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Antoine Al-Achi

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Botanical Medicine: The Need for Better Quality Research

Antoine Al-Achi*

Associate Professor, Department of Pharmaceutical sciences, Campbell University College of Pharmacy and Health Sciences, Buies Creek, North Carolina, USA

Herbal or botanical remedies consumption by the public is on the increase in the western world [1,2]. This demand is often rooted in the belief that herbal products, being natural, are safe to take and can contribute positively to the management of disease states. This tendency of using natural products for managing illnesses is by no means new to health care [2]. While the earlier demand for herbs has been diminished due to the new advances in drug synthesis, a review of current drugs revealed a high percentage of them (about 25%) still had a botanical origin [3]. In response to the public's demand for a better recognition of the natural products in health care, the United States Congress established in 1994 the Dietary Supplements Health and Education Act, also known as DSHEA. According to DSHEA, dietary supplements (DS) are "intended to supplement the diet" by providing the consumer with specific nutrients including vitamins, minerals, herbs, amino acids, and others [2,4]. As such, the intention of DSHEA was not to use these products for the management of disease state, but rather to use them as "supplements" to the regular diet. The US Food and Drug Administration (FDA) is the Federal agency that regulates DS products available on the US market, while the Federal Trade Commission monitors the "truth-in-advertising" claims for any misleading information in DS advertisements [4]. Unlike prescription or over-the-counter medications, DS manufacturers do not have to submit to the FDA any safety or efficacy data prior to marketing. In fact, it is the FDA's responsibility to monitor the safety of DS while they are being consumed by the public [2,4]. The current Federal regulations require the manufacturer of DS to formulate and package them under cGMP-controlled (current Good Manufacturing Practice) environment [4]. The label on DS products usually contain information related to the "structure-function" relationship that a product is intended to provide, however it cannot state that the product is useful for treating a specific "medical" condition. For example, it can be stated on the label that *St. John's Wort* (*Hypericum perforatum*) is useful as a "mood enhancer," but the manufacturer cannot claim the herb's usefulness in treating clinical depression. Additional information on the standardized product's label lists the component(s) to which the standardization was based upon. For *Hypericum perforatum* products, these are standardized with respect to *hypericin* which is one of the "active" constituents in *St. John's Wort*.

Some of the major concerns in health care are drug interactions. The use of DS along with medications can result in drug-herb interactions. Clinical investigations have documented major drug-herb interactions especially those seen with sedative, anti-diabetic, and anti-coagulation medications [2]. Moreover, there is a lack of communication existing between the patients and their clinicians concerning DS use; only 1 out of 4 patients communicates with their physicians about DS use [5]. In addition, most consumers get the information about DS products from friends and relatives and not from their health care providers [6]. This combination of factors presents a real concern in our current health care system. Some of the DS products can produce serious side/toxic effects on their own [4], and some are found adulterated with pharmaceutical drugs, a problem often encountered with imported Traditional Chinese Medicine products [5,7].

Research in the area of botanical medicine has been inadequate

in its quality and quantity. This is perhaps related to the limited availability of funding from the government. The US government makes some fund available to researchers through its agencies such as the National Center for Complementary and Alternative Medicine (NCCAM) (National Institutes of Health). In addition, there is a broad "dis-interest" by the pharmaceutical industry to devote more time and money for scientific investigations related to DS products. Review articles in the area of botanical medicine often cite the various shortfalls of research which include inadequate sample size, unacceptable experimental design, and/or various host of methodological issues [8]. To overcome this negativity which is often associated with DS research, more utilization of randomized placebo-controlled clinical trial (RCTs) along with the use of acceptable state of art scientific methodologies would certainly usher a new era of discoveries. With respect to RCTs, researchers must provide detailed information describing the patient population (age, gender, weight, disease state, etc.) along with a clear description of the randomization method, which is chosen in the research. In addition, researchers must report all adverse events and side effects documented during the course of the study. One of the major flaws in this area is the lack of information pertaining to the DS product being investigated, as preparations of the same botanical can vary greatly in their composition [2]. Researchers in this area must use well-defined standardized DS products and provide characteristics that include the product's natural origin (scientific name and parts of the plant being used), source (geographic region, manufacturer, etc.), dosage form (tablet, fluidextract, cream, etc.), and composition (a detailed list of components with their concentrations). It is known that various components of the same plant can produce synergistic or opposing pharmacologic effects on individuals when present together in the same formulation [e.g., ginsenosides' effect (from *Panax ginseng*) on blood glucose level] [1]. And, knowledge of the composition assures that the subjects are certain to receive the *desired* dose of the "active" ingredient(s) under investigation. It is also desirable that the dietary supplements industry takes initiatives for identifying the toxicity and the teratogenicity of the various components existing in the DS formulation.

In conclusion, herbal preparations are being used alone or in combination with pharmaceutical preparations, oftentimes without the knowledge of the clinicians. Most consumers get their information on DS from friends and family members. Major research flaws are often encountered in the DS literature which may be remedied by

*Corresponding author: Antoine Al-Achi, Associate Professor, Department of Pharmaceutical sciences, Campbell University College of Pharmacy and Health Sciences, Buies Creek, North Carolina, USA, Tel: 910-893-1703; Fax: 910-893-1697; E-mail: alachi@campbell.edu

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standardizing the herbal preparations being tested and using more appropriate experimental designs.

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