrary, both protective awareness and abilities of enterprises with foreign capital are stronger, a consequence resulting from the high administrative capacity (see table 4-8~4-11).

Table 4-8

**The statistics of patent applications examined of state-owned enterprises from 1995 to 2002 (item)**

| Year                             | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 |
|----------------------------------|------|------|------|------|------|------|------|------|
| Chemical pharmaceutical products | 162  | 41   | 61   | 24   | 88   | 68   | 34   | 209  |
| Processing of TCM                | 25   | 27   | 64   | 21   | 38   | 52   | 140  | 189  |
| Biology products                 | 4    |      | 12   | 9    | 6    | 8    | 2    | 16   |
| Total                            | 191  | 68   | 137  | 54   | 132  | 128  | 176  | 414  |

Table 4-9

**The statistics of patent applications certified of state-owned enterprises from 1995 to 2002 (item)**

| Year                             | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 |
|----------------------------------|------|------|------|------|------|------|------|------|
| Chemical pharmaceutical products | 110  | 19   | 51   | 31   | 68   | 101  | 53   | 63   |
| Processing of TCM                | 17   | 8    | 26   | 36   | 61   | 16   | 8    | 54   |

|                  |     |    |    |    |     |     |    |     |
|------------------|-----|----|----|----|-----|-----|----|-----|
| Biology products | 1   |    | 3  | 2  | 2   | 12  | 11 | 3   |
| Total            | 128 | 27 | 80 | 69 | 131 | 129 | 72 | 120 |

Table 4-10

**The statistics of patent applications examined of enterprises with foreign capital from 1995 to 2002 (item)**

| Year                             | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 |
|----------------------------------|------|------|------|------|------|------|------|------|
| Chemical pharmaceutical products | 2    | 3    | 3    | 7    | 14   | 15   | 25   | 70   |
| Processing of TCM                | 20   | 64   | 35   | 88   | 10   | 44   | 108  | 46   |
| Biology products                 | 1    |      |      |      | 6    | 28   | 6    | 12   |
| Total                            | 23   | 67   | 38   | 95   | 30   | 87   | 139  | 128  |

Table 4-11

**The statistics of patent applications certified of enterprises with foreign capital from 1995 to 2002 (item)**

| Year                             | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 |
|----------------------------------|------|------|------|------|------|------|------|------|
| Chemical pharmaceutical products |      | 2    | 3    | 5    | 5    | 11   | 11   | 64   |
| Processing of TCM                | 19   | 52   | 22   | 57   | 8    | 34   | 43   | 27   |
| Biology products                 | 1    |      |      |      | 3    | 23   | 8    | 32   |
| Total                            | 20   | 54   | 25   | 62   | 16   | 68   | 62   | 123  |

### 4.3. 3 The awareness of protecting intellectual property is weak in China

The authorities are short of enough recognition for the importance of protecting intellectual property of TCM because many have been looking down on the tradition and antiquity of TCM.

For example, a great many Chinese patent medicines have lost the independent intellectual property for they are listed in National Pharmacopoeia before patent applications.

People in China have been used to getting trade protection in the planned economy system for years and pharmaceutical enterprises as well as researchers run short of awareness of legal protection<sup>53</sup>. In China, papers and prizes often draw more attention and high appraise than achievements and patents.

According to some investigations, 70% big and medium enterprises and 95% small enterprises which are state-owned in China have never applied for pharmaceutical patent. Meanwhile, no-service patent applications increased from 57.8% in 1987 to 84.5% in 1998 and service patent

<sup>53</sup> HuBin Zhou, Qingkui Zhou, Junying Xue. The Protective State of Chinese Medicine. <http://www.yy2000.com/xinyaodongtai/tanzhongguoyaoawudebaohuxianzhuang.htm>

applications conversely decreased from 42.2% to 15.5%<sup>54</sup>.

In Chinese academies, about 10-30% people have certain knowledge and awareness of intellectual property; about 60% people are lack of such knowledge and about 3-10% people know nothing about it<sup>55</sup>. So, the nuclear information often leaked carelessly when companies and academies cooperated with foreign corporations. So does it during the academic intercommunions.

