

## **Why We Should Not Use the Term "Patent Medicines"**

By Bob Flaws, LAc, FNAAOM (USA), FRCHM (UK)

Most acupuncturists and practitioners of Chinese medicine in the West refer to ready-made Chinese medicines (*cheng zhong yao*) as "patent medicines." For years now, I have argued against this term. Not only is it factually inaccurate, it also stigmatizes our medicines in the eyes of those who actually know what patent medicines are. The following is a definition of patent medicines I found on the Web:

The words "patent medicine" refer to products that were marketed, mostly in the 19th century, as medicines that would cure a host of diseases. Many of the diseases which these medicines were supposed to cure are still not curable today - cancer and diabetes, for example. Why did people buy these products? Well, given that the access to medical practitioners was limited, especially in rural areas, and the state of medical technology in the 19th century, who wouldn't buy these products? After all, going to your general store and purchasing a prepared medicine was a lot easier and a lot more pleasant than going to a doctor and having him perform blood-letting!<sup>1</sup>

In other words, "patent medicines" refer to 19th century "snake oil," and the use of this term plays directly into the hands of those who would denigrate our medicine as quackery. Why were these 19th century ready-made medicines called patent medicines? The explanation is given by the same e-source:

In mid-18th century England, some producers of medical preparations applied for and obtained royal patents for their products. The patents protected the owners' rights to the products and gave some prestige to the medicines. Robert Turlington was one of the very first to receive a royal patent for his "Balsam of Life." Later on, the term patent medicine was applied to any of this type of product, whether patented or not.<sup>2</sup>

The fact that this term is pejorative and detrimental to the public perception of our medicine is aptly demonstrated by the following FDA page on patent medicines published under the title, "The Patent

Medicine Menace." Because it is the "official" U.S. governmental position on patent medicines, I am presenting it here below in its entirety. It should be a wake-up call to all those within our profession who insist on using this archaic, inaccurate, and defamatory term.

Patent medicines have had a long and ignominious history in the U.S., reaching their zenith in the late 19th century. As the population became more urban and somewhat more capitalized, a ripe target emerged for some postindustrial entrepreneurs, entrepreneurs who would thrive in a marketplace best characterized by the dictum, "caveat emptor." Communications had expanded, and the printed word became a crucial venue for the proliferation of patent medicines. The rise of advertising in America, not coincidentally, paralleled the rise of nostrums. At the same time, the biomedical sciences in this country were still in their infancy, and medicine was ill-equipped to deal with most diseases. An army of enterprising individuals were prepared to step in and alleviate the suffering.

Nostrums permeated American society by the late 19th century. Products appealed to exotica, the medical knowledge of Native Americans, death, religion, patriotism, mythology (a natural for this industry!), and especially new developments in science. There was nothing to stop patent medicines makers from claiming anything and putting anything in their products, clearly seen in the famous morphine- and alcohol-laced soothing syrups for teething and colicky babies. Cancer and arthritis cures, baldness remedies, bust developers, manhood restorers - wherever a need existed, patent medicine makers stepped in. They did not have a monopoly on the market, though. The ethical pharmaceutical industry, those firms that advertised for the most part directly to health professionals, sold their share of nostrums as well.

Quacks developed successful marketing techniques, but they also promoted their interests in more surreptitious ways. For example, they subdued any curiosity in the press with their economic strength. By the 1890s, patent medicine manufacturers used so-called "red clauses" in their advertising contracts with newspapers and magazines. These muzzle clauses voided the contract if a state law regulating nostrums was passed. Thus, not only were many editorials silent on the need for such laws, they actively campaigned against them.

But quacks and their trade associations were not able to stifle the entire fourth estate. A few muckraking journalists helped expose the red clauses, the false testimonials, the nostrums laden with harmful ingredients, the unfounded cures for cancer, tuberculosis, syphilis, narcotic addiction, and a

host of other serious as well as self-limited diseases. The most influential work in this genre was the series by Samuel Hopkins Adams that appeared in *Collier's* on October 7, 1905, titled "The Great American Fraud." Adams published 10 articles in the series which concluded in February 1906. He followed this up with another series on doctors who advertised fake clinics. The shocking stories of the patent medicine menace were accompanied by startling images, such as "Death's Laboratory."

That same month saw the publication of another work which, more than any other single event, spurred on passage of the 1906 act. Socialist writer Upton Sinclair published *The Jungle*, a fact-based novel about immigrant life in the meat-packing industry of Chicago. Sinclair's shocking and revolting story, verified by government undercover investigators, primed the final push for a federal law.

