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Overview of Herbal Medicine Practice in the USA

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Abstract – An overview of the history of the evolution of health practice in the United States. The development of selected laws regulating the marketing of botanical commodities and recent efforts to standardize them. Some consideration is given to the clinical testing and clinical use of botanical commodities.

Key words – Herbal medicine, standandization, laws, USA.

Introduction

This article addresses those aspects of complementary medicine in the United States that involve commodities such as drugs and devices, i.e. pharmaceuticals (phytomedicines) including herbs and their extracts by health professionals practicing clinical medicine in the United States (allopathic physicians, nurses, pharmacists, naturopaths, herbalists, *etc.*). The distribution of such commodities in the United States principally involves health food stores (ex GBI); pharmacies or drug chain stores (ex Walgreens); large food (ex Cub) or sundry products store (ex Target, Walmart); and mail order or pyramid programs. The use of these commodities by society is significantly influenced by medical insurance programs, advertisements, and legislative acts and sometimes by the judgement of health professionals.

This is a biased presentation. There is no doubt that it represents the thoughts and experiences of myself and my wife Joyce, a registered practitioner of pharmacy for some 44 years in the States of New York, Connecticut, Nebraska, and Minnesota. We hope it will be useful to those concerned with providing health care to the public, those concerned with health education, as well as those concerned with providing resources such as money and drugs for health care fundamental and clinical research.

Historical Perspective – A brief chronology of medicinal plant use by some health professionals in the U.S. from approximately 1820 to 1960 is as follows:

Botanical Commodities sold in the USA – In 1993-94 it was estimated that Herbal Medical Sales in Europe were approximately 6.5 billion US $; in Asia and Japan 4. 4 billion; and in North America 1.5 billion[4]. The attractive market valley still remaining to be filled in North America is very seductive to many. The Three major herbal and botanical companies of some 250 in the U. S. are Herbalife ($400 million), Sunrider ($300 million), and Natures Sunshine ($183 million)[5].

A comparison of the top selling herbs in Europe in 1995 (Germany) and Asia in 1994 (China) is as follows. Interestingly, no plant or commodity is duplicated in these two lists!

The bulk herbs in U.S. commerce in 1995 and those top commodities sold in approxi-

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1820	Term Pharmacognosy introduced.
	United States Pharmacopoeial convention (USP) established.
1825	Homeopathy-introduced into the U.S. by Hans Birch Grama, a student of SCF Hahnermann in Germany in the 1790's[1].
1825-50	Formulative years of the American Medical Association (AMA) and the American Pharmaceutical Association (APhA).
1830-1900's	Thomsonian and Eclectic Medicine[2].
1850's on	Naturopaths evolved.
1850's on	Nostrums and Patent Medicines (some containing opium, cocaine, mercury).
1897	Aspirin introduced.
1880-1935	Materia Medica defined.
1904	Food and Drug Administration(FDA) established.
1910	Pharmacology defined.
	Flexner Report defining Medical Practice Accreditation.
	Eclectic physicians vs Allopathic[3] physicians.
1939	Ecletic Medical College, Cincinnati-Last to close
1930's	Sulfa drugs introduced.
1940's	Antibiotics introduced.
1950's on	Synthetic drugs rapidly developed.
1960's on	Pharm D clinical pharmacy degree developed.
1960-1980	Pharmacognosy and Naturopathic Colleges at low point.

EUROPE[6]	CHINA[7]
1. Ginkgo biloba	Licorice (*Glycyrrhiza uralensis*)
2. Horsechestnut	Rehmannia (*Rehmannia glutinosa*)
3. Hawthorn	Astragalus (*Astragalus membranaceus*)
4. Yeast	Paria (*Paria cocos*)
5. St. John's wort	Peony root (*Paeonia latiflora*)
6. Myrtle(Myrtus communis)	Dong quai (don qui) (*Angelica sinensis*)
7. Stinging nettle	Atractylodes (*Atractylodes macrocephala*)
8. Echinaceae	Ligusticum (*Ligusticum chuanxiong*)
9. Saw palmetto	Deer Antler, Pilose Antler
10. Milk thisto	Forsythia fruits (*Forsythia suspensa*)
11. Ivy	Codonopsis (*Codonopsis pilosula*)
12. Mistletoe	Yam root (*Dioscorea opposita*)
13. Soy beans	Orange (peel?) (*Citrus aurantium*)
14. Chamomile	Honeysuclke flower (*Lonicera japonica*)
15. Comfrey	Platycodon (*Platycodon grandiflorum*)
16. Kava-Kava	Chrysanthemum flowers (*Dendranthemax morifolium*)
17. Greater Celandine	Corydalis (*Corydalis ambigua*)
18. Cineole (essential oil)	Ginseng root (*Panax ginseng*)
19. Bromelain (pineapple enzyme)	Lychee fruit (*Litchi chinensis*)
20. Black snakeroot (Black cohosh)	

mately 200 health food stores in 1996 are:

