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Mixing the Old with the New: Chinese Traditional Medicine and The Regulation of Food and Drugs in the United States

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Mixing the Old with the New

Chinese Traditional Medicine and

The Regulation of Food and Drugs in the United States

Introduction

The practice of traditional Chinese healing methods has secured a small but noticeable foothold in some sectors of American society. Whether this is simply yet another incarnation of the West's centuries-old romantic obsession with the exotic lure of the East, or a reserved but genuine concession to the virtues of a foreign medical discipline remains unclear. The purpose of this paper is to study the economic significance of Chinese traditional medicine and its implications for the American pharmaceutical industry and United States food and drug regulation.

PART I: THE CASE FOR ACTIONEnter the Dragon: The Importance of the Chinese Market

American industry unabashedly considers East Asia, particularly China, as the world's next great consumer market¹. This is especially so as regards health care - with a population of approximately 1.24 billion², China is fourfold as

¹National Trade Data Bank, U.S. Department of Commerce, Report on China - Leading Sectors for U.S. Exports and Investment, September 23 1999. See <http://www.tradeport.org/ts/countries/china/sectors.html>.

²CIA World Factbook 1999. See <http://www.odci.gov/cia/publications/factbook/ch.html>.

populous as the United States – and that population is an aging one. Lacking a developed domestic health care infrastructure, China is fertile ground for economic colonialism, both in terms of exports of American medical products to, and the location of American production facilities within, China. Notwithstanding notable regulatory restrictions, the U.S Government’s Country Commercial Guide for the Fiscal Year 1999 for the People’s Republic of China³ advises:

All of these measures pose a challenge to the foreign pharmaceutical importer or foreign domestic producer. Profit margins are considered slim, and most companies currently in the market place concentrate on niche markets where they may have up to a ninety-percent market share. Even so, the sheer (sic) size of the “potential” market, as well as impressive growth numbers (estimated to be fifteen percent annually into the next decade) makes the Chinese market difficult to ignore.

Even assuming a market free of government regulation, however, American pharmaceutical companies will face two significant barriers to entry, namely the relatively high cost of drugs and lack of Chinese consumer knowledge about Western medical science and treatments. The most formidable challenge facing these companies today is how to address the significant economic and educational disparities between the United States and East Asia.

³U.S Government Country Commercial Guide FY 1999: People’s Republic of China. The Guide is available online at http://www.state.gov/www/about_state/business/com_guides/1999/eastasia/china99_05.html.

A Tale of Two Countries: Contrasting American and Chinese Healthcare

The American healthcare industry is riding the crest of a huge wave of medical research and technological advancement. For the American healthcare patient this means more sophisticated and effective drugs and medical procedures. Aggressive advertising and promotion of these new developments continue to elevate the average consumer to new heights of medical self-awareness and information of treatment options, to the point where the range of choices available to the consumer may be conservatively described as bewildering.

These developments, however, have not come cheaply. Medical treatment now costs more than it ever has before. For example, the price of prescription drugs increased by 172% between 1982-1984 and the second quarter of 1999⁴. Medical care costs in general increased 154% between 1982-1984 and November 1999⁵. By contrast, consumer prices for food and beverages between 1982-1984 and November 1999 increased only 65.8% and transportation only 47.2%⁶. Of the US\$1.09 trillion total national health expenditure in 1997, \$348 billion was borne by insurance companies and \$507 billion by State and Federal government. Excluding taxes, the actual healthcare consumer directly bore only \$187 billion of total expenditure or about 17 cents to the dollar⁷.

⁴Health Care Financing Administration, U.S. Department of Health and Human Services, Index Levels of Medical Prices. See <http://www.hcfa.gov/stats/indicatr/tables/t08.htm>.

⁵United States Consumer Price Index. This is available at various sources including <http://www.bsu.edu/business/bbr/IBB/US/pcpi/pcpi.htm>

⁶*Ibid.*

⁷Health Care Financing Administration, U.S. Department of Health and Human Services National Health Expenditures, by Source of Funds and Type of Expenditure: Selected Calendar Years 1992-97. See <http://www.hcfa.gov/stats/nhe-oact/tables/t11.htm>.

China is a study in opposites. The majority of China's population resides in rural areas and has only basic schooling. There is little, if any, exposure to Western medical science, treatments or procedures. The rural populace is also desperately poor. While American consumers bore only a fraction of their total medical expenditures, Chinese consumers lack comparable resources to pay even for that fraction. China's per capita GDP in 1998 was estimated at \$3,600 compared to \$31,000 for the United States in the same year⁸.

Chinese consumers spend comparatively less (in terms of percentage share of GDP) on health care than American consumers. Total pharmaceutical exports from the United States to China in 1998 exceeded \$477m, almost a third of total Chinese pharmaceutical imports at \$1.72 billion. Total imports, however, accounted for a scant 12.46% of the Chinese pharmaceutical market in 1999, which, though totaling \$13.8 billion⁹, constituted only 0.31% of total GDP of \$4.42 trillion¹⁰. Although it was not possible to find same-source data to form an accurate comparison, the Department of Commerce's Bureau of Economic Analysis reported¹¹ the GDP of the United States' in 1998 as totaling \$8.76 trillion; of which medical care constituted \$910 billion. A different report¹² estimated total health care expenditure in 1997 at \$1.09 trillion, of which expenditure on "drugs and other medical nondurables" totaled \$108.9 billion or 1.24% of the 1998 GDP – exactly fourfold that of China in percentage terms.

⁸CIA World Factbook 1999

⁹U.S Government Country Commercial Guide FY 1999: People's Republic of China

¹⁰CIA World Factbook 1999

¹¹Bureau of Economic Analysis, U.S. Department of Commerce, News Release, December 22, 1999. See <http://www.bea.doc.gov/bea/newsrel/gdp399f.htm>

¹²*Ante*. See footnote 7.

Given that China's GDP is less than twice that of the United States, it is perhaps unsurprising that a country four times as populous as the United States spends comparatively four times less on health care. This phenomenon is undoubtedly compounded by the severe lack of private funding (whether through insurance or otherwise) for healthcare services, for the country in general and for rural areas in particular. In a keynote speech¹³ given at Beijing Medical University shortly after taking office as Director-General of the World Health Organization, Dr Gro Harlem Brundtland stressed the lack of comprehensive insurance schemes for the financing of preventive care in China. In particular, she emphasized the importance of extending social insurance to the families of those covered under state schemes (such as civil servants and workers) and other sectors of society, such as those in rural areas, who are not covered at all. The dearth of healthcare practitioners and the sheer logistical difficulties of providing healthcare infrastructure to rural areas complicate the problem further.

