2006 marked the 40th year of publication for *The Annals*. Throughout its history, *The Annals* has provided important contributions to the development of clinical pharmacy. In 2007, we are continuing to publish articles reflecting on the history of clinical pharmacy through the eyes of practitioners, including those pioneering clinical pharmacy, as well as those who have more recently entered the profession and a well-established specialty. In addition, we are presenting articles and editorials from the early history of *The Annals* that have given direction and shape to the practice of clinical pharmacy (see page 1268).

The History of Complementary and Alternative Medicine in the US

Cathy Creger Rosenbaum

The World Health Organization estimates that 30–80% of adults in industrialized countries use complementary or alternative medicine (CAM) to prevent or treat illness, including 60 million in the US.[1] In the US in 1990, more visits were made to CAM practitioners (425 million visits) than to primary care physicians (388 million visits). An estimated 40 billion out-of-pocket dollars are spent in the US per year on CAM therapies.[2] In 1994, The Robert Wood Johnson Foundation survey of 3450 individuals indicated that a majority of consumers sought professionals for chiropractic, relaxation techniques, massage, and acupuncture.[3] Yet herbal products, vitamins, other dietary supplements (eg, nutraceuticals), and homeopathic remedies enjoy a prominent place in the armamentarium of many CAM therapies.[4-6]

Typical CAM consumers are white and 25–49 years of age, with some college education and an income above $35 000.[7] Only 20% of patients disclose CAM use to their physicians.[8] Pharmacists are uniquely poised to gather this information about CAM from their patients because they are trusted healthcare professionals (as indicated by annual Gallop Poll surveys) and have the opportunity to perform supplement utilization reviews alongside medication utilization reviews.

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In 1994, the first *American Herbal Pharmacopoeia* was published, including more than 300 monographs on Ayurvedic, Chinese, and Western dietary supplements. The *Complete German Commission E Monographs* (380) was published in 1998. Both texts are used worldwide by professionals as evidence-based references. Prior to these publications, most herbal studies in the latter twentieth century were published in languages other than English. Prescription and over-the-counter (OTC) homeopathic remedies, marketable as drugs from a legal and regulatory perspective, are listed in the *Homeopathic Pharmacopoeia of the United States* (HPUS). These latter products must have a drug claim for a self-limiting, self-diagnosable condition on the drug product label. Kampo medicine, the Japanese adaptation of Chinese medicine, incorporates herbal products found in the *Japanese Pharmacopoeia*. Since 1994, Japanese herbal manufacturers have been required to conform to the same quality standards as do other Japanese pharmaceuticals and have less product quality issues than do western herbs found in the US.

Only a few US pharmacy schools teach pharmacognosy, a discipline focused on natural medications and herbs referenced in the above compendia. By comparison, pharmacognosy is a required course in pharmacy curricula taught at European universities. Very few clinical pharma-

cists have been formally trained in the OTC practice of recommending and monitoring herbal products based on well-designed clinical research and postmarketing data.

In 1992, Congress established the Office of Alternative Medicine (now the National Center for Complementary and Alternative Health [NCCAM]) at the National Institutes of Health (NIH). NCCAM defines CAM as "a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine," and integrative medicine as the art of "[combining] mainstream medical therapies and CAM therapies for which there is some high-quality scientific evidence of safety and effectiveness."[9] Holistic medicine, by comparison, is defined as "an approach to medical care that emphasizes the study of all aspects of a person's health, including physical, psychological, spiritual, social, economic, and cultural factors." For purposes of this review, CAM will represent all 4 categories (eg, complementary, alternative, holistic, and integrative).[10]

CAM, which dates back to the early nineteenth century, is evolving dramatically in the US. Since the 1970s, CAM has advanced from political suppression by mainstream healthcare professionals to a more open practice of evidence-based CAM modalities. In the US, major physician pioneers (including Andrew Weil MD, best known for establishing the field of integrative medicine; David Eisenberg MD[2,11]; Deepak Chopra MD; Dean Ornish MD, a nutrition "guru"; Brian Berman MD, who became involved with homeopathy and acupuncture early in his career and is one of the most highly funded NIH researchers specializing in CAM; Larry Dossey MD, a pharmacist and physician interested in the role of religious practice and prayer in healthcare) have dramatically expanded our knowledge of CAM over the past 15 years.

Due in part to the passion and perseverance of these colleagues, CAM is among the fastest growing aspects of US health care. Six basic fields of CAM treat and prevent illness: mind-body; bioelectromagnetic; alternative medical practice systems (ie, acupuncture); manual healing (ie, healing touch); herbal supplements; and diet, nutrition, and lifestyle changes.[12] One study examining the attitudes of pharmacy faculty and students toward CAM reports positive views about including CAM in pharmacy curricula.[13] Conventional American physicians who were surveyed report that they are referring patients to acupuncturists, chiropractic, and massage and, to a lesser degree, homeopathic and/or herbal medicine practitioners (including pharmacists), or spiritual healers.[3,7,14]

Training

On March 8, 2000, President Clinton signed an order establishing a White House Commission on Complementary and Alternative Medicine Policy for 2 years. The order called for more education, training/credentialing, research, accessibility, and guidance for access to CAM practitioners. The doctor of naturopathy credential is available to pharmacists in the US from 4 full-time 4 year schools of naturopathy and 8 correspondence schools. Collegiate debate is ongoing regarding whether there should be credentialing, as opposed to licensing, for CAM pharmacists and other CAM practitioners.[11,15,16] Credentialing is more comprehensive than licensure. The former takes into account clinical experience and preparation for recommending herbs, vitamins, and other dietary supplements for appropriate indications, in addition to professional licensure and relicensure. The Council on Credentialing in Pharmacy defines 3 types of credentials: university/college degree, licensure, and postgraduate work or competencies.

