

PART I

INTRODUCTION AND OVERVIEW

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INTRODUCTION TO COMPLEMENTARY AND ALTERNATIVE MEDICINE

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1.1 INTRODUCTION TO COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM)

The past 109 years have witnessed amazing advances in medicine, and, without a doubt, the world's population has benefited from the scientific discoveries elucidating the mechanisms of diseases, as well as the therapeutic interventions that followed. We live longer, healthier lives compared with our ancestors, with much of that due to medical advances. A child born at the beginning of the twentieth century had a life expectancy of ~50 years, while a child born today can expect to reach 75–80 years, or beyond [1, 2]. True, we have yet to conquer heart disease, cancer, and many other diseases, but we are making advances in every corner. In the United States, where cancer is the second leading cause of death, the mortality rate attributed to cancer has declined steadily since 1950 for both men and women across all age groups [3, 4]. But shouldn't we expect such benefits in a country with one of the best healthcare systems in the world? A recent World Health Organization (WHO) report suggests the benefits extend well beyond the United States as adult and childhood mortality rates around the world have declined steadily since the 1990s [5]. The reasons for this decline are many, but the WHO attributes a significant portion specifically to medical advancements. For children, oral rehydration treatment

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during severe diarrhea, the use of artemisinin-based combination therapies for the prevention and treatment of malaria, and the use of immunizations (for the prevention of measles, diphtheria, pertussis, tetanus, hepatitis B, and hemophilus influenzae B) made the difference. For adults, the decline in mortality rates was related to improved therapies for infectious diseases such as tuberculosis, HIV, and malaria [5].

From these and other studies, it is clear that scientific and medical advancements now permit many diseases and conditions to be diagnosed earlier and to be treated more effectively, with the end result of a longer, higher-quality life for many individuals. For this reason, it is intriguing that so many individuals have turned to and embraced the CAM treatments and systems that will be discussed in the following chapters.

1.2 WHAT IS COMPLEMENTARY AND ALTERNATIVE MEDICINE?

CAM encompasses a variety of practices and products ranging from recently introduced New Age modalities to complete medical systems that have evolved over thousands of years. Many of the practices are readily recognized as outside of allopathic (conventional or mainstream) medicine, but others are less obvious. Furthermore, some practices that were once considered CAM have moved into the mainstream. The definition applied by Eisenberg et al. 17 years ago—“medical interventions not taught widely at US medical schools or generally available in US hospitals”—has certainly changed as medical schools have initiated courses in CAM and hospitals have developed departments of integrative medicine [6–8].

Today, the National Center for Complementary and Alternative Medicine (NCCAM) has broadened the definition to “a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine” [9]. NCCAM further distinguishes between CAM and complementary medicine consisting of those practices used in conjunction with allopathic (conventional) medicine, whereas alternative medicine encompasses those practices used instead or in place of allopathic medicine [9]. The Center also uses the term “integrative medicine” to describe the combination of allopathic medicine with those CAM treatments that appear “to be safe and have merit based upon scientific study” [9] (though it is not clear how safety and efficacy were demonstrated for this definition).

Using the NCCAM classification scheme, practices can be divided into five categories (Table 1.1):

- Biological-based therapies employ naturally occurring substances derived from plants, animals, and minerals, such as herbal preparations (the most widely used of all CAMs), botanicals, and dietary supplements.
- Energy therapies include both those involving energy fields believed (by practitioners) to surround and penetrate the body, as well as the applica-

TABLE 1.1 NCCAM Classifications of Complementary and Alternative Practices

| |
|---------------------------------------|
| Whole medical systems |
| Mind–body medicine |
| Biological-based practices |
| Manipulative and body-based practices |
| Energy medicine |

tion of an energy field (magnetic, electric, or electromagnetic) to the body. Examples include Reiki, bioelectromagnetic therapy, and therapeutic touch.