#### **4.3. 4 The function of current protection of intellectual property is limitative**

Firstly, it is difficult to confirm who is the ultimate beneficiary as most of TCM knowledge has often been possessed by the country or some communities.

Secondly, the current protective systems fail to cover all fields of TCM like acupuncture in China<sup>56</sup>.

Thirdly, current protections of intellectual property like patent system mainly were developed according to the characteristics of chemical drugs so that it is lack of exercisable approach and valid effect for TCM.

For example, TCM prescriptions are usually made up of more than one Chinese medication and it is hard to tell which part or component works. Thus, it is hard for enterprises to hold the market by applying patent, because others could enroll and produce the medicines if some unimportant medications are added to the prescriptions.

Fourthly, there is no enough and valid regulations and laws to discover the tortious behavior and execute the punishment so that the enterprises pay too much for protecting their rights. Some items listed in national laws aren't easy to be executed yet.

For instance, though in the *Technical List of Forbidden or Limited Items for Export of PRC*, it has definitely contained the processing technics and the original process after harvesting of 13 kinds of toxic Chinese medications like Wutou (Radix Aconiti) in the chapter of *technologies of processing Chinese prepared herbal slices*, many enterprises with foreign capital have the productive ability and have been providing customers those forbidden products for years<sup>57</sup>.

Fifthly, the examination period of patent application in China is 48 months, which is considerably longer. It is respectively 24.7, 28, 22.6 and 25 months in U.S., Japan, South Korea and Canada.

**As a result, influence on TCM is in many aspects.**

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<sup>54</sup> Yujing Bai, Renlan Liu. The Situation and Challenge of Intellectual Property of TCM. *Journal of TCM College of ShanXi*. 2003,4(1): 47-49

<sup>55</sup> ChunHua Fu. Analyze the Function of Intellectual Property in the TCM Academies. *Journal of Chengdu University of TCM*.1996,19(4):58-59

<sup>56</sup> Jiangxiu Song. The Strategy of Application for TCM Patent. *Chinese Journal of Information on TCM*. 2003,10(7): 33-35

<sup>57</sup> Junying Fu, Qian Jia. Strengthening the Protection of Intellectual Property Right of TCM and Making TCM Develop in A Sustainable Way. *World Science and Technology-Modernization of TCM*.2004,6(4):10-12

The rights of inventors and enterprises have been damaged badly and it does do harm to their activities. It would surely influence those decisions to invest on TCM because the investors wouldn't receive high returns, which is often brought by patent application of the new chemical drugs<sup>58</sup>.

Meanwhile, it is hard to guarantee satisfaction of the quality of Chinese medicines as there are too many similar products which would result in lack of raw material and out-of-order competitions. At the same time, the evil competitions would affect the TCM reputation and the business profits when China exports TCM products to countries<sup>59</sup>.

#### **4.3. 5 The experts in intellectual property of TCM are in badly need.**

TCM, special traditional knowledge, needs professionals who master both TCM theories and laws of protection of intellectual property for administration and research.

Such insufficiency has frequently resulted in secrets leaking rather than keeping the valuable information during protective course because of lack of protective ability and skill in institutes and enterprises of TCM.

At the same time, consecutive and official researches in this field are seldom carried out so that it is difficult to offer valuable information as well as required skill. It couldn't help to influence the development of relative national regulations and laws as well as the decisions of TCM enterprises.

For example, 4 items of patent about Folium Ginkgo applied by foreign enterprise almost covered all extractive technics. Conversely, more than 10 items of patent applied by Chinese enterprises have concerned nothing about the significant technology<sup>60</sup>.

#### **4.3. 6 The international situation of intellectual property of TCM**

Many developed countries have recognized the great scientific and potential economic value of TCM, which is completely different from allopathic medicine, and start the collection of TCM knowledge and innovation in new drugs from Chinese medications based on their adequate capital and advanced technology.

Based on achievements made by Chinese and with some improvement, some foreign enterprises applied for patent or sold the products all over the world including in China. For example, in Japan the GOV of a pill developed on the basis of the Chinese well-known prescription Liushen pill reached to U.S. \$120 million yearly<sup>61</sup>.