Research and Reimbursement

In 1990, a report from the Committee on Technological Innovation in Medicine from the Institute of Medicine stated that conducting randomized controlled trials (RCTs) to answer all CAM-related clinical questions is not feasible. Yet the number of published clinical trials and information regarding supplement-related adverse effects available on MEDLINE and in other indices, although still limited relative to the category of dietary supplements as compared with conventional medications,[17] has greatly increased in the past 10 years. More than 462 000 citations have appeared in the CAM section of PubMed from 1966 to today,[18] and the NIH is spending $300 million per year on CAM research (Table 1). For perspective, NIH's total research budget for fiscal 2006 exceeded $28 billion. In addition, private foundations fund many CAM activities.[3] Third-party payers such as Anthem are starting to offer expanded benefits to their members for CAM therapies. Public funding has stepped up to the plate in 46 states surveyed, whereas 36 Medicaid programs now cover at least one CAM therapy.[19] Despite this trend, CAM modalities are largely delivered and billed as fee-for-service products.

Table 1. Examples of National Institutes of Health NCCAM Clinical Trials

Energy Therapies	Physical Therapies	Mind/Spirit Therapies
acupuncture/acupressure	antioxidants	art therapy
meditation	aromatherapy	biofeedback
Qigong	chelation	cognitive–behavioral relaxation
Reiki	homeopathy	distant healing
T'ai Chi	macrobiotic diet	guided imagery
traditional Chinese medicine	massage	hypnotherapy
yoga	naturopathic medicine	music therapy

NCCAM = National Center for Complementary and Alternative Health.

In addition, CAM pharmacists who recommend dietary supplements are generally not reimbursed by third-party payers or the Centers for Medicare and Medicaid Services for their cognitive services.

Regulatory Drivers

The major regulatory driver for nutraceutical consumption has been the Dietary Supplement Health and Education Act (DSHEA), which amended the Federal Food, Drug, and Cosmetic Act and was signed into law by President Clinton in 1994 to define the category of dietary supplements. This bill liberalized labeling and marketing of dietary supplements and removed preemptive control of the Food and Drug Administration (FDA) over unsafe natural products. Dietary supplements are regulated by the FDA as foods under the Center for Food Safety and Applied Nutrition (CFSAN).[20] Research indicates that supplements act like drugs, may have adverse effects, and can be involved in drug/supplement interactions.[21,22]

Today, health food stores supply a plethora of herbal combinations from Europe, the US, China, India, and Japan. In addition, some medicinal herb shops, called botanicas, sell herbs from South America and Mexico. Nonpharmacist, nondietician health food store clerks recommend dietary supplements for medical conditions and symptoms, largely without follow-up on any unwanted effects. Dumoff[23] recommends federal and state policy changes advancing CAM practice, research, and quality testing for dietary supplements, as well as reimbursement for the same. Pharmacists must monitor their patients' use of supplements when made aware of it or when invited to make recommendations. They should also take the lead in reporting supplement-related adverse effects to the FDA and know when to relay questions more appropriate for dietitians.

The number of professional CAM associations available to pharmacists and other healthcare professionals has grown over the past 80 years and includes the American Association of Homeopathic Pharmacists (1923), the American Holistic Medical Association (1978), the American Naturopathic Medical Association (1981), the American Association of Naturopathic Physicians (1985), the American Botanical Council (1988), the Association of Natural Medicine Pharmacists (1994), and the American Alternative Medical Association (1996).

By contrast, with regard to CAM practices incorporating dietary supplements into health regimens in the US (eg, Ayruveda, homeopathy, naturopathy, Western herbology, Chinese herbology, Kampo medicine), there are only 10 Ayurveda clinics and no certification programs for Ayurvedic physicians. However, the number of homeopathic practitioners has increased in recent years. Pharmacists are acknowledged as doctors of homeopathy in some states (eg, California). Homeopathy, based on the laws of similars and infinitesimals, does not use the HPUS to identify symptoms/diseases for which homeopathic remedies should be used. Instead, homeopathic practitioners make that decision based on a patient's constitutional type (eg, Ignatia Type, Pulsatilla, Nux Vomica Type).

Homeopaths are certified by one of the following: American Board of Homeotherapeutics, Homeopathic Academy of Naturopathic Physicians, or the North American Society of Homeopaths. In December 1996, the Homeopathic Medicine Research Group, convened by the Commission of the European Communities, published a report evaluating controlled studies using homeopathic remedies and found 17 well-designed small trials with positive outcomes.[24] Full-time naturopathic schools require that students take courses in homeopathy.