It is obvious that from the above commodity list that everyone should be concerned from the very beginning of its use in commerce about the species being used (ex ephedra, ginseng, licorice, yam,) and the part of the plant being used (ex kava, St. John's wort).

The approximate $2 billion herb and botanical market in the U.S. in a very small segment of the 1995 supermarket food/non-food industry total of $378 billion. The beverage tea market including herb formulation is $4.2 billion but yet it is also significantly smaller than the total soft drink category ($23.4 billion). Ra-

	BULK HERBS[8] (Alphabetical)	HEALTH FOOD STORES[9] (Top Selling)
Aloe	(*Aloe vera*)	Echinaceae
Astragalus	(*Astragalus membranaceus*)	Garlic
Cayenne	(*Capsicum* spp.)	Ephedra
Chamomile	(*Matricaria recutita*)	Psylllium
Dong Quai	(*Angelica sinensis*)	Siberian Ginseng
Echinaceae	(*Echinacea purpurea*)	Saw Palmetto
Ephedra	(*Ephedra sinica*)	Cascara sagrada
Feverfew	(*Tanacetum parthenium*)	Cayenne
Garlic	(*Allium sativum*)	Aloe
Ginger	(*Zingiber officinale*)	Valerian
Ginkgo	(*Ginkgo biloba*)	Cat's Claw
Ginseng	(*Panax ginseng*)	Grape Seed extract
Goldenseal	(*Hydrastis conadensis*)	Primrose
Gotu Kola	(*Centella asiatica*)	Dong Quai
Hawthorn	(*Crataegus oxycantha*)	Pau d'arco
Hops	(*Humulus lupulus*)	Ginger
Licorice	(*Glycyrrhiza glabra*)	Cranberry
Milk Thistle	(*Silybum marianum*)	Milk Thistle
Pau d'arco	(*Tabebuia impetiginosa*)	Yohimbe
Peppermint	(*Mentha piperita*)	
Red Clover	(*Trifolium pratense*)	
Saw Palmetto	(*Serenoa repens*)	
Siberian Ginseng	(*Eleutherocaccus senticosus*)	
Valarian	(*Valeriana officinalis*)	
White Willow	(*Salix alba*)	

pid economic growth is anticipated and estimated to be approximately $100 billion for Functional Foods and Nutraceuticals[10].

Legalities – Prior to 1994 botanicals were expected to be Clean and Unadulterated (Food and Drug Act of 1906). In 1962 prescription and Over-the-Counter (OTC) drugs from botanicals or of any origin had to be Safe and Effective (Food, Drugs and Cosmetic Act). The elements of a drug as being Clean, Unadulterated, Safe, Effective and manufactured under Good Manufacturing Practices (AMP;11) are regulated by the Federal Food and Drug Administration (FDA).

Eisenberg, *et al.* publication in the New England Journal of Medicine[12] established that complimentary and/or alternative medicine (CAM) was a very significant event for America's society and that this event was not known by the majority of the health professionals. After extensive lobbying by the public, and most probably by national and international health food industries, Congress established in 1992 the Office of Alternative Medicine, National Institutes of Health (NIH) and passed the Dietary Supplement Health and Education Act (DSHEA) in 1994.

A commodity can be recognized as a Dietary Supplement if the label states that it has a body structure or function use and that it has not been evaluated by the FDA. The commodity cannot be used to treat a disease but it can be marketed 30 days after FDA notification. The commodity can be removed from the market if the FDA can prove it is not safe.

The Office of Alternative Medicine and the Office of Dietary Supplements have received increase allocations from Congress since 1992, and may be reorganized into a more functional organization in the near future-perhaps

an NIH Center of Integral Medicine[13]. The Major mission of these NIH offices is to support clinical research and information in complementary and alternative medicine.