Now traditional knowledge, biologic resources and processing technology which are derived

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<sup>58</sup> Yingying Liu. TCM Experts Review the Prospect of Innovation of TCM. Capital Medicine. 2004(3): 12-13

<sup>59</sup> Zhongde Cai. The Influence of Medical Patent on Development of TCM. Domestic TCM. 1994(3)

<sup>60</sup> Xinhuanet. The Phenomena That Foreign Company Applied for Patent of TCM Draws Experts' attention. Chinese Journal of the Practical Chinese with Modern Medicine, 2004,4(17): 516

<sup>61</sup> Linggen Yan. Cogitating about Popularization of TCM All Over the World. Chinese Journal of TCM Administration. 2004, 14(2): 37-38

from China are extensively employed by developed countries without any compensations. It has severely damaged the benefits of developing countries and it will influence the sustainable development of Chinese pharmaceutical industry too.

At the same time, foreign countries have applied actively for patent of TCM. For instance, in U.S. there were 234 items of patent application certified of TCM in which Chinese prescriptions and active components or parts accounted respectively for 47% and 38% in 1976-2003 (shown in table 4-12 and figure 4-4). Like the patent on acupunctural treatments is obtained by an American in U.S.<sup>62</sup>.

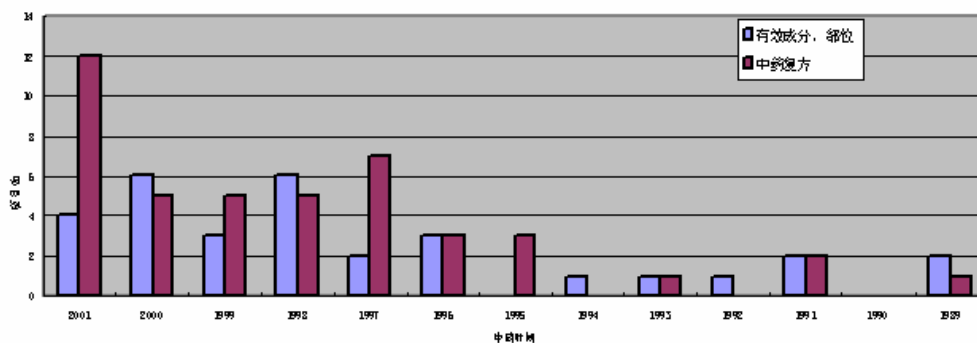
Table 4-12

**The items of patent application certified in U.S. in 1976-2002**

| Year | Item | Year | Item | Year | Item | Year | Item |
|------|------|------|------|------|------|------|------|
| 2002 | 4    | 1995 | 9    | 1988 | 4    | 1981 | 0    |
| 2001 | 29   | 1994 | 16   | 1987 | 3    | 1980 | 0    |
| 2000 | 25   | 1993 | 13   | 1986 | 4    | 1979 | 2    |
| 1999 | 26   | 1992 | 4    | 1985 | 2    | 1978 | 0    |
| 1998 | 29   | 1991 | 9    | 1984 | 1    | 1977 | 1    |
| 1997 | 26   | 1990 | 1    | 1983 | 2    | 1976 | 1    |
| 1996 | 16   | 1989 | 5    | 1982 | 0    |      |      |

Figure 4-4

**Comparison of Chinese prescriptions (colored in red) and active components or parts (colored in blue) of patent application certified in U.S. in 1989-2001**



<sup>62</sup> Chaohui Chen. Analyses on the Application and Grant of TCM Patent in U.S.. Chinese Journal of Information on TCM. 2004, 11(3): 276-277



## **Proposal:**

Effective forms of protecting intellectual property of TCM should be developed.

**1 Generalization movements**, aiming at raising the general public awareness and abilities of protecting intellectual property of TCM, should be carried out especially among the local governments, TCM enterprises, researchers and individuals.

It is necessary to let personnel involved know what nuclear secrets of TCM especially listed in the national laws are and how to keep these secrets from careless leak. And it is useful to generalize the information of intellectual property on the websites and improve the speed and capability of relative personnel to get valuable information on Internet.

**2 It is suggested to establish an independent national commission of intellectual property of TCM** that would improve and execute correlative laws and regulations in view of the difficulty and complexity of protecting intellectual property of TCM.

Though many national departments are now concerned, no one is responsible for it in practice and they are lack of mutual communication and harmonious cooperation one another.

