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Editorial

Alternative Medicine

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Editorial

Alternative medicine may be defined as any healing practice that does not fall within the realm of conventional medicine. It is based on historical or cultural traditions, rather than on scientific evidence, and it has features resembling faith or spiritual healing. This definition includes a broad array of therapeutic interventions unstudied by conventional contemporary methods, and so it operates apart from evidence based medicine.

More than 100 million Americans consume vitamins, minerals, herbal ingredients, amino acids, and other naturally occurring products in the form of dietary supplements. Of the huge number of unproven remedies on which over $28 billion yearly are spent, most are obtainable without a prescription from health food stores, many pharmacies, and through the internet. Most fall into the category of "herbal" medicines. In the present era, nearly 1 in 5 adults in the United States reports taking an "herbal" product [1]. For more than 5,000 years this was the only form of medicine. Even as recently as 1890, 59% of the listings in the US Pharmacopeia were herbal in origin. An herb can be any form of plant or plant product, including leaves, stems, flowers, roots and seeds. They are sold either raw or as extracts. The resulting products usually contain multiple substances of various chemical types. Since any given herb contains several ingredients, some manufacturers try to create standardized herbal products by identifying a suspected active ingredient and altering the manufacturing process to obtain a consistent amount of this chemical, but such attempts themselves are fraught with considerable uncertainty created by variations in the analytical methods. For most herbs, the exact chemical, or combination of chemicals, that produces a biological effect is unknown, and it is therefore difficult—if not impossible—to create a precise "chemical fingerprint" of the optimum herbal product.

As one might anticipate, regulation of herbal products is a daunting challenge. The Dietary Supplement Health and Education Act (DSHEA) of 1994 classified herbs loosely as "dietary supplements", that is, "anything" that supplements the diet—a nebulous concept indeed! Supplements, therefore, may include vitamins, minerals, herbs, amino acids, enzymes, organ tissues, metabolites, extracts, or concentrates.

All ingredients sold in the U.S. before 1994 are allowed to be marketed without any evidence of efficacy or safety. Given the complexity of most ingredients and their combinations, accurate studies of safety are almost totally lacking. The Federal Act of 1994 (DSHEA) attempted to provide more regulation of the safety of these products, stipulating that ingredients introduced after that time must be accompanied by evidence that there is a "reasonable expectation of safety" (whatever that means) acceptable to the FDA. Unfortunately even this meager expectation has never been adequately enforced. The FDA has received notification of only 170 new supplement ingredients since 1994, despite an estimated 51,000 new supplements appearing on the market [2].

Because of these obvious shortcomings, the FDA proposed in July 2011 guidance clarifying evidence necessary to assess the safety of ingredients introduced after 1994. This involved documented history of use, formulation and proposed daily dose, and duration of consumption relative to historical standards. If a new ingredient was marketed in doses exceeding those historically used, or if formulated or synthesized in a new manner, the FDA would require animal and/or historical documentation for safety. These apparently more stringent regulations remain seriously flawed, e.g., the FDA would not require studies in humans for ingredients lacking evidence of historical use. Even prior use is relevant only if one would have expected to detect adverse effects, which has seldom been accomplished in careful analysis. Even more damning, however, the new guidance would not mandate that all data—both favorable an unfavorable—be submitted to the FDA; a manufacturer could perform multiple studies and submit only the favorable data.

Thus even if these new guidelines were enacted into law, they would provide little assurance to the public that many of these products were actually safe. From this information, we can conclude that, unless compelling evidence (see below) indicates that any of these supplements are effective for any disorder—which is seldom the case—one should avoid all of them.

A major difference between a drug and a dietary supplement is that dietary supplements may not claim to "diagnose, cure, mitigate, treat, or prevent specific illnesses." Consequently, dietary supplement manufacturers can make only general "structure/function" claims, which are often vaguely worded assertions of health benefits such as "support the body's natural defenses", "promote heart health," "better circulation," "increased energy," "better joint health and mobility", etc. They regularly provide a disclaimer that their product "has not been evaluated by the Federal Drug Administration (FDA)." Their wording is regularly evasive, for claims to treat specific diseases cause products to be considered drugs. Firms making such assertions legally must follow FDA's premarket new drug approval process to show the products are safe and effective—an onerous and expensive task! Singh and Ernst [3], have aptly summarized this situation with the statement, "Conventional medicine and alternative medicine both have the same ambition, namely to cure the sick, and yet one is tightly regulated and the other operates in the medical equivalent of the Wild West. This means that patients who venture towards alternative medicine are at risk of being exploited, losing their money and damaging their health."

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Angell and Kassirer [4] best sum up the feeling of the scientific community toward alternative medicine: "It is time for the scientific community to stop giving alternative medicine a free ride. There cannot be two kinds of medicine—conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted. But assertions, speculation, and testimonials do not substitute for evidence. Alternative treatments should be subjected to scientific testing no less rigorous than that required for conventional treatments." The authors state further that alternative medicine also distinguishes itself by an ideology that largely ignores biologic mechanisms, often disparages modern science, and relies on what are purported to be ancient practices and natural remedies, which are seen as being simultaneously more potent and less toxic than conventional medicine. Thus herbs or mixtures of them are considered superior to active compounds isolated in the laboratory. Notwithstanding these statements, unorthodox healing methods continue to be fervently and widely promoted.

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