The first federal Food and Drugs Act was passed four months later. The exposés of muckrakers like Adams and Sinclair had a major impact on passage of the bill, as did the untiring work of the General Federation of Women's Clubs, state food and drug officials, the American Medical Association, and the American Pharmaceutical Association. Most notable among the reformers was the head of the Bureau of Chemistry of the U.S. Department of Agriculture, Harvey Washington Wiley, who stumped for remedial legislation since his arrival in Washington in 1883 (though Wiley was much more concerned with food supply). The law prohibited adulteration and misbranding of food and drugs, and though it had many shortcomings, it was arguably the pinnacle of Progressive Era legislation. It did not put quackery out of business; that still thrives. But it brought some disclosure and accountability into the marketplace, an important first step in consumer protection.<sup>3</sup>

At this point in time, Chinese herbal medicine is experiencing an image problem. There have been deaths from kidney failure in Europe and the U.S. due to aristolochic acid; there has been the discovery and broadcasting of the adulteration of a number of Chinese ready-made medicines with Western scheduled drugs; and, most recently, there has been the FDA banning of *ma huang* (*herba ephedrae*) and *ban xia* (*rhizoma pinelliae ternatae*) from all dietary supplements. As the FDA has made clear in public communications, if this last ban is made to stick, it plans to ban other substances from dietary supplements, including all of the citrus family of herbs, such as *chen pi* (*pericarpium citri reticulatae*), *qing pi* (*pericarpium citri reticulatae viride*), *zhi ke* (*fructus citri aurantii*), *zhi shi* (*fructus immaturus citri aurantii*), and *fo shou* (*fructus citri sacrodactylis*), due to these herbs' inclusion of the medically active ingredient sinephrine. Ready-made Chinese medicines sold in the U.S. are done so legally as "dietary supplements" under DSHEA (the Dietary Supplement & Health Education Act) even though, in actuality,

that is not what they are. At the moment, we need all the good press and PR we can get. Therefore, I believe we should immediately jettison our use of the term "patent medicine" and switch to the direct English translation of what these medicines are called in Chinese: *cheng zhong yao*, prepared or ready-made Chinese medicines.

Ready-made Chinese medicines includes all those Chinese medicines which are available in ready-made form, such as pills, capsules, tablets, powdered extracts, tinctures, medicated oils, and plasters, whether made in Asia or in the West. Several years ago, the government of the People's Republic of China realized that ready-made Chinese herbal medicines had a problem with perceived quality. Currently, quality control is job #1 of the Chinese medical division of the SDA, the State Drug Administration, China's equivalent of the FDA. The Chinese herbal business represents \$25 billion dollars per year of income to the PRC, mostly in hard currencies from countries such as the U.S., Germany and Canada. In fact, the U.S. accounts for 15 percent of this total, more than domestic Chinese sales, so the U.S. market is extremely important to the rulers of the PRC, and they are doing everything they can to insure that access to this cash cow is well protected. For instance, by governmental fiat, all Chinese drug manufacturers must be GMP-certified by the end of this year, and China will be the first country in the world to institute Good Agricultural Procedures (GAP, 2007) that have been specifically designed for the Chinese herbal industry. Further, American distributors and manufacturers of ready-made Chinese medicines have taken great strides in the last several years to insure quality control on this end. These companies now routinely require testing on every batch of every medicine with set standards for microbial, heavy metal, and pesticide residue contamination. In addition, all of these American companies will be required by the U.S. FDA in the near future to comply with GMPs, and already all companies selling ready-made Chinese medicinals in the U.S. must meet FDA labeling standards for herb identifications, etc., on their packaging.

The point I am trying to make is that the ready-made Chinese medicine industry in the U.S., China and Taiwan has greatly improved quality control over even just five years ago, but we prescribers and consumers continue to spread a false perception of the poor and even dangerous quality of these products by their erroneous labeling as "patent medicines." I believe that, in order for this medicine to survive in an increasingly hostile regulatory environment, we as a profession need to make a concerted effort to abandon this outdated and pejorative label, and switch to the more correct and neutral term of prepared or ready-made Chinese medicines. If we continue using this outdated and erroneous label, we will only have ourselves to blame when the FDA attempts to regulate us out of business.

*Endnotes*

1. [www.cyberus.ca/~sjordan/pmhist.htm](http://www.cyberus.ca/~sjordan/pmhist.htm).
  2. Ibid.
  3. [www.fda.gov/cder/about/history/gallery/galleryintro.htm](http://www.fda.gov/cder/about/history/gallery/galleryintro.htm).
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