The Price Isn't Right: Challenges for American Industry

Poor consumer information, low income levels and an absence of private funding have stifled demand for expensive Western drugs, affording a partial explanation for the insubstantial penetration of foreign pharmaceuticals in China. One response of American pharmaceutical companies might be to focus its energies on the only course genuinely within its control: convince Chinese consumers of the superior value and potency of Western medications, notwithstanding their

¹³The full text of the speech is available on WHO's website at http://www.who.int/director-general/speeches/english/19981123_beijingbmu.html

higher prices, by educating them about Western scientific methods. However, as recently as in 1998 the State Department's United States Foreign and Commercial Service ("USFCS") published a report¹⁴ acknowledging that:

Price vs. cost will probably remain one of the most important considerations in [the Chinese pharmaceutical] market. Some leading U.S research-based pharmaceutical firms have found this market to be less than receptive to their newest – and priciest – cutting-edge products.

It is likely that American pharmaceutical companies will also find themselves up against opposition of a substantially different kind. Healthcare costs are borne primarily by the Chinese government through a State-run healthcare regime that presents further barriers to entry. Medical expenses have up till now been paid for by the government or treatment has been provided by state-owned enterprises. The government also publishes a National Essential Drug Bulletin, which lists those drugs for which the state will reimburse consumers. In the interests of protecting domestic industry and promoting a healthy balance of trade, the only foreign drugs which are listed are those for which there is no domestic substitute. Although a new urban insurance scheme was introduced in 1999 under which enterprises will make contributions to medical insurance and a general medical fund for employees, the scheme does not cover dependants or the rural sector¹⁵.

¹⁴Bruce Quinn, United States Foreign and Commercial Service, U.S. State Department, Drugs & Pharmaceuticals, (1998). See <http://www.corporateinformation.com/data/statusa/china/chinapharmaceutical.html>

¹⁵Nancy Xu, United States Foreign and Commercial Service, U.S. State Department, New Urban Medical Insurance System, (1999). See

Now It's Time for Double Jeopardy: Traditional Chinese Medicine

Even if these difficulties can be circumvented, American pharmaceutical companies will face the uphill task of combating *cultural* resistance to their products. Market penetration is crucially dependent on the substitution of American brand names for traditional Chinese remedies in the minds and wallets of Chinese consumers. These traditional remedies take two forms, both of which are relevant to the discussion that follows. The first is dispensed by the village healer, a master of traditional Chinese medicine, trained through apprenticeship in the ways of an ages-old medical philosophy. For a nominal fee he diagnoses the patient's spiritual and elemental as well as physical health. His living is made off the sale, from his personal stock, of made-to-measure raw herbal materials - medicinal remedies for preparation and administration by the patient or his family in his home. These "herbs" may include both animal and plant products, including spices, roots, plants, and even insects. Because of the personal interaction and communal spirit that characterizes these transactions, this is in many ways akin to medication prescribed by family doctors in the West, although as will be seen, the approach to the diagnosis and treatment of illnesses is starkly different.

The second form of traditional medicine is distributed by Chinese state-owned pharmaceutical enterprises that have utilized the technological advancements of the 20th century to formulate tablets, capsules and mixtures of these <http://www.tradeport.org/ts/countries/china/mrr/mark0119.html>.

botanical combinations for commercial distribution. These pre-packaged medicines constitute the bulk of Chinese pharmaceutical exports and are readily available throughout East Asia.

Centuries of tradition and culture have ingrained the holistic, philosophical character of Chinese medicinal practice into the purchasing decisions of Chinese consumers worldwide. Both forms of traditional healing remain popular not only in China, but Japan, Hong Kong, Taiwan, Singapore and among traditional Chinese in the United States. For example, a September 1996 World Health Organization (WHO) Fact Sheet on Traditional Medicine reported that Japan experienced a 15-fold increase in “kampo”, or Chinese-method herbal preparations compared with a 2.6-fold increase in the sales of mainstream pharmaceutical products¹⁶. In October 1995, the Singapore Ministry of Health Committee on Traditional Chinese Medicine reported that about 12% of all outpatient attendance is overseen by practitioners of traditional Chinese medicine¹⁷.

Within China, the projected growth figures are astonishing. The 1996 WHO Fact Sheet¹⁸ reports herbal preparations as accounting for 30-50% of total medicinal consumption in China. That trend appears likely to continue. A United States Department of Commerce USFCS report on the dietary supplements market in China published on 1 August 1999 estimates that the health foods industry in China (which includes dietary supplements) is currently worth

¹⁶World Health Organization Fact Sheet No 134. See <http://www.who.int/int-fs/en/fact134.html>

¹⁷An Executive Summary of the report is available at <http://www.gov.sg/moh/mohiss/tcm/tcmrpt.html>

¹⁸*Ante*. See Footnote 16.

\$2.4-3.6 billion and may expand to as much as \$12.1 billion by 2010¹⁹. The report emphasizes that Chinese consumers' demand for products with curative or health enhancing effects prompted a 30-fold increase in the number of Chinese dietary supplement suppliers between 1992 and 1999²⁰. A 1998 USFCS report²¹ outlines the challenges facing the pharmaceutical industry in approaching the Chinese market. Significantly, it ranks health foods and supplements on par with over the counter drugs as having the greatest growth potential for American exports.

The good news is that this appears to match trends within America. An FDA Report²², updated in January 1999, cites growth of dietary supplement sales in the United States as having risen from \$3.3 billion to \$6.5 billion between 1990 and 1996. These reports may give American dietary supplement manufacturers reason to expect not only an increase in domestic sales, but also increased exports of American dietary supplement products to China, replicating overseas the domestic turf war between pharmaceutical companies and the dietary supplements industry. The bad news for American enterprise is that the USFCS report on the dietary supplements market in China estimates that Chinese manufacturers dominate 80 to 90 percent of the Chinese market. The argument advanced here is that the vice-like grip of these domestic enterprises

¹⁹Lily Chou & Xianmin Xi, United States Foreign and Commercial Service, U.S. State Department, Dietary Supplements, (1999). See <http://www.tradeport.org/ts/countries/china/isa/isar0011.html>

²⁰*Ante*. See footnote 1.

²¹*Ante*. See footnote 14.

²²Paula Kurtzweil, Food and Drug Administration, U.S. Department of Health and Human Services, An FDA Guide to Dietary Supplements, 1998-1999. An online version is available at <http://www.fda.gov/fdac/features/1998/598.guid.html>

over the Chinese market is unlikely to loosen without first, serious reconsideration of existing corporate strategy and second, substantial legislative reform in America.

Whereas one may interpret upward trends in the United States dietary supplements market as a preference by higher-income American consumers²³ for luxury medical products, it is difficult to extend the same analysis to China. It is my case that for the economic, educational, political and cultural reasons that have been discussed, locally produced traditional remedies may continue to form the first-choice remedy amongst Chinese consumers. For American pharmaceutical companies the fiercest competition will not come from the dietary supplements industry or unaffordable high priced European alternatives, but from more familiar low cost domestic botanical remedies, manufactured by state-owned or recently privatized enterprises operating under the umbrella of the Chinese government protectionist policies. The 1999 USFCS report²⁴ on the dietary supplements market in China cautions:

The history of trust in Traditional Chinese Medicines (TCM's) has driven [Chinese] consumers to readily accept herbs and other natural products, paving the road for success of the health food industry. Health foods are now playing a role previously filled by TCM's, addressing problems ranging from high blood

²³Center for Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services, Economic Characterization of the Dietary Supplement Industry Final Report, (March 1999) Section 4.2.1. The report cites a 1990 report by Subar and Block finding that the incidence of dietary supplement consumption was highest amongst high school and college graduates and increased with income. See <http://vm.cfsan.fda.gov/~comm/ds-econt.html>.