- Manipulative and body-based practices apply physical stimulation, movement, manipulations, and massage or rubbing of muscles and other soft tissues to stimulate blood flow and oxygenation for preventative or healing purposes. Chiropractic, osteopathic manipulation, and therapeutic massage are among the most popular.
- Mind–body therapies use a number of techniques to enhance the mind’s ability to control bodily functions. Examples of practices within this classification include meditation, yoga, prayer, tai chi, biofeedback, and relaxation.
- Whole medical systems are quite complex and often include combinations of practices from the aforementioned groups. A number of these have evolved over thousands of years, notably, traditional Chinese medicine, Indian Ayurvedic medicine, and Arabic Unani medicine.

Agreeably, the practices listed in Table 1.2 are quite varied, and often overlap between the broad categories given. Many individuals would also argue that some, however, are not CAMs but are recreation or even conventional forms of therapy. For example, is the massage enjoyed at a spa a practice of CAM? Is the practice of taking a daily vitamin? If tai chi and yoga are CAM, is running? How should prayer for health and spirituality be classified (some surveys have considered prayer for health a form of CAM practice) [10]. Are these truly complementary and alternative medical practices or perhaps an overclassification? Added to the controversy is the question as to when does a practice make the transition from CAM to conventional—and how? Does the transition occur simply out of acceptance, or must there be sound evidence supporting its use?

1.3 DEMOGRAPHICS OF CAM

Interestingly, the demographics of CAM use in the United States have changed little over the past 17 years. The majority of studies characterizing the use of CAMs in this country are based upon the data generated through the National

TABLE 1.2 Listing of Practices Defined as CAM

| | | |
|--|--------------------------|--------------------------------------|
| Acupuncture/acupressure | Cupping diets | Phytomedicine |
| Alexander technique | Dietary supplements | Prayer |
| Aromatherapy | Electromagnetic therapy | Qi gong |
| Ayurvedic medicine | Enzyme therapy | Reiki |
| Autogenic training | Herbal medicine | Reflexology |
| Autologous blood therapy | Homeopathy | Relaxation therapy |
| Bach flower remedies | Hydrotherapy | Spa therapy |
| Balneotherapy | Hypnotherapy | Spiritual healing |
| Bioelectromagnetic therapy | Iridology | Tai chi |
| Biofeedback and bioresonance | Kampo | Thalassotherapy |
| Bone setting | Kinesiology | Therapeutic touch |
| Chelation therapy | Kirlian photography | Tongue diagnosis |
| Chinese herbal medicine, traditional Chinese medicine | Laser therapy | Traditional medicine |
| Chiropractic therapy | Massage | Trager psychophysical integration |
| Colonic irrigation | Meditation | Transcranial magnetic stimulation |
| Counterirritation | Mental healing | Vega testing |
| Craniosacral therapy | Naturopathy | Water injection |
| Crystal therapy | Osteopathic manipulation | Yoga |
| | Pulse diagnosis | |

Center for Health Statistics of the Centers for Disease Control and Prevention (CDC) [10, 11]. There are additional, though smaller, surveys focusing on specific subpopulations. When reviewing any of these, it is important to realize that the data acquired are directly dependent upon both the survey tool and the surveyor. As mentioned previously, there is disagreement as to what is a CAM, and surveys differ with regard to what is or is not included. For example, the 2007 National Health Interview Survey (NHIS) survey included nine additional CAM therapies and 10 additional biological-based products not captured in the 2002 survey. The 2002 survey included prayer as a CAM practice, though the 2007 survey did not. Neither survey included the use of some types of home remedies. The point here is that these surveys, while extremely valuable, have limitations when trying to discern specific details regarding CAM use and may, in fact, underestimate utilization (a problem reemphasized in subsequent sections). Several investigators have tried to probe more deeply into the differences in CAM use and in practices between the various populations that make up this country's citizenship. The results of these studies reflect the diversity of ethnicity and demonstrate the need for much more work in this area.