The commission is supposed to be absorbed in the correlative affairs of intellectual property of TCM and have experts of various aspects such as TCM, industry, institute, law and politics engaged in the jobs. Existing regulations and laws should be reviewed and detailed in order to guarantee exercisable performance.

For example, the item of “*traditional processing technique of Chinese prepared herbal slices*” listed in laws has failed to be defined clearly and it therefore results in that herbal slices that are forbidden have been enrolled and manufactured by enterprises with foreign capital.

On the other hand, some nuclear and key technology as well as special species of Chinese medicines which haven't been recognized yet should be inspected and listed in laws again. And enterprises and individuals which act against the laws and regulations should be punished severely and the penalties should be raised extraordinarily.

**3 Governments should attach importance to the experts of both TCM and intellectual property.**

Governments should provide experts such as a few advanced pharmacutists of TCM who master the nuclear information with homologous status and favourable treatments so that they aren't employed by foreign enterprise and leak classified technology to it. If it happened, correlative personnel should receive legal penalty according to laws.

Advanced researchers on intellectual property of TCM should be trained and the general capability and skills of using various protective methods together should be improved in enterprises and academies of TCM.

**4 It is necessary to encourage innovations in TCM as the initial traditional knowledge is hard to be protected according to current regulations and laws.**

Patent system is useful to protect the Chinese medicine innovated such as the Chinese patent medicine which was derived from traditional prescriptions or was reformed the dosage form. Thus, it should be regarded as one of the main purpose of scientific researches on TCM to get the patent right and legal protection.

For instance, the trueborn medicinal herbs like special gene fragment differed from the same species harvested in other places should be researched and applied for patent. Therefore, one more valid protective method should be established except the geographical indication.

**5 Governments of developing countries should establish specific policy and regulatory issues for traditional medicines all over the world.**

Innovative protection of intellectual property of traditional medicines according to their particularity should be developed as it is hard for TCM which aren't gifted with novelty, originality and industrial utility to meet the need of current protective system of intellectual property<sup>63</sup>.

The experience of some developing countries could be employed. For example, in 2002 the southern pacific countries attempted to pass a law for the purpose that "traditional owners 'should be paid'" when any companies want to utilize the traditional knowledge or culture there commercially<sup>64</sup>.

**6 "Database of TCM knowledge" should be established**

It is the first step to collect and document TCM knowledge including the minority medicines like medicine of Zang ethnic minority group, which haven't drawn enough attentions now.

It is one of the important and effective methods such as developing digital data to preserve and develop traditional medicines including natural, documental and oral resources, especially the scattered data, as it did in the case of a plan developed by India that "Traditional Knowledge Digital Library" should be established by the Council of Scientific and Industrial Research<sup>65</sup>.

It is therefore helpful to prevent traditional medicine from applying patent by foreigners and to raise its value. It is suggested that WHO and WIPO participate in this job in order to explore and utilize traditional information resources.

**7 It is also a practical measure for government to encourage the establishment of service agencies of intellectual property of TCM, which would offer professional service, and the**

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<sup>63</sup> Yishan Wu. To Pay More Attention on the Function of Traditional Knowledge in the National Innovative System. Reports of Internet Information. the 18<sup>th</sup> Periodical ,2002/12/12

<sup>64</sup> Quirin Schieremeier, Traditional Owners "should Be Paid", Nature, 2002, 419 (6906): 423

<sup>65</sup> CII Seminar. Enhancing Human Capital Index: New Approaches for The Knowledge Economy. March 14, 2002 <http://www.giic.org/events/indiaconference/joshi.asp>

construction of self-discipline organizations, which could contribute to run the TCM industry and carrying out international cooperation too.

**4.4 The existing evidence revealed a serious flaw in the educational system of TCM including textbooks, curriculum and faculty and so on because many graduates from TCM academies couldn't master the essentials of TCM and employ TCM to treat patients.**

TCM education has changed from apprentices-master training into academic education since 1956. It is true that TCM academies have trained a great many TCM providers. But it couldn't cover up the facts that academic education run lack of TCM character and make educational mode humdrum.

