34 - 29.34 Nutritional Supplements and Medical Foo

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29.34 Nutritional Supplements and Medical Foods Thousands of herbal and dietary supplements are being marketed today. Some are purported to have psychoactive properties. A number have even shown promise in the treatment of certain psychiatric symptoms. Although certain compounds may be beneficial, in many cases the quantity and quality of data have been insufficient to make definitive conclusions. Nevertheless, some patients prefer to use these substances in place of, or in conjunction with, standard pharmaceutical treatments. If electing to use herbal drugs or nutritional supplements, bear in mind that their use may come at the expense of proven interventions and that adverse effects are possible. Though more research is needed, information published to date is still of clinical interest in diagnosing and treating patients who may be taking dietary supplements. Additionally, herbal and nonherbal supplements may augment or antagonize the actions of prescription and nonprescription drugs. Thus, it is important for clinicians to remain informed on the latest research involving these substances. Because of the paucity of clinical trials, the clinician must be extraordinarily alert to the possibility of adverse effects as a result of drug–drug interactions, especially if psychotropic agents are prescribed, because many phytomedicinals have ingredients that produce physiological changes in the body. NUTRITIONAL SUPPLEMENTS In the United States, the term nutritional supplement is used interchangeably with the term dietary supplement. The Dietary Supplement Health and Education Act (DHSEA) of 1994 defined nutritional supplements as items taken by mouth that contain a “dietary ingredient” meant to supplement the diet. These ingredients may include vitamins, minerals, herbs, botanicals, amino acids, and substances such as enzymes, tissues, glandulars, and metabolites. By law such products must be labeled as supplements and may not be marketed as conventional food. The DSHEA

places dietary supplements in a special category, and therefore the regulations governing them are more lax than those for prescription and over-thecounter drugs. Unlike pharmaceutical drugs, nutritional supplements do not need the approval of the U.S. Food and Drug Administration (FDA), and the FDA does not evaluate their effectiveness. Because dietary supplements are not regulated by the FDA, the contents and quality on store shelves vary dramatically. Contamination, mislabeling, and misidentification of herbs and supplements are important problems. Table 29.34-1 provides a list of dietary supplements used in psychiatry. Table 29.34-1 Dietary Supplements Used in Psychiatry

MEDICAL FOODS In recent years the FDA has introduced a new category of nutritional supplement called medical foods. According to the FDA, medical food, as defined in the Orphan Drug Act, is “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.” A clear distinction can be made between the regulatory classifications of medical foods and dietary supplements. Medical foods must be shown, by medical evaluation, to meet the distinctive nutritional needs of a specific population of patients with a specific disease being targeted. Dietary supplements, on the other hand, are intended for normal, healthy adults and may not require proof of efficacy of the finished product. Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods are to be used under medical supervision. Medical foods do not have to undergo premarket approval by the FDA. But medical food firms must comply with other requirements, such as good manufacturing practices and registration of food facilities. Medical foods do have some additional regulations that dietary supplements do not because medical foods are intended to treat illnesses. For example, a compliance program requires annual inspections of all medical food

manufacturers. In summary, to be considered a medical food a product must, at a minimum, meet the following criteria: (1) The product must be a food for oral or tube feeding; (2) the product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there is distinctive nutritional requirements; and (3) the product must be intended to be used under medical supervision. The most common medical foods with psychoactive claims are listed in Table 29.34-2. Table 29.34-2 Some Common Medical Foods PHYTOMEDICINALS The term phytomedicinals (from the Greek phyto, meaning “plant”) refers to herb and plant preparations that are used or have been used for centuries for the treatment of a variety of medical conditions. Phytomedicinals are categorized as dietary supplements, not drug products, and are therefore exempt from the regulations that govern prescription and over-the-counter medications. Manufacturers of phytomedicinals are not required to provide the FDA with safety information before marketing a product or give the FDA postmarketing safety reports. Thousands of herbal drugs are being marketed today; the most common with psychoactive properties are listed in Table 29.34-3. Ingredients, to the extent they have been identified, are listed, as indications, adverse events, dosages, and comments, particularly on interactions with commonly prescribed drugs used in psychiatry. For example, St. John’s wort (wort is an old English word meaning “root or herb”), which is used to treat depression, decreases the effectiveness of certain psychotropic drugs such as amitriptyline (Elavil), alprazolam

(Xanax), paroxetine (Paxil), and sertraline (Zoloft), among others. Kava kava, which is used to treat anxiety states, has been associated with liver toxicity. Table 29.34-3 Phytomedicinals with Psychoactive Effects

Adverse Effects Adverse effects are possible, and toxic interactions with other drugs may occur with all phytomedicinals, dietary supplements, and medicinal foods. Adulteration is possible, especially with phytomedicinals. There are few or no consistent standard preparations available for most herbs. Medical foods are not tested by the FDA; however, strict voluntary compliance is required. Safety profiles and knowledge of adverse effects of most of these substances have not been studied rigorously, however. Because of the paucity of clinical trials, all of these agents should be avoided during pregnancy; some herbs may act as abortifacients, for example. Because most of these substances or their metabolites are secreted in breast milk, they are contraindicated during lactation. Clinicians should always attempt to obtain a history of herbal use or the use of medical foods or nutritional supplements during the psychiatric evaluation. It is important to be nonjudgmental in dealing with patients who use these substances. Many do so for various reasons: (1) as part of their cultural tradition, (2) because they mistrust physicians or are dissatisfied with conventional medicine, or (3) because they experience relief of symptoms with the particular substance. Because patients will be more cooperative with traditional psychiatric treatments if they are allowed to continue using their preparations, psychiatrists should try to keep an open mind and not attribute all effects to suggestion. If psychotropic agents are prescribed, the clinician must be extraordinarily alert to the possibility of adverse effects as a result of drug–drug interactions because many of these compounds have ingredients that produce actual physiological changes in the body.

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