About 40% of adults report using at least one form of CAM within the previous year, most often in pursuit of general good health or to prevent illness [10, 11]. Biological-based therapies are, by far, the CAM of choice with ~20% of respondents reporting use of these types of products (Table 1.3). Deep breathing exercises, meditation, and manipulation therapies round out the

TABLE 1.3 Ten Most Popular Biological-Based Products, 2002 versus 2007

| 2002 (Past Year) | 2007 (Past 30 Days) |
|-------------------------------------|--------------------------------|
| Echinacea (40.3%) | Fish oil/omega-3 (37.4%) |
| Ginseng (24.1%) | Glucosamine (19.9%) |
| Ginkgo biloba (21.1%) | Echinacea (19.8%) |
| Garlic (10.9%) | Flaxseed oil (15.9%) |
| Glucosamine (14.9%) | Ginseng (14.1%) |
| St. John's wort (12.0%) | Combination herb pills (13.0%) |
| Peppermint (11.8%) | Ginkgo biloba (11.3%) |
| Fish oils/omega fatty acids (11.7%) | Chondroitin (11.2%) |
| Ginger (10.5%) | Garlic supplements (11.0%) |
| Soy supplements (9.8%) | Coenzyme Q10 (8.7%) |

TABLE 1.4 Use of CAMs by College Students

| <i>N</i> | % | Products |
|----------|------|--|
| 1000 | 26.3 | Ginseng, echinacea, protein power/amino acids |
| 272 | 48.5 | Echinacea, ginseng, St. John's wort, ginkgo biloba, ephedra, chamomile |
| 1754 | 51.0 | Echinacea, ginseng, St. John's wort, chamomile, ginkgo biloba |
| 506 | 79.0 | Green tea, ginseng, chamomile, ginger, echinacea |
| | 58.0 | |

more popular practices. Consistently, surveyors find the person who chooses to use a CAM is most likely to be a middle-aged Caucasian female with a higher education level and of higher economic status. It is extremely important to recognize, however, that CAMs are used by all ages and all populations.

In fact, the 2007 survey found ~12% of U.S. children use a CAM [11]. Not surprisingly, the parents of these children are more likely to turn to these therapies and, accordingly, the children tend to use practices similar to those used by the parent(s): herbal products followed by manipulation therapies and deep breathing exercises [11]. This may have been the case for sometime, as between 26% and 80% of young, college-age adults (~18–21 years) (Table 1.4) have reported using a CAM within the past year since the late 1990s [12–15]. Consistent with other surveys, herbals and supplements are the CAM of choice for this group and are used in pursuit of health and as preventatives.

CAM use peaks between ages 50 and 59 (44.1%) but is relatively consistent from ages 18 to 84 (36.3% and 32.1%, respectively). Many are surprised to discover that older individuals use CAMs at rates similar to younger individuals. Biological-based products, notably, supplements, were most frequently reported in the NHIS survey. Others have found many of this population turn to a range of home remedies involving materials readily available to them such

as vinegar, baking soda, and homegrown or local herbs [16]. Even those living under supervised, or semisupervised, conditions such as in assisted living facilities are found to use CAMs. A limited survey conducted by Moquin et al. found that 5–9% of residents in assisted living facilities used some kind of herbal remedy [17]. More concerning was the fact that the use of such was not known to the facility staff in many cases. Since the older population is more likely to be receiving prescriptive medications, their use of herbals is important as some of these are known to increase the risk of adverse drug reactions (ADRs) when combined with prescriptive medications. If herbal use is not documented or suspected in such an individual, the ensuing ADR could be misdiagnosed and could lead to inappropriate care.

Adequate documentation of CAM use, both on the part of the patient/individual and the healthcare provider, remains a significant problem. This problem is not unique to the United States but is reported worldwide with less than half of patients who use CAM reporting such activities to their healthcare providers [18–22]. Although most physicians, nurses, and other providers are now trained to seek the information, many patients still report not being asked about use, and some providers report being uncomfortable with the inquiry [23, 24]. Shelley et al. determined that whether or not these discussions take place is largely determined by three factors: the patient's perception of the provider's acceptance of CAM and how nonjudgmental the provider appears to be, whether or not the provider initiates the conversation, and concerns the provider has about the safety and efficacy of the specific CAM [24]. They found that patients who use CAMs expect the conversation to be initiated by the provider and that patients were more likely to admit to use if they felt the response was or would be nonjudgmental. Patients specifically reported that they were unlikely to admit use if the response was negative—that they did not want to disappoint or, more importantly, anger the provider. Furthermore, most patients did not expect their allopathic provider to necessarily be a CAM expert. This study was particularly revealing because it also found providers correlate low communication on the part of the patient to be indicative of low CAM use, which may be anything but the case!