²⁴*Ante*. See footnote 19.

cholesterol to weight gain to aging. Furthermore, mass-marketing has lent health foods an air of legitimacy that TCM's never had with handsome packaging and clearly defined product functions.

Says WHO? International Views on Traditional Medicine

The domestic Chinese pharmaceutical industry is highly unregulated and differs significantly from that of the United States. The 1998 USFCS report cites numerous factories as producing copyright or trademark infringing counterfeit drugs. Of more direct concern as far as human health is concerned, production standards fall short of acceptable levels: the same report cites only 18 of over 4000 pharmaceutical factories as meeting Good Manufacturing Practice standards²⁵. There is no reason to believe that factories manufacturing traditional Chinese medicines fare any better. A further concern pertaining to the traditional medicine (dietary supplement) industry is what would constitute "misbranding" under United States law. Many medicines are marketed claiming the ability to address a wide range of medical ailments. Some claims are medicinally accurate, but simply unproven by Western methods; others are downright questionable.

Notwithstanding these concerns, traditional medicine continues to enjoy strong endorsement by the World Health Organization, an approach that varies markedly from that of the U.S. Food & Drug Administration ("FDA"), which is discussed below. There are three possible reasons for this difference. First,

²⁵Non-compliance with GMP standards constitutes unlawful adulteration under 21 U.S.C. § 351(a)(1)(B) of the 1938 Food, Drugs and Cosmetics Act.

WHO recognizes the economic barrier between third world citizens and Western medication - many of those whose health the organization addresses can only afford traditional remedies. Secondly, as an organization of the United Nations, it has a necessarily accommodating, internationalist, culture, and does not play favorites to Western medical science. Thirdly, unlike the FDA, it is not subject to lobbying and political pressure from the sizable U.S. domestic pharmaceutical industry.

In May 1998, the 51st World Health Assembly in Geneva adopted a resolution urging WHO Member States “to develop and implement national plans of action or programmes (sic) on indigenous people’s health while “respecting, preserving and maintaining the knowledge of traditional healing and medicine in close cooperation with indigenous people²⁶. Following the appointment of the current Director-General, Dr Brundtland, WHO underwent restructuring, in which a specific Essential Drugs and Medicines (EDM) team on traditional medicine was established to research policy on traditional remedies²⁷. More specifically, WHO’s Special Programme (sic) for Research & Training in Tropical Diseases (TDR) endorsed the importance of traditional medicines in tropical disease research. Having determined that several important classes of anti-malarial drugs originate from plant products identified in traditional medicine, it now seeks to further research into traditional medicine in the hope of discovering new lead compounds for other diseases²⁸.

²⁶World Health Organization Press Release, 16 May 1998. See <http://www.who.int/inf-pr-1998/en/pr98-WHA8.html>

²⁷See http://www.who.int/medicines/teams/mgt/edm_funding.html.

²⁸See http://www.who.int/tdr/research/progress/mal_prd/lead1.htm.

Wheel of Fortune: The Market for Traditional Chinese Medicine in the United States

Ironically, this modicum of international recognition may have done just enough to legitimize Chinese traditional medicine in the minds of Western consumers, drawing it in from the lunatic fringe of medical quackery. Yet, the lack of firm endorsement by the mainstream Western medical community dresses it with the mystique that appeals so strongly to archetypal dietary supplement enthusiasts. New discoveries and conflicting laboratory studies have created a sense of uncertainty in modern medical science. In turn, this perceived lack of consensus among mainstream medical experts pronounces the frustration of educated, higher income consumers who feel disillusioned with the high cost of health care, and its focus on curative (as opposed to preventive) medicine. That sense of frustration has driven these consumers to search for alternative remedies that they feel may be effective even though clinically unproven.

Ironically, then, notwithstanding its lack of endorsement by the Western scientific community, demand for

As part of this reclassification, FDA has determined that the current investigational use labeling requirements no longer apply to acupuncture needles intended for general use by qualified practitioners.

A Reuters Health Information³⁰ article dated October 26, 1999 on the American Medical Association's 18th Annual Science Reporters Conference suggests that unreported self-treatment using Chinese traditional medicine alongside con-

²⁹See <http://www.fda.gov/bbs/topics/ANSWERS/ANS00722.html>

³⁰See www.reutershealth.com. Unfortunately, Reuters Health Information only keeps articles for 10 days. A copy of the report is available at <http://www.acupuncture.com/News/Reuters.Health.NY.htm>.

ventional remedies has reached the point where medical practitioners ought to be concerned about possible incompatibility with prescription drugs³¹. The same article cites the following US National Institutes of Health statistics: 40% of US citizens say they used some form of alternative medicine in 1997, with total US spending on alternative medicine practitioners exceeding \$21.2 billion.

Demand for Oriental health food products has also increased. Soyatech Inc, a research company for the soybean industry, estimated the soybean product market to be worth \$1 billion in 1997 and growing at 20% annually in 1999 compared to 5% for mainstream foods³². That projection now appears conservative in light of the FDA's announcement on 26 October 1999 that it now permits claims relating to coronary heart disease ("CHD") in connection with soybean products. The FDA finally concluded that foods containing soy protein included in a diet low in saturated fat and cholesterol might reduce the risk of CHD by lowering blood cholesterol levels. As a marker point for arguments made later in this paper, it should be noted here that the nutritional value of soy products has been a given in East Asia for centuries.

In conclusion, Chinese traditional medicine is economically significant for American companies in two respects. First, within the Chinese and Japanese markets, and to a lesser but still notable extent in other parts of East Asia, it is the predominant competitor with Western pharmaceuticals for consumer health expenditure. Levels of American pharmaceutical exports to China remain low

³¹The problem has sparked litigation. See Product Watch, 3 No. 18 Mealey's Litig. Rep.: Drugs & Med. Devices 24

³²Soyatech Inc, Soya and Oilseed Bluebook Update Vol 6 Issue 4 (October-December 1999)

notwithstanding the fact that low production standards in Chinese factories have given American-made pharmaceuticals an exceptional reputation for quality. Particularly because of income levels, American pharmaceutical products are likely to remain unpopular, delaying or preventing establishment of widespread brand name recognition in the short term. Given the recommendation made in the 1998 USFCS report on Drugs and Pharmaceuticals in China³³ that “a ‘Made in USA’ designation may well lead to greater sales”, closer examination of the Chinese traditional medicine industry, including the development of American-made substitutes, may be one strategy worth careful consideration.

Secondly, the popularity of Chinese traditional medicine within the United States justifies greater research into the validity of preventive and curative claims. In 1992, the National Institutes of Health established the National Center for Complementary and Alternative Medicine (NCCAM). According to the NCCAM web site,

The Congressional mandate establishing the NCCAM stated that the Center’s purpose is to facilitate the evaluation of alternative medical treatment modalities to determine their effectiveness.