**4.4.1 The situation of current TCM education**

Up to now, there are 32 TCM academies excepting 3 colleges of minority medicine, 45 secondary TCM schools as well as more than 100,000 enrolled students in China now<sup>66</sup>. The students eligible would get their degrees of bachelor, master and doctor after 3 to 7 years' education. In recent years TCM students enrolled are growing up quickly (see table 4-13)<sup>67</sup>.

Table 4-13

**The number of students in TCM academies, secondary TCM schools and modern medicine academies that contain TCM specialty in 1999-2003**

| Schools                      | Year | Students graduated | Students recruited | Students enrolled |
|------------------------------|------|--------------------|--------------------|-------------------|
| Secondary TCM schools        | 2003 | 20,808             | 26,444             | 79,641            |
|                              | 2002 | 13,369             | 20,967             | 62,830            |
|                              | 2001 | 12,745             | 20,831             | 63,100            |
|                              | 2000 | 12,977             | 18,627             | 56,214            |
|                              | 1999 | 12,496             | 19,082             | 53,499            |
| <b>Including:</b>            | 2003 | 149                | 242                | 510               |
|                              | 2002 | 166                | 228                | 569               |
| Schools of minority medicine | 2001 | 118                | 161                | 631               |
|                              | 2000 | 83                 | 242                | 588               |
|                              | 1999 | 81                 | 228                | 429               |
| TCM academies                | 2003 | 14,780             | 44,562             | 142,236           |
|                              | 2002 | 11,079             | 36,426             | 108,591           |
|                              | 2001 | 8,951              | 28,759             | 83,239            |
|                              | 2000 | 7,741              | 22,835             | 63,492            |
|                              | 1999 | 8,452              | 16,673             | 48,857            |

<sup>66</sup> The Situation and Administration of TCM Introduced by the Health Ministry of Chinese P. R. C.. [http://news.xinhuanet.com/health/2004-10/09/content\\_2065948.htm](http://news.xinhuanet.com/health/2004-10/09/content_2065948.htm)

<sup>67</sup> The Chinese Annual Reports of TCM, 1999-2003, <http://www.satcm.gov.cn>

|  |      |       |       |        |
|--|------|-------|-------|--------|
| <b>Including:</b>  | 2003 | 88    | 428   | 1,376  |
|  | 2002 | 101   | 354   | 1,025  |
| Colleges of<br>minority<br>medicine                      | 2001 | 83    | 396   | 787    |
|  | 2000 | 105   | 217   | 597    |
|  | 1999 | 305   | 386   | 1431   |
| Academies of<br>modern<br>medicine<br>(TCM<br>specialty) | 2003 | 2,545 | 6,698 | 18,412 |
|  | 2002 | 1,476 | 5,330 | 15,996 |
|  | 2001 | 1,545 | 5,625 | 14,722 |
|  | 2000 | 1,782 | 5,809 | 14,155 |
|  | 1999 | 1,483 | 2,633 | 7,370  |

Postgraduate students of TCM were started to recruit in 1978. Now the number of postgraduate students of TCM, which account for 7% of the total students of TCM, is still little considerably (see table 4-14).

Table 4-14

**The situation of graduate students of TCM in TCM academies in 1999-2003**

|                               | Year | Students<br>graduated | Students<br>recruited | Students<br>enrolled |
|-------------------------------|------|-----------------------|-----------------------|----------------------|
| Total of graduate<br>students | 2003 | 1,892                 | 4,427                 | 10,387               |
|                               | 2002 | 1,392                 | 3,239                 | 7,906                |
|                               | 2001 | 1,066                 | 2,631                 | 5,961                |
|                               | 2000 | 918                   | 1,887                 | 4,358                |
|                               | 1999 | 764                   | 1,358                 | 3,383                |
| Including<br><br>Doctor       | 2003 | 366                   | 836                   | 1,990                |
|                               | 2002 | 306                   | 609                   | 1,515                |
|                               | 2001 | 227                   | 512                   | 1,232                |
|                               | 2000 | 192                   | 397                   | 949                  |
|                               | 1999 | 159                   | 301                   | 740                  |
| Master                        | 2003 | 1,526                 | 3,591                 | 8,397                |
|                               | 2002 | 1,086                 | 2,630                 | 6,391                |
|                               | 2001 | 839                   | 2,119                 | 4,729                |
|                               | 2000 | 726                   | 1,490                 | 3,409                |
|                               | 1999 | 605                   | 1,057                 | 2,643                |

At the same time, the in-service educations of TCM are strengthened and the correspondence education is the main form (showed in table 4-15).