1.3.1 Variations in U.S. CAM Utilization Based upon Ethnicity

As noted previously, the 2007 NHIS found that ~40% of the U.S. population used at least one of the more than 40 CAMs queried [11]. Highest use was reported by Native American and Alaska Natives, while lowest use was reported among Hispanics and African Americans. Use among Asians and Pacific Islanders was similar to that reported by Caucasians. How race and ethnicity impact CAM use has been the focus of numerous studies of previous NHIS data and independent surveys, and their findings are quite interesting.

For example, Native Americans and Alaska Natives report the highest use of alternative medical systems primarily in the form of traditional medicine, a complex and often challenging system to study since Native American tradi-

tional medicine does not represent a single, unified medical system [11, 25–28]. Practices and beliefs vary between the more than 600 distinct tribes (including both those officially recognized by federal or state governments and those that remain unrecognized). However, a common theme is the interconnection of everything (living or not) on Earth and the relationship of the mind, body, and spirit. Health and well-being are related to the harmony and balance within and between an individual and the external world [25–28]. Since illness may result when this harmony and balance is disturbed, an important and fundamental part of the healing process is to restore this balance. Traditional healers take a very personalized approach in assessing the situation and in guiding the individual through steps necessary for healing. These may include the use of rituals and practices such as dances, smudging, sweats, and quests, to name but a few. Minerals, animals, and plants are often used as well, and it should be noted that many of the popular herbals discussed in later chapters have a historical use by Native Americans. Ginseng, garlic, echinacea, and St. John's wort are all documented to have been used as traditional medicines though often for very different purposes than currently [29].

Several studies evaluating prevalence of use among African Americans have found this population to engage in the use of home remedies, manipulation (chiropractic) therapies (15–20%), and mind–body practices (~13%) such as meditation and religiosity (prayer). Home remedies not only include the use of herbals but also many other items found within the home. For example, a small amount of vinegar may be taken to help prevent hypertension related to salt intake [16, 30–32]. These types of practices often go unreported or recognized in many surveys.

The use of CAMs among Asian Americans is quite diverse and is dependent upon the region of origin, that is, China, Japan, Vietnam, Korea, Pacific Islands, or India. This group may significantly underreport use in the NHIS as many other surveys have reported higher incidence of use. Ahn et al., for example, found use to range between 55% and 72% among Chinese and Vietnamese populations in several large cities around the United States [33]. A consistent finding is that, in general, Asian Americans are among the most likely to use herbal therapies [10, 11, 34–37]. One should use this statement with caution, remembering the diversity of the population, and indeed there is considerable variability in the pattern of CAM and herbal use within Asian Americans that is further complicated by their geographic distribution within the United States. In practice, Chinese Americans are more likely to use herbals and acupuncture, while Vietnamese Americans typically turn to coining, massage, and cupping, and Asian Indians are more likely to engage in mind–body therapies [33–35]. Across all Asian populations, CAMs are more likely to be used for health maintenance or for prevention rather than for the treatment of a specific condition [34, 35].

