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# HERBCLIP<sup>TM</sup>

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FILE: · Herbs — General

DATE: May 15, 2000

HC 031305

RE: **Prof. Tyler's Speech on the Status of  
Phytomedicines In the U.S.**

Tyler, Varro. E. Phytomedicines: Back to the Future. *Journal of Natural Products*. Vol. 62, 1999. pp. 1589–1592.

In an address to the American Society of Pharmacognosy in April 1999, Professor Tyler discusses the history of phytomedicine and its lessons, through which plant-derived medicines can be developed and used to the best advantage.

While humans first used plants, animal parts, and microorganisms as medicines in their unmodified forms, concentrated extracts were later developed to improve intensity and uniformity of action, and, using these compounds as prototypes, synthetic chemicals were developed that possessed even greater activity. "Herbal medicines were discarded from conventional medical use in the mid 20th century not necessarily because they were ineffective but because they were not as economically profitable as the newer synthetic drugs."

However, as the potency of synthetic drugs grew, so did their side effects and costs. Their use required a physician's supervision. These problems have caused many people to "back up" and look at the original, crude substances again. In many cases, plants can be used direct from nature. They are generally milder, cheaper, lack serious side effects, and can be self-administered.

The last decade has seen a great deal of progress, with the development of standardized extracts and new scientific evaluations of herbal medicines, such as those of the German Commission E. Tyler emphasizes the need for "well-designed, randomized, double-blind, placebo-controlled studies involving a significant number of human subjects", in order for herbal medicine to play a significant role in future health care. He suggests that organizations unable to afford the costs of carrying out such studies on their own form research cooperatives, sharing costs and benefits of such studies.

The author addresses problems of standardization of herbal products, whose activity is often not due to a single chemical but to a mixture of constituents (many still unidentified), and often to the synergistic activity of several components. "(T)he only practical way to ensure uniformity of action of (an) herb is to prepare an extract, determine its activity by pharmacological and clinical methods, and then prepare a qualitative and quantitative chemical

profile of all the significant constituents in it by some method such as HPLC, GC-MS, or the like. Other extracts fitting that chemical profile should have identical physiological properties." In determining such "phytoequivalence", he points out that excipients and other diluents used in preparing various dosage forms may impact activity. Due to the costs of determining true phytoequivalence, he predicts more interim use of other methods, such as enzymatic in-vitro assays.

Bioavailability is also an area of interest, and one where "surprisingly little is known." For example, berberine and hydrastine, compounds of goldenseal (*Hydrastis canadensis*), are not absorbed following oral ingestion. Studies showing systemic effects in animals have all involved parenteral administration. However, goldenseal is widely "accepted by a misinformed public as a nonspecific immunostimulant."

"Rational phytotherapy need not proceed beyond the determination of phytoequivalence ... That is, it is not necessary to isolate the active constituents ... and market them in highly purified form. It is necessary to determine the identity of the principal actives so that chemical profiling and establishment of phytoequivalence can be made more precise, but beyond that point phytotherapy separates from nonphytotherapy."

Development of reliable phytoequivalence will, he believes, lead to the approval of herbal products as drugs. "The Food and Drug Administration ... simply must find a way to allow drug-approval of effective, but generally nonpatentable, botanicals to take place with a reasonable investment. The \$350-\$500 million standard ... for new chemical entities requires modification. A system allowing this has been in place in Germany (i.e., the Commission E) for many years and has functioned essentially problem-free. We should emulate it here." Drug-approval of herbal products, with required standards of quality, would mean that students of medicine and pharmacy would learn about phytotherapeutic agents as part of their education. Doctors and pharmacists would prescribe or recommend phytomedicines and synthetic medicines for various conditions, depending on which was most appropriate in a given situation.

The author points out that the single biggest problem today in the field of herbal medicine is that of consistent quality. "The consumer simply has no way of identifying a quality product other than by the perceived reputation of the producer. In some cases, perception is definitely not reality." Another problem is the prejudice of many conventional practitioners against herbal products, and the equally unreasonable conviction of some herbalists that extraction and standardization will destroy the "mystical aura" of herbs. Greedy manufacturers who use hyperbole and faulty processing simply to increase profits are also a problem. Finally, he points out the wealth of misinformation found in books, journals, and especially on the Internet, "much of it written to sell products, some of it written to express a point of view based on hope, not facts." Many clinicians now using herbal products do not fully realize the need for adequate dosage form definition in their published papers, reporting erroneous and unreproducible results. Publication of reliable information is greatly needed. —*Mariann Garner-Wizard*

***[Editor's note: A copy error in Column 1 of page 1590 incorrectly associates the German company Madaus A.G. with clinical trials on ginkgo. Ginkgo trials have been pioneered by W. Schwabe GmbH. Madaus has pioneered clinical research in echinacea and milk thistle.]***

Enclosure: The American Botanical Council has chosen not to enclose the original article with this HerbClip memo due to the prohibitive reprint costs required by the original publisher.

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