Monograph Development – Botanical quality is best assured by the development of legal and enforceable monographs developed by a just process. The United States Pharmacopoeial Convention, Inc. (USP) has in place such a process which encourages input and potential modifications by all concerned parties to monographs that are being developed and that are in its publication-Pharmacopeial Forum. In July, 1996 an Open Conference on Botanicals for Medical and Dietary Uses: Standards and Information was held. Since 1996 botanical monographs assuring legal quality have been in development in the Pharmacopeial Forum as either Pharmacopeial Previews or as an In-Precess Revision. To date, monographs in various stages of development are *Valerian, Powdered Valerian; Garlic, Powdered Garlic; Ginkgo biloba; Feverfew, Powdered Feverfew; Ginseng, Powdered Ginseng; Hypericum, Powdered Hypericum; Saw Palmetto.* Previews are expected to appear in Pharmacopeial Forum early next yeat for; *Hawthorn, Milk Thistle, Matricaria.*

The USP and its sister publication Drug Information (DI) has been published in Japanese, Russian, and Spanish by The United States Pharmacopeial Convention, Inc. Clinical information on the above botanical monographs and Comfrey are in development by the DI and are presented for public comment in the publication USP DI Update.

A review of herbal monographs being developed in the United States and internationally has recently been published in the HerbalGram[14].

Difficulties

Quality Assurance – It is well recognized that reliable, simple, and relatively inexpensive botanical and biochemical tests are needed for monograph compliance. It is unfortunate that peoples in the US have experienced toxicities from belladonna contamination of mate tea and chamomile tea, and recently digitalis contamination of plantago. The complexisies of quality assurance are significantly increased when multiple botanical products are made. The best safeguard is to enforce meaningful GMP regulations and to have trustworthy suppliers.

Efforts are being made to develop chemical and physical methods[15] to minimize bacterial, fungal, insect, rodent contamination herbal raw materials adulteration. Although sophisticated methods for ginseng species identification[16,17] and ginseng botanical constituent assay exist[17,18] they are not universal or practical yet for the herbal industry. If PharmaPrinting as developed at the University of Southern California for global standardization is reliable and effective remains to be demonstrated[19].

One must not assume that product standardization results in clinical effectiveness. The major reason for product standardization is to assure uniformity from production batch to production batch or, for some, to increase product sales by advertising.

Clinical – Botanical dosage forms range from the crude botanical to infusions or decoctions: or full-spectrum to semi-purified liquid, solid, or dry extracts; or perhaps to purified fractions or ingredients. To assure uniform marketing, obtaining reliable clinical or research information, and comparisons with other products each product forms should be at least standardized and perhaps "fingerprinted" by some analytical technique. The compositions of "fingerprints" will of course vary with the process and the solvents used, i.e. organic, aqueous, liquid gas.

A significant forward step would be to complement botanical and chemical tests of botanical commodities with meaningful biological tests. Why can't kombucha[22,23], shitake[24],

maitake[25], and reisi[26] mushroom products be examined and possibly quality controlled by shrimp brine tests. Daphnia protozoans have been used for the assay of cardioactive materials; in vitro heart organ tissue cultures exist and perhaps other serial organ cultures could be established. Kidney, heart, and liver perfusion systems exist. What might be the effect of an immunomodulating product on an in vitro thymus, or an adaptogenic product on an in vitro adrenal or growing neuron tissue culture? Why can't hepatoprotective Kampo herbal products[21] be tested on liver perfusion systems.

Clinical results will not only depend upon the product but upon the experimental design i.e. placebo use, cross-over protocol, dosage protocol, population selected, *etc.* Can useful Therapeutic Index values an quantitative Risk/Benefit assessments be made for synergistic or antagonistic interactions with foods, other drugs, or among the numerous constituents in a complex dosage form when taken for a chronic ailment? Are metabolites or artifacts from the herbal formulation responsible for a clinical or toxic effect? Indeed, it is not surprising that we see response variations in the literature for the therapeutic effectiveness of ginkgo in the treatment of tinnetis; garlic in the treatment of hyperlipidaemia and colon cancer; and beta-carotene in the treatment of lung cancer.

If herbal commodities are known to be safe we should benefit from societies use of them and to know if they have had good, bad and indifferent experiences over designated periods of time. Reporting mechanisms have long been established by the Food and Drug Administration[20] and the USP for adverse reactions. Why can't an individual be interviewed orally or on the internet at appropriate time intervals by independently trained professionals for their experiences. Why can't the interviewed individuals be given a rebate or the herbal commodity at a reduced cost by the industry or the government? Evaluation and feed back from society is important for their protection and to acquire new knowledge. At an appropriate time the herbal manufacturer should be expected to perform well designed clinical studies on their known safe but now demonstrated effective products.