Another diverse, heterogeneous group, the Hispanic population in the United States, represents individuals primarily from Central America, South America, and the Caribbean. The health-related traditions brought from each

**TABLE 1.5 Examples of Hot/Cold Theory
Disease Classification**

| Hot | Cold |
|--------------|-----------------------------|
| Constipation | Arthritis |
| Diarrhea | Childbirth |
| Diabetes | Common cold |
| Fever | Indigestion and stomachache |
| Hypertension | Menstrual pain |
| Pregnancy | Muscle spasm |
| Ulcer | |

country are as distinct as the dialects and foods. This is another population that underreports CAM use as evidenced by the NHIS finding of only 23.7% of this group reporting CAM use, yet other reports find use as high as 75% [11, 38, 39]. As a whole, this group participates in a wide range of CAM practices that includes biological-based practices, mind–body, manipulative, and traditional practices. As with the Caucasian population, women are more likely to use CAM products compared with men, and ~36% of Hispanic women report using a CAM [32]. Quite a few studies have found medicinal herbs, teas, and traditional medicine practices to be widely used, often for digestive complaints, pain, and osteoporosis [32, 40, 41].

The traditional medicine form most practiced within the Hispanic population is *curanderismo*, a practice that has evolved from the melding of Central and South American indigenous beliefs, in which the natural forces of the sea, the earth, and the moon are central, and from humoralism, brought by the Spanish conquistadors. This blending has given rise to a hot and cold theory in which disease occurs as a result of an imbalance between these two humors, and specific diseases or conditions are classified accordingly, that is, as hot (*caliente*) or cold (*frio*) (Table 1.5). Treatments are similarly classified and usually have the opposite property of the disorder for which they are used in order to negate or neutralize the problem—a hot disease is thus treated with a cool or cold remedy. For example, hypertension, a hot disease, is treated using cold remedies such as lemon juice, linden tea, passion flower tea, and *sapodilla* tea [40].

1.4 THE REASONS FOR USING CAM

A number of surveys have found correlations between health and CAM use, and in fact the U.S. surveys consistently reveal prevalence of use among those who have been hospitalized in the past year. While those who use CAMs for medical purposes are usually satisfied with the allopathic medical care they receive, they often have a chronic condition or illness that is difficult to treat

or manage and report seeking greater control over their health care [42–44]. Hypertension, upper respiratory infections, arthropathies and related disorders, malignancies, diabetes, depression, and lipid disorders are among the most frequently listed reported conditions leading to visits to primary care providers so it should not be surprising that these are often associated with CAM use [45–51].

In the United States, peri- and postmenopausal women (age 40–65 years) may be one of the largest groups who use CAMs for symptomatic relief. With the baby boomers well into this age range, this group now includes ~18 million women. The Study of Women's Health Across the Nation (SWAN) has shown that more than half of women in this period turn to a CAM to control or alleviate their symptoms [52]. Most often, nutritional remedies were used, followed by herbal remedies and folk medicine [53]. Typically, the women in this group reported a greater range of symptoms than those who did not use CAM. Importantly, the few who were surveyed had consulted their primary care provider for information, obtaining their information solely from alternative practitioners. Perhaps even more important was the finding that <50% reported having been asked about the use of herbals by their primary care providers. Black cohosh, St. John's wort, and dong quai were the most commonly used products, and the users rated symptom relief at about 50%. This is one group that does deviate from the finding of many other studies that those who turn to CAM are relatively satisfied with allopathic care for this group tends to turn to herbals out of fear or distrust of hormone replacement therapy (HRT) [52, 53].

1.5 GROWTH OF CAM AND HERBAL USE

To understand the growth of CAM utilization by the U.S. population, consider that ~\$10 billion was estimated to have been spent on these practices in 1990, an impressive figure that increased to ~\$30 billion by 1997 [54]. Given this was during a time of public concern and focus on rising healthcare costs, it is remarkable that the U.S. population was willing to spend this amount of money out of pocket! Expenditures have continued to increase slightly as reported in the 2007 NHIS survey, which found ~\$34 billion spent toward CAM [55]. This represented 354 million visits to CAM practitioners at a cost of \$11.9 billion and ~835 million purchases of which ~\$14.8 billion went toward non-vitamin, nonmineral natural products (typically herbals) and \$7.2 billion for other products. In economic terms, the dollars spent represent ~11% of total out-of-pocket healthcare expenditures. To be fair, it is important to recognize that while these figures are staggering, they represent only a small portion of the \$2.2 trillion in estimated total costs for healthcare services.