Verification of such claims will undoubtedly stimulate demand, in which event products developed for Chinese consumers may find a secondary market in the United States.

It’s time for American pharmaceutical companies to take stock. The di-

³³ *Ante*. See footnote 14.

etary supplement industry at home has grown too economically and politically powerful to be conveniently ignored. Turning a Nelsonian blind eye to the vast potential foreign market for traditional remedies will only contribute to the redistribution of power that has taken place in the last 30 years. Only by re-assessing the true value of their vested interests in the status quo can pharmaceutical companies avail themselves of new possibilities waiting in the wings. Chinese traditional medicine may be the booster shot the industry so badly needs and it's certainly an attractive candidate as a catalyst for change: the market is huge and it has millennia of pre-clinical study. This necessitates reconsideration of the current regulatory structure, both in terms of the unrealistic demands it places on the FDA and the incompatibility of the FDCA's conceptual basis with the pressures of an increasingly integrated world economy.

PART II: LEGAL AND REGULATORY ISSUES

The passing of the Dietary Supplement Health and Education Act in 1994 ("Dietary Supplements Act") marked the advent of a day of reckoning between the pharmaceutical industry and the alternative medicine community. The clear signal to Congress was this: American consumers believe that the legislative structure for the regulation of new drugs has failed. In the context of Chinese traditional medicine, the principal defects are these. First, the system of product classification, which dates back to 1938, and method of claims-verification, instituted by the 1968 Amendments to the FDCA, both strongly favor curative over preventive medicine. Second, the approval cycle for new drugs takes too

long and results in unrealistically expensive products.

Hobson's Choice: Classification Issues Under Existing Legislation

The first difficulty is one of definition – how do we determine the applicable regulatory scheme to Chinese traditional medicine? The FDCA's approach, which is to distinguish between food and drugs on the basis of intended use, is perforated with ambiguities that, while investing the FDA with enormous regulatory discretion, provide little guidance for articles, such as Chinese traditional medicines, that defy easy classification.

“

Food” is defined as including “articles used for food or drink for man³⁴”; “drugs” are defined as including “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man³⁵” and “articles. . . intended to affect the structure or any function of the body of man³⁶”. While there are easy cases, such as the classification of synthetic pain relieving substances like Ibuprofen, the active ingredient in Advil, as drugs, there are also difficult ones.

With the exception of the proviso to § 321(g)(1)(c) pertaining to articles affecting structure and function, the definitions of “food” and “drug” are not mutually exclusive. It is possible for an article satisfying the definitions of both food *and* drug. Common table salt is one example: it may be used as food when used as flavoring, or as a salt when used as an antiseptic. When used as a food

³⁴21 U.S.C. § 321(f)(1)

³⁵21 U.S.C. § 321(g)(1)(B)

³⁶21 U.S.C. § 321(g)(1)(C)

preservative, it may be both, for it is not only intended to be ingested when the food is taken, but intended to keep the food from decomposing, thus “intended for use in the . . . prevention of disease in man”. We only avoid the conundrum because common table salt is common enough that it is generally recognized as safe (and effective), and avoids having to comply with regulatory requirements relating to disease-related claims.

But how do we treat Chinese traditional medicines, say herbal soup preparations, which are primarily intended to cure, treat or prevent disease, but which may be intended to be taken as part of a meal? Being unpleasant to taste, the preparation may be prepared with “superfluous” ingredients such as chicken or pork to grease the palate for its ingestion. To cast the dilemma in more familiar terms, when Walt Disney penned the marvelous counsel of the childhood fictional character Mary Poppins that “a spoonful of sugar makes the medicine go down³⁷” did she intend that the sugar become part of the nasty syrup, or did the syrup become part of a tasty treat? It may not have occurred to the notorious nanny, but the distinction is crucial: classification as a drug invokes the pre-market approval procedures for new drugs. Classification as a food restricts the types of claims that may be made in relation to the product.

Yet another difficulty lies within the “food” classification itself. It is not always clear how to determine whether to classify Chinese traditional medicines as food or a sub-category of foods, dietary supplements. The relevant parts of

³⁷The book, published by British author P. L. Travers, in 1934, narrates the scene popularized in the film musical, but the catchphrase is that of brothers Richard M. and Robert B. Sherman, who wrote the music for the 1964 movie and received Academy Awards for Best Musical Score that year. Curiously, the modern provisions of the FDCA preceded the movie by only two years, in 1962.

the FDCA's definition of dietary supplements read as follows³⁸:-

The term "dietary supplement" means a product... intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

...

(B) a mineral,

(C) an herb or other botanical

...

The definition also includes products labeled as dietary supplements meant to be taken in capsule or tablet form which are not represented for use as conventional food or as a sole item of a meal or diet³⁹. Products which are labeled as dietary supplements but which are not taken in capsule or tablet form and which are not represented as conventional food or use as a sole item of a meal or of a diet are also included in the definition⁴⁰. The FDCA only permits, in relation to the sale of dietary supplements, claims relating to classical nutrient deficiency and structure/function claims⁴¹.

As a matter of statutory interpretation, the FDA's classification of herbs and herb extracts sold in capsule, tablet or liquid form as dietary supplements is less problematic than other types of traditional medicine. Where, however, herbs are sold in combination – either pre-packaged or tailor-made by the ori-

³⁸21 U.S.C. § 321(ff)(1)

³⁹21 U.S.C. § 321(ff)(2)(A)(i)

⁴⁰21 U.S.C. § 321(ff)(2)(A)(ii)

⁴¹§ 343(r)(6)(A)

ental medicine practitioner – for preparation as a soup, they bear resemblance to instant food products that are not regarded as dietary supplements. The instructions are similar: add water, boil 30 minutes, drink. The FDA’s approach would again appear to turn on the intended use of the product and the claims that are made in connection with its sale. The National Institutes of Health (NIH), office of Alternative Medicine (OAM, the predecessor organization to NCCAM) and the FDA sponsored a symposium between 14 and 16 December 1994 to consider these very points. The FDA’s position on the matter at the time has been reported as follows⁴²:

... herbs are in the Category of “dietary supplements” and can be marketed freely as long as there is no medicinal claim made on the label. If there is a claim then it is illegal to market the product unless it has been approved as either an Over the Counter or Prescription drugs... The main example of herbal medicine that was debated was garlic. Proponents of herbs argued that if garlic is useful to lower cholesterol then it would suddenly become a drug. The FDA countered by saying that was true, but only if the garlic was available in bottles with labels that claimed that it was effective for lowering the cholesterol. In the absence of claims on the label, the FDA indicated that they have no jurisdiction.

This is fine and dandy for the easy cases but inadequate for the harder ones. Translated into plain English, the definition of “dietary supplement” in

⁴²See <http://www.acupuncture.com/News/FDA.htm>. The site is devoted to the promotion of alternative oriental medicine, and the report should be read in that light. The FDA’s regulations published on 6 January 2000 (*infra*), however, remain consistent with the summary.