Education – The passage of DSHEA and the resulting influx of dietary supplement products containing natural substances has resulted in a recognition that most health professionals are unable to respond intelligently to questions regarding them. The reason for this professional inadequacy may range from inadequate training and experiences to the non-existence of precise scientific answers. Many health professional programs, health professionals, and various government, industrial and independent groups are now reversing this knowledge void.

Pharmacy – Pharmacognosy instruction and graduate programs in most college of pharmacy have been minimized or have disappeared. However, natural product instruction that relates to the prescription and OTC drugs has been retained to some extent in most pharmacy program and is often taught by anyone interested. Nutritional programs have had a similar fate.

The pharmacy profession has responded in a small but increasing number of programs by establishing pharmacognosy-type courses with a clinical-health food industry type aura[27] and continuing education programs[28]. Some pharmacy trained individuals have been supportive of the American Botanical Council, the American Herbal Pharmacopoeia and Therapeutic Compendium (St, John's wort monograph insert)[28], and the Association of Natural Medicine Pharmacists (PO Box 150727, San Rafael, CA 94915).

Naturopathy – Naturopaths or ND's have established themselves as a profession that is very interested in the clinical aspects of natural medicine. Bastyr University (as JBC)

received full national accreditation in 1987, has offered an MS in Acupuncture/Oriental Medicine since 1995, and has received significant grants from the NIH. There are approximately four to six Naturopathy practice is recognized in approximately 12 states. In 1996 a Botanical Medicine Academy for certification of qualified naturopaths, other licensed practitioners, and herbalists from the American Herbalists Guild was established[2].

Other – Many CAM programs are being initiated in Colleges of Medicine and in University Health Science Programs. In addition, independent organizations, government, associations, industry have offered a large number symposia, journals, magazines, programs, and point-of-purchase (POP) materials to professionals, the health industry, or the consumer.

Future

A part of the DSHEA law was the establishment of The Presidential Commission on Dietary Supplement Labels (CDSL). Dr. Norman Farnsworth, University of Illinois was appointed to this seven person Commission[29]. Two aspects of their report released on June 24, 1997 were to encourage further study of how "significant scientific agreement" can be established so that the FDA would permit some diet supplement products to make health claims and to study how tracking or surveillance systems of herbal commodities might be established.

It will be interesting to observe if the NIH Office of Alternative Medicine (OAM) and Office of Dietary Supplements (ODS) will continue to request proposals (RFP) to study herbal commodities such as they did in July, 1997 to clinically study Hypericum (St. John's wort).

Will future US Congressional actions be passed to encourage complementary medicine such as the Access to Medical Treatment Act[30,31]; will standards be developed for foods such as the Codex Alimentarius[32]; will regulation for Organic Foods come about; and should importation requirements for botanical commodities be more stringent?

It will be interesting to see if the future will bring multidisciplinary clinics facilitating complementary medicine[33,34]; reasonable reimbursement and liability insurance; and enforceable State laws for the registration and regulation of other health practices.

Will complimentary medicine practice become more, or less, acceptable in the scientific and professional arena for concepts such as homeopathy[35], immunomodulators[36-38], adaptogens, and tonics?

Summary

Our summary is expressed as 10 idealized goals:

1. To optimize a Patients health and to minimize his/her disease state at a low and reasonable cost to society.
2. The patient is to be an informed and an active participant in his/her health maintenance.
3. Only safe and relatively non-toxic materials are to be used and to have an acceptable, quantitative risk-benefit value.
4. Products should not be made if their manufacture impacts negatively upon the earth and its environment.
5. The best quality of health service from ANY origin should be allowed to surface and be examined critically.
6. A reporting mechanism be established that enables an independent body to evaluate if a commodity is a useful drug or is harmful.
7. Humans want attention and HOPE that their illness will be improved or cured even if no cure is known to practitioners. Practitioners should provide HOPE to their patients or refer them to quality sources that might provide HOPE to the patient through means

that involve the Mind, and/or Spirit.

8. Create a paradigm in flux that utilizes health knowledge known or gained in time from health practitioners and their patients.
9. Establish clinical environments that are shared and used by patients and their health care providers.
10. Self-gain or Corporate-gain shall not transcend the above goals.

To best achieve these goals individuals should use whatever ethical, philosophical, or religious guidelines of their choosing that enables altruism, truth, honesty, and compassion to BE in health care.

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