A few studies have begun to attempt to answer the question of cost-effectiveness of these practices. In one, Eisenberg et al. compared the effectiveness and cost of standard care for acute low back pain versus standard care

plus the choice of acupuncture, chiropractic, or massage therapy. Patients presenting with low back pain at four study sites were randomized to two groups: those to receive “standard” care and those who had the additional choice of the aforementioned therapies. After 5 weeks of treatment, there was no difference between the two groups in terms of clinical outcome—neither group had a significant benefit in terms of reduction in symptoms and functional status. However, the group allowed to choose additional alternative therapy reported greater satisfaction with care. Although an important part of medical care, this increase in satisfaction came at an increased cost of ~\$244 per patient, with most of the added costs as out-of-pocket expenditures [56].

1.6 REGULATION OF HERBAL SUPPLEMENTS IN THE UNITED STATES

Pharmaceuticals are regulated by the Center for Drug Evaluation and Research of the Food and Drug Administration (FDA). In contrast, the majority of herbals and supplements sold in the United States are overseen by the Center for Food Safety and Applied Nutrition of the FDA and are regulated under the 1994 Dietary Supplement Health and Education Act (DSHEA). As a result, there are a number of differences in the way supplements are regulated compared to pharmaceutical preparations.

To start, the manufacturer assumes responsibility for assuring premarket safety. The manufacturers must register with the FDA and adhere to the 2007 Current Good Manufacturing Guideline, but the actual products are neither registered with the FDA, nor do they go through any regulatory approval process as do pharmaceutical products. The FDA becomes involved when there are concerns about the product’s safety after marketing or concerns are raised about the product’s labeling, package inserts, or claims.

Under DSHEA, there are strict limitations to the claims a manufacturer of a product may make regarding its actions. In fact, the statements must be of a broad, general nature. A manufacturer may, for example, claim that taking the product helps to “maintain cardiovascular function and a healthy circulatory system,” but it cannot claim to “reduce the risk of heart disease.” While the FDA has authority for ensuring that a manufacturer’s claims fall within the laws, the Federal Trade Commission is also involved as it has oversight of advertising for all food products (including supplements). Herbals and supplements must be labeled with all ingredients, other food ingredients and additives such as preservatives or processing aids, and the net contents of the product. The labels must also provide information about the manufacturer or distributor.

Consumers and healthcare providers can report suspected adverse effects to the FDA through the MedWatch program. Many of these may also reported through the Toxic Exposure Surveillance System of the American Association of Poison Control Centers. If there is sufficient evidence, the FDA will issue

TABLE 1.6 Examples of FDA Alerts and Recalls

| Date | Alert or Recall |
|-----------|--|
| 2001 | Alert regarding nephrotoxicity associated with aristolochic acid used and recall of products containing the compound |
| 2001 | Alert regarding hepatotoxicity associated with comfrey and removal of products from the market |
| 2001 | Warning regarding dietary supplement “Lipokinetix” |
| 2002 | Alert regarding PC SPES and SPES |
| 2001–2002 | Reports of hepatotoxicity associated with kava use |
| 2004 | Warning regarding use of Better than Formula Ultra Infant Immune Booster 117 |
| 2005 | Alert regarding Liqiang 4 |
| 2007 | Alert regarding red yeast rice products (possible contamination with lovastatin) Recall of erectile dysfunction supplements (contain undeclared drugs: tadalafil, aminotadalafil, acetildenafil, piperadino vardenafil) |
| 2008 | Recall of erectile dysfunction supplements due to contamination with hydroxyhomosildenafil |
| 2008 | Recall of dietary supplements containing bumetanide (diuretic) |
| 2008 | Recall of dietary supplements containing sibutramine (appetite suppressant) |
| 2009 | Recall of steroid-containing bodybuilding supplements |
| 2009 | Advisory to consumers and healthcare professionals that products containing colloid silver may cause discoloration of skin and mucous membranes |

an alert and/or a product recall. Since 2001, alerts have been issued regarding aristolochic acid, products containing colloidal silver, kava, and others (Table 1.6). When an adverse event is suspected, there is often the question of how can one determine the contents or have it tested. Such testing is beyond the scope of most clinical laboratories. While there is the possibility that the laboratory could test for specific compounds (undeclared drugs such as digoxin or phenytoin) or heavy metals for which the laboratory has a validated analytical method, a better solution is to contact an analytical laboratory that specializes in such testing.