§ 321(ff)(2) is patently unsatisfactory: it it's not a capsule or meal substitute, then it's a dietary supplement if its labeled as a dietary supplement. The definition, with respect, begs the question⁴³. The question, however, remains critical because qualification of an article as a "dietary supplement" permits certain types of health-related claims to be made that may not be ordinarily made in relation to ordinary food.

On January 6, 2000, the FDA published its final rule on structure/function claims for dietary supplements⁴⁴. The rule prohibits express and implied disease claims. Implied claims include those made through the name of the product, its formulation, or pictures. Non-disease claims pertaining to health generally or effects not associated to a specific disease, such as weight loss or muscle relaxation, are permitted. Some clarification has also been provided on the gray distinction between structure/function claims and disease claims. Claims relating to certain minor conditions associated with menopause or pregnancy have been permitted, while claims relating to serious conditions are not. Manufacturers are required under existing regulations to keep on file evidence substantiating the claims they make in relation to a product. The requirement to print a disclaimer stating that the FDA has not approved the product and that it is not

⁴³Similar difficulties were encountered in relation to Merck's drug Mevacor. The active ingredient in the drug, lovastatin was similar or identical to a product made from a fungus fermented on red yeast rice and claiming to lower cholesterol. See Arnold I Friede, Dietary Supplements: Background For Dialogue Between The Industry And The Medical Profession, 53 Food & Drug L.J. 413, 418.

⁴⁴21 C.F.R § 101, 65 Fed. Reg. 999-1050 (January 6, 2000). The actual guidelines are available at <http://vm.cfsan.fda.gov/~lrd/fr000106.html>. The FDA's press release is available at <http://vm.cfsan.fda.gov/~lrd/tpdsclm.html>.

a drug also stands⁴⁵.

What does this all mean? For a prospective distributor or manufacturer of Chinese traditional medicine it means he has three options. He may choose to label it as a savory instant beverage product and put it on the same supermarket shelf as Lipton's Cup-A-Soup. Alternatively, he can call it a dietary supplement by labeling as such, make the strongest claim he dares without attracting the FDA's attention and state specifically on the label that it is unapproved and not a drug. Lastly, he can expend the money needed to demonstrate, in accordance with the FDA's regulations, its effectiveness in clinical trials, try to patent the formula (he will probably fail if it is a naturally occurring substance), and market it as a drug.

A Game of Chess: The Impact of Strategic Behavior on Marketing Strategies

This trinity of choices regulates a triangle of competing tensions. First, in making purchasing decisions, consumers have an interest in having the best information about the nutritional value and physiological impact of the products (whether food or drug) on the market. Second, the legal right to supply that information is determined by the classification of the product as food, drug or dietary supplement. The third prong of this devil's pitchfork bridges these two tensions: the availability of valuable information turns not on its objective

⁴⁵§ 343(r)(6)(C) provides that any claim made on the label of a dietary supplement must be accompanied by the words "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

accuracy but on the manufacturer's decision, as a matter of economic feasibility and corporate strategy, whether to jump through the hoops the FDA sets before it as a precondition to the legal right to those claims.

The upshot of all this is to trap pharmaceutical companies in somewhat of a prisoner's dilemma. Say corporation A discovers that compound X, a naturally occurring substance, as an objective fact, cures disease Y, to which there is no known existing cure. Before corporation A can sell compound X making the claim that it cures disease Y, it has to obtain pre-market approval of compound X as a new drug under § 355 of the FDCA. Today, such a process can cost up to an average (per approved drug) of \$500 million and take, from Phase I to Phase III, an average of 12 to 15 years⁴⁶ to complete. If corporation A can establish in clinical trials the effectiveness of compound X and obtain FDA approval of the processed compound, it can market the processed compound as a drug designed to cure disease Y.

There is nothing under the current regulations, however, to prevent corporation B from marketing a competing product that contains compound X as an active ingredient as a dietary supplement, provided it does not make the specific claim that it can cure disease Y. Corporation B, by electing not to establish the effectiveness of its particular product in relation to disease Y by undertaking expensive clinical trials, can afford to vastly undercut the price of corporation A's drug while drawing substantial benefits from the publicity associated with the common active ingredient. As more companies catch on to the trend, cor-

⁴⁶Pharmaceutical Research and Manufacturers of America (PhRMA), *Pharmaceutical Industry 1999 Profile*, Ch. 2. The publication is available online at <http://www.phrma.org/publications/industry/profile99/index.html>

poration A's product will be crowded from the market, vastly diminishing the product's effective life, already so drastically curtailed by the unsatisfactory current rules on the start date of drug patents⁴⁷. This was, in fact, the experience of the pharmaceutical industry in relation to Omega-3 fatty acids.

The effect is to deter corporations like corporation A from seeking to establish the scope of application of natural substances save where they are confident of both identifying the active ingredient and synthesizing it in a manner capable of proprietary protection. Even if it succeeds in doing so, capture of market share will depend on consumers' willingness to pay the premium for the synthesized product, which in turn depends on establishing through even more expensive clinical trials the superiority of the synthesized drug. Electing to synthesize the active ingredient also has inherent risks: side effects and contraindications may be greater than in the natural product.

In short, the current regulatory structure does not confer sufficient incentives to pharmaceutical companies to experiment with naturally occurring substances. The current state of affairs gives rise to socially and economically important questions that will be addressed in the remainder of this paper.

Checkmate: Social and Economic Implications of Current Regulation

The current state of affairs has two possible social effects, both of which are flip sides of the same coin. The first is emotionally appealing argument: that as matters stand, consumers may be deprived of potentially life-saving or pain-

⁴⁷Notwithstanding the passing of the Patent Term Restoration Act in 1984, the duration of the testing, review and approval process for new drug applications (NDAs) continues to surpass the 5 year extension given by Congress.

relieving products because on the one hand pharmaceutical companies have no incentive to develop traditional remedies and on the other hand dietary supplements manufacturers have no right to advertise arguably valid claims⁴⁸. In view of the documented effectiveness of herbal remedies outside America, there are real reasons to believe that genuinely effective products are being kept from consumers because pharmaceutical companies consider themselves too vulnerable to piracy from the dietary supplements sector to undertake the effort of establishing their effectiveness. One possible reform to address this concern might be greater deregulation of the dietary supplements market to permit advertisement of disease-related claims for herbal remedies across the board.

The contrary argument, however, is that deregulation of the dietary supplements market threatens to magnify the incidence of consumer fraud and the consumption of dangerous products based on unproven claims. In 1996, for example, as many as 17 deaths and 800 illnesses associated with protracted or heavy ingestion of the substance ephedrine (a naturally occurring substance derived from the Chinese medicinal herb “ma huang”) were reported. The FDA issued a press release⁴⁹ cautioning consumers not to use dietary supplements containing ephedrine on the basis of claims spelt out in product labels claiming the substance could “produce such effects as euphoria, increased sexual sensations, heightened awareness, increased energy”. The FDA, taking the view that such representations violated the permissible limits for claims that could

⁴⁸This in turn raises a Constitutional question, outside the scope of this paper but treated elsewhere, whether consumers have a right to information regarding those claims as a matter of commercial speech. See Melinda Ledden Sidak, *Dietary Supplements and Commercial Speech*, 48 Food & Drug L.J. 441.