Table 4-15

### The situation of in-service education of TCM in TCM academies in 1999-2003

| Year | Students graduated |                        |                                   | Students recruited |                        |                                   | Students enrolled |                        |                                   |
|------|--------------------|------------------------|-----------------------------------|--------------------|------------------------|-----------------------------------|-------------------|------------------------|-----------------------------------|
|      | Subtotal           | Regular college course | Specialized subject (Three years) | Subtotal           | Regular college course | Specialized subject (Three years) | Subtotal          | Regular college course | Specialized subject (Three years) |
| 2001 | 7,350              | 619                    | 6,731                             | 23,081             | 4,777                  | 18,304                            | 53,576            | 9,458                  | 44,118                            |
| 2000 | 6,066              | 621                    | 5,445                             | 14,860             | 2,777                  | 12,083                            | 35,499            | 5,240                  | 30,259                            |
| 1999 | 4,298              | 413                    | 3,885                             | 8,958              | 1,545                  | 7,413                             | 26,256            | 3,091                  | 23,165                            |

#### 4.4.2 Challenges existed of TCM education

Many students graduated couldn't be thought as TCM providers eligible according to their degree of mastering TCM theory and treating patients though there are more than 30,000 graduates left schools yearly.

##### 4.4.2.1 There is lack of early basic and correlative education of TCM in China

It is necessary for learners to have profound understanding of traditional culture because TCM, which are based on traditional philosophy and has characters of higher abstract and generalization, are often difficult to understand without such foundation.

##### 4.4.2.2 TCM courses is too little in TCM schools

At present, hours of TCM courses gradually decreased. Let's take example by specialty of Chinese medicine, its TCM hours account for 42.88% only, but the hours of modern medicine and public courses like English respectively account for 31.12% and 26%<sup>68</sup>.

##### 4.4.2.3 Faculty of TCM academies needs improvement

TCM teachers have to possess rich clinic experiences as TCM derived and developed in clinic. But nowadays teachers often have never worked in clinic and have no idea what is primary or secondary so that the teaching is always deviated from practice.

##### 4.4.2.4 It is more disturbing to discover lots of challenges in advanced TCM education

In recent years, there are more and more "modern TCM providers" who are accomplished in animal studies, while people who possess firmly both basic TCM theories and clinic practice became less and less. Almost all studies of graduate students now emphasize pharmaceutical experiments that are lack of TCM characteristics.

#### 4.4.3 Proposal

<sup>68</sup> Shaoying Wang. Where Is the Status of TCM Strategy.  
[http://www.tcmgap.com/main\\_viewdoc.asp?STID=1&AID=2764](http://www.tcmgap.com/main_viewdoc.asp?STID=1&AID=2764)

How to improve the quality of TCM education is significant for existence and development of TCM. Authorities should emphasize the insistent use of TCM and improve the efficacy of TCM.

**4.4.3.1 To enhance education of Chinese traditional culture** as the early education of TCM in elementary and middle schools.

**4.4.3.2 To give prominence to TCM characteristics**

It is significant for beginners to succeed traditional medicine by learning classic, so reading classic is the best and shortcut to master the train of thought of TCM and methods of deciding TCM syndromes accurately.

**4.4.3.3 To reform the current TCM teaching**

Experts suggested that teaching of TCM such as medical classics and ancient Chinese prose should be added. And it is important to improve the capability of using TCM in practice.

**4.5 Some serious side effects and toxicity of Chinese medications occurred because many people including most doctors who don't understood TCM enough haven't used TCM following the theory of TCM.**

In recent years, some reports pointed out that Chinese medications have become the third large resources of toxicity and adverse effects of medicine after antibiotic and antipyretic analgesics like the "Chinese herb nephropathy". And it was therefore put forward that toxicological study of Chinese medical herbs should be carried out.