1.7 REGULATIONS OUTSIDE THE UNITED STATES

Some have criticized the regulatory system and suggested the United States turn to a more rigid process similar to those of other countries. Most of the member countries of the European Union consider herbals to be medicinal products and regulate them accordingly under the 2004 Traditional Herbal Medicine Directive. Any plant, a part of a plant, or a plant-based preparation for which there is a therapeutic claim is considered a medicinal product and

must go through an approval process before being marketed. Exceptions are made for products compounded by an herbalist for an individual. The classification of some herbs is a bit complex and they may fall under different criteria depending on the specific use or claim—for example, senna can be classified as either a food or a medicinal.

Manufacturers must show traditional use for at least 30 years with 15 years of traditional use within the EU. Evidence of traditional use includes bibliographic or expert evidence of use including authoritative manuscripts, expert testimony, and records of products in use. The products can be administered only by mouth, require no physician supervision, and the marketed use must be consistent with tradition or supporting data. The packaging must include a warning to seek medical attention should the symptoms persist or if unexpected symptoms develop. Imported products are usually treated as new “chemical entities.” The manufacturer or distributor must present proof of quality, safety, and efficacy as part of the review process.

In Australia, where more than 50% of the population reports using herbals or complementary medicines, herbals are regulated by the Australian Therapeutic Goods Administration (TGA) as medicines under the Therapeutic Goods Act 1989. Complementary medicines include herbals, vitamins and minerals, nutritional supplements, homeopathic medicines, and traditional medicines (Australian indigenous medicines, Ayurvedic medicine, Chinese medicines, etc.). The TGA uses a risk-based premarket assessment that includes evaluation of the toxicity of the ingredients, dosage form, indications for use, and potential adverse side effects, and from this assessment, products are classified as listed (low risk) or as registered (higher risk). Listed medicines are restricted to indications for health enhancement or for nonserious, self-limiting conditions and claims relating to health maintenance. They cannot indicate they are to be used for treatment or prevention. Registered medicines must undergo evaluation for quality, safety, and efficacy. All products are produced under the same code of good manufacturing practice adhered to by pharmaceutical manufacturers, and postmarket surveillance is similar to any other drug.

1.8 RESOURCES

Obtaining reliable information about herbals and other forms of CAM is challenging. The tendency is to simply conduct Internet searches using one’s favorite search engine. This approach will bring a plethora of sites of mixed reliability. Table 1.7 provides a listing of several sites that may be useful. The information found on these databases is regularly updated and assessed using systematic, evidenced-based approaches. The sites also provide excellent resources for reported drug interactions, toxicities, and interferences with laboratory tests. The reader may also find the translations of the German Commission E monographs to be quite useful.

TABLE 1.7 Useful Resources

| | |
|---|--|
| National Center for Complementary and Alternative Medicine | http://www.nccam.nih.gov/ |
| Food and Drug Administration | http://www.fda.gov/ http://www.fda.gov/Food/DietarySupplements/default.htm |
| Centers for Disease Control | http://www.cdc.gov/ |
| Natural Medicines Comprehensive Database | http://www.naturaldatabase.com/ |
| Cochrane Collaboration | http://www.cochrane.org/ |
| National Health Statistics Reports | http://www.cdc.gov/nchs/index.htm |
| American Botanical Council (translations of German Commission E monographs available) | http://abc.herbalgram.org/ |

1.9 CONCLUSIONS

CAMs are widely used within the United States with between 23% and 75% of the American population reporting use of such a practice within the previous year. Most individuals report using CAM as a means of improving health or preventing illness. CAMs are used by all populations and ethnicities and across all ages, though the type of CAM favored varies.

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