⁴⁹See FDA website at <http://www.fda.gov/bbs/topics/NEWS/NEW00531.html>

be made under the Dietary Supplements Act, warned that clinically significant effects such as heart attack, stroke, seizures, psychosis and death might result.

An additional concern is that patients might misdiagnose themselves, resulting in delayed treatment when they take the herbal remedy where a more drastic procedure might be appropriate. Addressing concerns of these types involves the opposite type of proposal: tighter enforcement of the Dietary Supplements Act or stricter regulation of the products that can be sold or the types of claims that may be made.

Turning to the economic concerns, one dilemma relates to the migration, here and abroad, of consumers from expensive pharmaceuticals to natural substances. For reasons already discussed, this trend threatens to unproductively aggravate the bifurcation of the medicinal remedies market along the lines of the drug/dietary supplement distinction. From the economists' viewpoint, the opportunities for rent-seeking inherent in the existing structure threaten to obliterate a useful contribution to the American economy.

Interestingly, both social and economic concerns can be addressed by a third proposal, that is, to require that once *any* company has established the effectiveness of the herbal compound to the FDA's satisfaction, that all products containing the active ingredient in the herbal compound be sold *by prescription only*. This would have two consequences. First, it would force dietary supplement manufacturers to undergo the formal pre-market approval process, whether or not they desired to make the disease-related claims, thus eliminating any economic rents from their strategic behavior. At the same time, the

approval process would abate the likelihood of fraudulent claims while the requirement that the drug be sold by prescription would reduce the possibility of misuse. The theoretical objective of such an exercise would be to produce a level playing field for pharmaceutical companies and dietary supplement manufacturers in the context where a herbal ingredient demonstrates the ability to treat disease.

The downside of this proposal is that it would raise the unit cost of herbal drugs across the board, an effect that militates directly against another, equally important, economic concern. It has already been argued that existing Federal policy, in its attempt to protect consumers from the potential dangers of herbal remedies without depriving them of their potential benefits, does so at the risk of critical long-term economic consequences to America's position in the *international* pharmaceutical market. However, any proposal that attempts to rework this compromise by making herbal drugs more costly also reduces the international marketability of those drugs, particularly in China. Perhaps more importantly, such a proposal would fail to address the trade issues examined in the next section.

Truth or Dare: Trade Issues Raised by Claims-Verification Methods under the FDCA

To make a specific disease-related claim under current legislation, the manufacturer of a product must satisfy, as interpreted by the FDA, the statutory provisions relating to food and drugs. Where food is concerned, a claim “characteriz[ing] the relationship of any nutrient [contained in the food and required

to be disclosed on the food label under 21 U.S.C. § 343 (q)(1) or (2)] to a disease or health-related condition” may only be made if

(1)

The Secretary promulgates regulations for the making of such claims, having determined, “based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence and the manufacturer complies with such regulations⁵⁰”; and

(2)

The food does not contain, as determined by the Secretary “any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet⁵¹”.

Alternatively, a food disease prevention claim may be made without an applicable FDA regulation if it is based on an authoritative statement of a United States public health agency or the National Academy of sciences and pre-market notification of at least 120 days is made to the FDA⁵².

Inssofar as drugs are concerned, the FDA must be satisfied of the safety

⁵⁰21 U.S.C. § 343(r)(1)(B) read with § 343 (r)(3)(A)(i) and § 343(r)(3)(B)(i)

⁵¹21 U.S.C. § 343(r)(3)(A)(ii)

⁵²21 U.S.C. § 343(r)(3)(C), introduced in 1997.

and effectiveness of the drug in question in treating the particular disease or condition that it purports to address. To qualify the drug for approval, the manufacturer must:

(1)

Conduct “adequate tests by all methods reasonably applicable” to establish that the drug is “safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling⁵³” and

(2)

Provide “substantial evidence that the drug will have the effect it purports or is represented to have under the [said] conditions of use⁵⁴”.

“

Substantial evidence” is defined in § 355(d) as “evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports. . .”.

In summary, a disease-related claim for a food product must accord with general medical opinion; a disease-related claim for a drug must be established by clinical trials. By way of recapitulation, disease-related claims are prohibited for dietary supplements with the exception of diseases related to nutrient defi-

⁵³21 U.S.C. § 355(d)(1)

⁵⁴21 U.S.C. § 355(d)(5)

ciency and structure/function claims⁵⁵, as clarified under the FDA’s final rule of 6 January 2000, *provided* the manufacturer has substantiation that the claim is truthful and not misleading⁵⁶. Non-compliance with any of these requirements constitutes “misbranding” under the FDCA.

As it stands, Chinese traditional medicines are regulated in the United States as dietary supplements. In terms of the type of claim that may be made in relation to these products, their status is secondary (in the sense of only weaker claims being permitted) to both approved drugs and foods on which there is widespread medical consensus about their role in the prevention of disease (such as soy products). This is primarily attributable to the lack of “substantial evidence” or “significant scientific agreement” establishing the effectiveness of Chinese traditional medicines in disease prevention, which disqualifies them from making those claims as either drugs or foods.

The arrangement is perfectly understandable if Chinese traditional medicines are either treated as “new drugs” or as foods, such as high-fiber/low sodium cereals, which were specifically designed in light of modern medical understanding of the cause of ailments such as cancer or heart disease. The arrangement, however, is vulnerable to two specific claims that may be made by the Chinese government under the WTO Agreement on Technical Barriers to Trade (ATBT). The ATBT is a specific agreement acceded to by WTO members adopting a procedure “establishing disciplines on the preparation, adoption and application of technical regulations, standards and conformity assessment procedures,

⁵⁵21 U.S.C. § 343(r)(6)(A)

⁵⁶21 U.S.C. § 343(r)(6)(B)

that might act as technical barriers to trade⁵⁷”. The preamble to the ATBT⁵⁸ recites two specific goals of the Agreement that are relevant to the argument. The first, which is more generally stated, is

“
...to ensure that technical regulations and standards, *including packaging, marking and labeling requirements*, and *procedures for assessment of conformity with technical regulations* and standards do not create unnecessary obstacles to international trade;”

The second, which is of particular relevance, is

“
... that no country should be prevented from taking measures necessary... for the protection of human, animal or plant life or health... *subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail...*”

(emphasis added)

The primary fear is that it would be open to China to argue that the fore-mentioned definitional issues and the Western-scientific bias of the claims-

⁵⁷Introduction to the ATBT on the WTO website. See <http://www.wto.org/wto/goods/tbtindex.htm>

⁵⁸The full text of the Agreement is available at <http://www.wto.org/wto/goods/tbtagr.htm>.

verification methodology under the FDCA (both of which may be considered “procedures for assessment of conformity with technical regulations”) constitute “a means of arbitrary or unjustifiable discrimination”. The thrust of the argument would be the premise that the claims verification methodology of Chinese traditional medicine – namely the “trial-and-error” or “anecdotal evidence” method - is no less valid as a means of determining the accuracy of disease-related claims (i.e. “label requirements”). Furthermore, since the FDCA’s definitions of “food”, “drug” and “dietary supplement” are based on intended use, and therefore strongly associated with the types of claims that can be made, these provisions would also be vulnerable to criticism.