Homeopathy has been an integral part of naturopathic medicine for a long time. Naturopathy facilitates the body's inherent ability to heal itself. Naturopaths are licensed to practice in 13 states (Alaska, Arizona, California, Connecticut, Hawaii, Kansas, Maine, Montana, New Hampshire, Oregon, Utah, Vermont, Washington). The Alliance for the State Licensing of Naturopathic Physicians is promoting licensure in the remaining states.[25] The typical naturopathic practitioner may administer nutritional, manual, mechanical, or physiologic substances in treating conditions.

Where will CAM practices that use herbs be in the next 10–20 years? Expect to see a dramatic growth in the number of CAM pharmacists involved in any or all of the aforementioned disciplines, in partnership with multiple healthcare professionals, and in retail and institutional practices.[26] Endpoints and health outcomes for CAM multimodality and customized research protocols with herbs will be better defined, gaining NIH funding as well as approval from investigational review boards and finding their niche in mainstream inpatient hospital practice by 2015.[27] There will be a critical need for medical and pharmacy schools around the globe to include required courses in pharmacognosy that focus on the evidence-based role of herbs in health regimens.[28] To this end, the International Congress on Natural Products Research, organized by the American Society of Pharmacognosy, the Society for Medicinal Plant Research, the Phytochemical Society of Europe, and the Francophone Association for Research in Pharmacognosy, took place in Arizona in 2004 to discuss this topic. The pharmacognosists represented believe that pharmacy curricula should address a renewed worldwide interest in natural products for drug discovery, coupled with training in analytical quality-related methods (eg, high-performance thin-layer chromatography). Modern pharmacognosy is poised to launch a paradigm shift in medicine from monoprescription therapy to multitherapeutic approaches.[29,30] No American Society of Health-System

Pharmacists–accredited PGY2 CAM pharmacy residencies or fellowships exist in the US, but they are warranted in years to come.[31]

In the future, CAM pharmacists may serve as chaplain/pastor/rabbi pastoral care extenders helping to triage patients' emotional and spiritual issues, in addition to providing medication/supplement-related cognitive services.[32] CAM pharmacists will partner with physicians in triaging patients to credible holistic practitioners within their communities, thus enhancing healing strategies. In contrast, more traditional pharmacists will closely align with the safety side of medication/supplement use in careers such as institutional safety officers or clinical coordinators managing supplement formularies. Still others will choose a career in dietary supplement product development and/or research in head-to-head comparisons of supplements and OTC/prescription medications.

Regarding the regulation of dietary supplements, I predict more consumer pressure directed at the FDA to regulate the more than 20 000 proprietary supplements available worldwide as drugs under the Center for Drug Evaluation and Research (CDER) in the Division of OTC Drug Products instead of as foods under the FDA's CFSAN branch. The US needs a Dietary Supplement Advisory Committee, as well as more randomized, double-blind clinical trials, to establish Good Manufacturing Practice quality, determine supplement efficacy, and institute control for safety outcomes. The OTC Division of OTC Drug Products is overloaded with the review of OTC drug monographs and would need additional human resources to implement this recommendation. CDER and CFSAN must collaborate. Additionally, through the Ten Year Plan established in January 2000, the FDA will continue to encourage pharmacists and other healthcare professionals to identify and spontaneously report supplement-related adverse events to establish trending. Finally, many healthcare professionals in my circles believe that the DSHEA, which establishes supplement regulation and the content of supplement claims, needs to be revisited.

Physicians, nurses, and dieticians have become valuable members of the CAM healthcare team; pharmacists must quickly get on board in the next decade. With advanced automation platforms supporting the medication use process, CAM pharmacists could take the lead on teams as health coaches and patient advocates for change. All healthcare professionals can participate in taking comprehensive medication histories, adding open-ended questions about emotional and spiritual health (eg, stress management coping skills). This approach will lead the way for the evolution of team-based healing for our next generation.[33]

Cathy Creger Rosenbaum PharmD MBA, Founder and CEO, Rx Integrative Solutions, Inc., Loveland, OH; Clinical Effectiveness and Safety Officer, Department of Pharmacy, Bethesda North Hospital, Cincinnati, OH

Reprints: Dr. Rosenbaum, Rx Integrative Solutions, Inc., PO Box 351, Loveland, OH 45140, drcathy@rxintegrativesolutions.com

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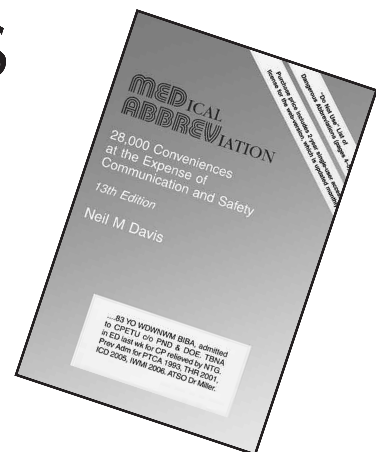

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