As a matter of fact, TCM has recognized toxicity of some medications for years. But toxic herbs could bring pharmaceutical efficacy to the full extent and their toxicity could be limited to the least extent if they are used properly, otherwise non-toxic herbs could also result in serious toxicity.

Thus, it is considerable reasonable to say that herbal toxicity has something to do with the users instead of the herbs themselves because Xiao Chaihu decoction that has been proved non-toxic by modern technology and science resulted in pneumonia and death in Japan.

At present, most of allopathic and TCM providers disregard the basic natural characteristics of Chinese medications as well as the TCM theory, and use the correlative herbs which have the certain pharmaceutical effects according to diagnoses of modern medicine based entirely on the therapeutic mode of allopathic treatment.

That is the reason why toxicity and adverse effects of Chinese medications are becoming increasingly serious. So we don't think it would resolve the toxicity of Chinese medication by only strengthening the herbal toxicological studies.

## **Proposal**

The important way to avoid toxicity of Chinese medication is to understand TCM theory as well as characteristics of Chinese herbs, and identify the difference between TCM and modern

medicine.

The government should encourage mastering appropriate use of TCM by training and additional education. And certain regulatory issues should be developed to promote proper use of TCM in order to assure the safety as well as efficacy of TCM in clinic like standardizing the process of herbs.

#### **4.6 Existing science and technology can hardly understand TCM because most of TCM knowledge exceeds the scope which modern science studies.**

Some TCM theories and treatment could now be explained partly by modern science and technology such as employing neuropeptide to account for the mechanisms of acupuncture<sup>69</sup>. It is great helpful to illuminate the great difference between TCM and superstition and encourage further understanding and acceptance of TCM worldwide.

But TCM, a harmonic medicine, often uses medication or non-medication therapies to adjust human being from abnormal status to normal rather than directly removing the pathogeny.

Thus we believe that TCM now couldn't be understood well because TCM knowledge is not entirely covered in the field of modern science. On the other hand, modern science and technology haven't had the capability to explain all natural and social phenomena now.

#### **Proposal**

Even now, TCM is provided with characteristic and advantage to be used by modern society especially against some stubborn diseases like multi-system diseases.

And TCM would be understood and accepted better only after the modern science and technology develop further.

#### **4.7 It is benefic for enhancing everyone's health to spread TCM all over the world.**

It is necessary to popularize TCM knowledge in order to let more and more people know the advantages and gradually accept it as a good treatment for health care though TCM hasn't been fully understood by modern science.

#### **Proposal**

##### **4.7.1 To publicize TCM in ways such as holding exhibition of TCM efficacy, introducing basic concepts and products around the world would let more people understand, accept and use TCM.**

First, government should pay more attention to TCM and encourage more TCM publicity developed like giving scientific lecture by TCM experts.

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<sup>69</sup> Jisheng Han. The Conventional Medicine, Non-conventional Medicine and Integrated Medicine. Medical Journal of Liaoning medical College, 2001,15(4): 169-170

Furthermore, it is significant to make appropriate use of the press too, like “Chinese herb nephropathy” reported in overseas and domestic media wasn’t pertinent because they ascribed all serious results to toxicities of Chinese herbs without further analyzing the relationship with improper ways of taking Chinese medicines.

Moreover, it is a good way to publicize TCM by remarkable cases, like the sample of Liu Hairuo who recovered mainly with TCM treatment though she was previously declared to be “brain death” for 3 times in Britain.

And we could employ the experience of the television competitions on knowledge of Beijing opera that have made great influence on raising new generation of fans<sup>70</sup>.

**4.7.2 Establishing international web sites** about TCM such as consultations online will have TCM resources shared well.

4.7.3 It is necessary to promote developed countries to understand TCM better and let TCM obtain its legislated status there. **TCM could meet the needs of health care in developed countries as well as developing countries.**

As we know, TCM which has more natural methods to prevent and treat diseases have showed great advantages. We believe that TCM would play a more important role to achieve the goal of WHO ‘Health for one’ all over the world.

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<sup>70</sup> Yishan Wu. Science Popularization of TCM Should Begin from Childhood. Science Time. 2004/10/29, [http://www.chinainfo.gov.cn/data/200411/1\\_20041101\\_94067.html](http://www.chinainfo.gov.cn/data/200411/1_20041101_94067.html)