Neither the importance of Chinese traditional medicine as a trade issue to China nor China’s willingness to raise it in trade talks should be underestimated. On 22 July 1999, China and Singapore formally signed a Memorandum of Understanding “to formalize bilateral coordination, liaison and cooperation in Traditional Chinese Medicine”⁵⁹. Although China has yet to raise these issues with the United States, it is not inconceivable, given the desire of United States pharmaceutical companies to increase exports to China and the growing demand within the United States for oriental medicines, that it will be advanced either in bilateral trade negotiations or as a condition for open markets in WTO talks. A more urgent concern for pharmaceutical companies is that such a development could also supply the dietary supplements industry with a vital opportunity to strengthen its position within the regulatory framework.

⁵⁹Singapore Ministry of Health Press Release, 22 July 1999. See <http://www.gov.sg/moh/releases/mou.html>

Segue: The Sixty-Four Thousand Dollar Question

To bring these issues into focus, the question raised here is whether the current regulatory structure, or the proposed “prescription only” alternative, strikes the only acceptable (albeit unsatisfactory) balance between these several competing factors. Is there a way to supply safe and effective herbal remedies to consumers, on a level playing field, in accordance with existing trade Conventions, without increasing their cost dramatically? The answer, particularly in the context of Chinese traditional medicine, would appear to be that there is.

As contradistinct from modern alternative medicines, in the field of Chinese traditional medicine the econ

You Say Po-tay-to, I Say Po-tah-to: Differing Philosophical Approaches to the Healing Art

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The main idea underlying Chinese traditional healing⁶⁰ is that specific illnesses are attributable to disruptions of a force that runs through all living things, the “Qi” (pronounced “chee”) or “vital substance”. This tenet is part of a larger philosophical concept, that of the “Tao” or the path all living things obey in following their true natures. The “Tao” advocates a lifestyle of simplicity, moderation and balance. This balance is represented by the “Yin-Yang” symbol:

“

⁶⁰See generally Carol Hart, Ph.D. & Magnolia Goh, L.Ac., Traditional Chinese Medicine (1997), and Jason Elias L.Ac. & Katherine Ketcham, The Five Elements of Self-Healing (1998), and William Collinge, Ph.D., Alternative Medicine (1996).

Yin” and “Yang” are descriptions of complementary opposites in things living and nonliving. In Chinese thought, equilibrium in the “Yin” and “Yang” dualism is not achieved by the competition of opposing forces, but by moderation. Deviation from the “Tao” – excessive drinking, eating, wealth or pleasure – causes blockages in the body through which “Qi” energy flows. Chinese traditional medicine seeks, by procedures such as acupuncture, massage, and the use of herbal medicines, to restore imbalances by removing these blockages. One of the most remarkable diagnostic techniques developed by Chinese medicine is “pulse analysis”. A skilled practitioner of this art can distinguish hundreds of variations of pulse, measured by pulse width, depth, strength, “quality” and rhythm, and determine from the pulse alone the particular disease that ails the patient⁶¹. In contrast to Western medicine, the objective of which is to identify a particular chemical, hormonal or biological imbalance and to treat the symptom with a counteracting drug or procedure, the Chinese medicinal technique is described as “holistic” and “non-intrusive”. Modern practitioners of Chinese medicine advocate it not as alternative, but complementary to Western science. The belief is that

Western medicine acts upon the Yin of the body, the substance of the body, the actual cells and chemicals. Oriental medicine works more on the energy that animates those cells.

What Western medicine tends to diagnose and treat is the effect that the

⁶¹See Hart & Goh, *ibid.* at pages 50 to 52.

disease state has on the body itself. The Practitioner of Oriental medicine diagnoses and acts upon the energy that creates the disease state⁶².

While these ideas may appear strange from a Western scientific viewpoint, the philosophy has a strong following today in both China and the United States. More importantly, however, the specific preventive and curative claims of particular herbs or herb combinations have been validated by the “trial-and-error” method (also referred to as the “anecdotal evidence” or “bibliographical evidence” methods) of ascertaining drug safety and effectiveness. These methods have a long pre-modern scientific history. The seminal text on Chinese medicinal healing, for example, *The Yellow Emperor’s Classic of Medicine*, was written in the 2nd century, BC. Unlike the clinical laboratory testing mandated by the FDA, the anecdotal evidence method depends on the administration of natural compounds to numerous patients over long periods of time. The patients’ reactions to the compounds can be recorded, forming a history of medicinal application for these compounds. Over time, it is possible to determine what natural substances work best in what combinations for a given disease or diseases.

In a worldwide survey of the regulation of herbal remedies published in 1998⁶³, the WHO, in reporting that “[t]he use of herbal medicines in the USA is less widespread than in the majority of developed nations,” also noted that

⁶²Al Stone, L.Ac., Western and Eastern Medicine Compared (internet article) at <http://www.acupuncture.com/Acup/Comparison.html>

⁶³Traditional Medicine Programme, World Health Organization, Regulatory Situation of Herbal Medicines: A Worldwide Survey (1998)

“... the FDA does not accept bibliographic evidence of effectiveness, but prefers randomized controlled trials as evidence of efficacy”. By comparison, in France, the criterion for the registration of “vegetable drugs” includes “historical proof of their widespread traditional use and their well established use in self-medication⁶⁴”. Bibliographic evidence is also accepted as basis for registration in Germany, where a survey found that 85% of the German population “believed that the experience of physicians, practitioners, and patients should be accepted as a proof for the efficacy of natural medicines⁶⁵”. In Switzerland, herbal remedies are permitted registration under an abridged application process requiring less clinical testing⁶⁶.

It is arguable that the anecdotal testing methodology is in fact not fundamentally unlike clinical trials – administer the compound to the test patient and observe his reaction to it. Of course we have no idea whether the ancient Chinese tests were conducted double blind against placebos. We also lack data on sample size and uniformity of test subjects. There is no specific chemical analysis of the precise physiological effect of the compound from which projections can be made about adverse reactions with other drugs or foods. The absence of raw data, however, does not disqualify the compound as either “unsafe” or “ineffective”. On the contrary, the anecdotal method’s greatest strength counteracts the greatest shortcoming of the FDA-sanctioned clinical method, namely that the product is only really tested when it is marketed to a large, diverse patient

⁶⁴ *Ibid.*

⁶⁵ *Ibid.*

⁶⁶ *Ibid.*

population, for it is only *then* that (statistically speaking) undetectable adverse reactions and contraindications are revealed. Although the FDA requires extensive pre-marketing testing, it relies heavily on post-marketing surveillance. The Center for Drugs implicitly recognized the shortcomings of the current approval methodology when it created in 1998 a new Office of Post-Marketing Drug Risk Assessment.

In 1998 itself, 177 prescription and 88 over-the-counter drugs were recalled. The average number of recalls over the six-year period from 1993 to 1998 came to 233.5 recalls of prescription drugs and 71.67 recalls of over-the-counter drugs annually⁶⁷. According to a May 10, 1999 FDA Report⁶⁸, unanticipated serious adverse events are occurring at a lower rate between 1994 and 1997 than between 1976 and 1985. The statistical data, however, is troubling. Between 1994 and 1997, 30.3% of new molecular entities underwent significant post-approval label changes. While this figure compared favorably to 51.5% in the earlier period, it does mean that between ? and $\frac{1}{2}$ of new drugs released in the United States in the last quarter century were seriously or significantly inaccurately labeled on their release date. The 1999 Report observes⁶⁹:

Although the 30-percent proportion is better than that previously found, it still raises the question of why these serious risks are not discovered before mar-

⁶⁷Center for Drug Evaluation and Research, Food and Drug Administration, U.S. Department for Health and Human Services, 1998 Report to the Nation, at pp. 26-27, available online at <http://www.fda.gov/cder/reports/rptntn98.pdf>

⁶⁸Food and Drug Administration, U.S. Department for Health and Human Services, Managing the Risks from Medical Product Use: Creating a Risk Management Framework, at pp. 35-36, available online at <http://www.fda.gov/oc/tfrm/riskmanagement.pdf>

⁶⁹*Ibid.* at page 36

keting. There are several reasons for this. For example, some kinds of serious side effects, such as those resulting from drug overdoses, cannot be studied ethically in humans and can only be learned about from overdoses of drugs that are on the market. In addition, in some cases, the Agency approves drugs intended to treat serious and life-threatening diseases with less information than usual, knowing that more will be learnt in the post-marketing period. Finally...it is impossible to detect or predict before medical product approval every possible drug interaction, unusual clinical situation or rare side effect that could lead to harm once a product is on the market.

Whereas there is no comparable data available for Chinese traditional medicines, a strong case can be built on the fact that these herbal remedies are not subject to the uncertain period of random testing that commences with the initial release of new drugs. Unlike new drugs and new dietary supplements, these medicines have already been “tried and tested”, their safety and effectiveness established by thousands of years of medical practice.

The fact is that China maintains a male life expectancy of 69.57 years compared to that of 72.95 years in America despite spending only a fraction of what America does on health care on four times the number of people⁷⁰. What relationship does this bear to the fact that China is a market, by WHO’s estimation, 30-50% dependent on Chinese traditional medicines, the vast majority of which are not available to consumers in America? All the more remarkable is that this takes place notwithstanding the documented inability of Chinese

⁷⁰CIA World Factbook 1999

production facilities to comply with Good Manufacturing Practices or produce safe medications. For example, between 1997 and 1999, twenty-two medicines sold in processed form were prohibited from import into Singapore on the basis of containing poisonous substances or toxic metals such as lead or mercury beyond safe levels⁷¹. The incidence of death or shortening of life due to the lack of product safety may well account for the marginal difference in life expectancy. It is my submission that Chinese traditional medicines should not be subject to the same precautionary safeguards as new drugs when there is no empirical evidence to show that those safeguards are more effective in protecting consumers or guaranteeing effectiveness than the (historically) more established trial-and-error system.

The trial-and-error method of proof is already widely accepted in Europe. In fact, Congress appeared to mandate a step in the direction of accepting European anecdotal evidence in 1997 when it passed § 803(c)(2) of the Food and Drug Administration Modernization Act. That section requires the FDA to support a move towards the acceptance of mutual recognition agreements between the European Union and the United States. Similarly, § 803(c)(3) requires regular FDA participation in meetings with foreign governments to discuss methods of harmonizing regulatory requirements. Thus, for example, if the United States were to admit pharmaceuticals the use of which has been approved in France or Germany, it would effectively be permitting back-door registration of herbal drugs by bibliographic evidence, since that is a valid method of proof in those

⁷¹Singapore Ministry of Health press releases, 1997-1999.

countries.

A Time to Kill, and A Time to Heal⁷²: Closing Case and Proposals for Reform

If Chinese traditional medicines are an established complement to Western medicine as a means of treating diseases, then the question why American consumers ought to be deprived of the information necessary to make an informed choice as to the proper and effective use of those drugs demands attention. This is particularly so given the FDA's strong emphasis on curative medicine. Under the FDA's priority approval system, life-critical drugs (such as AIDS or cancer drugs) receive the most attention. Drugs aimed at preventing disease receive very low priority, so much so that promotion of the preventive science has fallen almost exclusively to the hands of the dietary supplements sector.

If, additionally, the economic concerns that have been highlighted in this paper are not illusory but genuine, then the case for action is strengthened further. America needs to address the significant issues raised by the disparate regulatory treatment of two classes of products (drugs and dietary supplements) that Americans treat as a single consumer market (medicines). It is also clear that the American pharmaceutical industry needs to rethink its economic strategy for China, and that Congress must determine if the regulatory structure for pharmaceutical companies is sufficient to confront the challenges ahead.

Finally, if the anecdotal evidence method of proof is a viable alternative

⁷²Ecclesiastes 3:3

to the established means under current regulation, then there is no reason why reform should not be initiated – it only remains to ask what the final structure of the reform proposal might look like. The principal tasks would be the empirical matter of identifying the shortcomings of the anecdotal evidence system and compensating for them, and the administrative matter of creating a system for the review and approval of products. Implementing a broad proposal for reform would therefore require the conduct of feasibility studies in several areas:

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Definition of dietary supplements for which disease-related claims may be made upon submission of satisfactory bibliographic evidence, or a combination of bibliographic and clinical evidence;

-

Alternatively, classification of certain herbal remedies as drugs through a procedure (as in France and Germany) for pre-market review of bibliographic evidence or (as in Switzerland) a combination of bibliographic and clinical evidence;

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Development of administrative procedures for submission of bibliographic evidence to the FDA under either proposal;

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Development of administrative procedures for compilation and analysis of evidence in relation to specific claims by FDA under either proposal;

-

Investigation of sufficiency of evidence in demonstrating safety and efficiency;

-

Possible mandating of supplementary testing under clinical conditions e.g. relating to toxicity and dosage;

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Determination of what types of herbal remedies may be sold openly (self-diagnosis) and what type must be sold by prescription;

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Uniform inter-state procedures for qualification of Oriental Medicine Practitioners for the prescription and sale of herbal remedies; or

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Alternatively, provision for sale of prescription herbal remedies through pharmacies.

It is hoped, through the arguments offered here, that sufficient interest will be generated to initiate discussion about the issues at stake. It is my submission

that they merit utmost attention if the United States is to remain a serious contender in the international pharmaceuticals market in the 21st century.

Mixing the Old with the New
Chinese Traditional Medicine and
The Regulation of Food and Drugs in the United States

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