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Special Report: Alternative Medicine Update

Is alternative medicine poised for hospital formularies?

Standards, acceptance, and patient numbers are growing

The first U.S. multicenter clinical trial of a botanical alternative medicine, set to begin this summer to test the efficacy of St. John's wort as a treatment for depression, is the first step toward the scientific status of an herbal product becoming a prescription drug in the United States, a status St. John's wort already has achieved in Europe.

For hospital pharmacists, the news signals the integration of alternative medicine with the mainstream of the profession, where drug interactions, patient questions, and acceptance levels by the industry have already become issues. **(For more information on the impact of alternative medicine, see the April 1998 issue of *Drug Utilization Review*.)** Along with the advent of clinical trials, evidence that herbals could one day become part of a hospital's floor stock or an agenda item with the pharmacy and therapeutics committee is growing. Recent surveys of physicians and consumers show that professional referrals and popular acceptance are climbing, all while sales are increasing dramatically. That has caused drug makers to introduce new herbal lines this year, while the National Institutes of Health Office of Dietary Supplements is working to make scientific information available, and the Federal Trade Commission is fine-tuning its regulatory oversight on a host of remedies that carry no FDA approval process.

The St. John's wort trial will randomly assign the herbal (*Hypericum perforatum*), a placebo, or the antidepressant Zoloft (sertraline) in a six-month study funded by the National Institutes of Health Center for Complementary and Alternative Medicine.

"Research conducted in Europe suggests St. John's wort has the potential to relieve depression without some of the side effects of pharmaceutical antidepressants, but still, the botanical's own side effects must be rigorously evaluated as well as its true effect on mood," says **Jeffrey Kelsey**, MD, PhD, assistant professor of psychiatry and behavioral sciences at Emory University in Atlanta, one of 12 sites selected to

conduct the St. John's wort clinical trial.

Professionals like Kelsey are calling for such trials as a way to bring about standard scientific knowledge of herbals no matter what their future status because millions of consumers are using them regardless. At the same time, trials could help flatten out the learning curve for hospital pharmacists by giving them credible information.

Researchers believe that hypericum extract inhibits the reuptake of serotonin and other neurotransmitters similar to prescription selective serotonin reuptake inhibitors. What's still unclear is the mechanism of action and the specific concentrations of the herbal that provide positive results.

According to the publication *OTC Update*, U.S. sales of St. John's wort grew from $5 million in 1995 to $89 million just two years later. Similarly, sales for another popular herbal, ginkgo biloba, went from $85 million to $130 million in one year's time. This year the regulatory oversight that does exist for the herbals market tightened. New labeling regulations that went into effect in March require herbal manufacturers to list the nutrient content of their products. That rule stems from the Congressional Dietary Supplement Health & Education Act of 1994. The act also gave the FDA power to take herbal products off the shelves if safety or post-market circumstances warrant it, but the agency has no scientific approval capabilities as it does with prescription drugs.

Instead, the Federal Trade Commission is the largest overseer of the botanicals market, largely addressing issues of advertising and labeling claims.

Also this year, the FTC refined and reissued its set of advertising regulations, titled *A Guide for the Dietary Supplement Industry*. The guidelines cover the disclosure of a product's adverse effects, ensures that ads and labels disclose the limits of scientific research done on a product, frames the uses of anecdotal evidence, and even

Alternatives at a Glance

Some of the most popular and emerging products:

St. John's wort (*Hypericum perforatum*): Marketed as an antidepressant, its therapeutic value is likened to that of prescription selective serotonin reuptake inhibitors.

Saw palmetto (*Serenoa repens*): Marketed for its ability to reduce symptoms associated with enlarged prostate, including frequent urination.

Echinacea (*Echinacea purpurea*): Used for the prevention and treatment of colds and flu.

Ginkgo (*Ginkgo biloba*): Used to increase circulation to the brain and extremities, studies are including the herbal in Alzheimer's research.

Valerian root (*Valeriana officinalis*): Used as a sleep aid, and for anxiety.

Feverfew (*Tanacetum parthenium*): Used for headaches, fever, and in migraine research.

Milk thistle *(Silybum marianum)*: Marketed for the prevention and treatment of liver disorders.

Kava Kava (*Piper methysticum*): A nervous system herbal used for anxiety and tension reduction.

Acetyl-l-carnitine: Believed to promote nerve and brain functioning, the supplement is also being included in Alzheimer's research.

Alpha lipoic acid: An antioxidant being looked at for cellular regeneration.

Ipriflavone: A naturally occurring isoflavone involved in the enhancement of bone density and calcium utilization, the supplement is being promoted as a therapy for osteoporosis.

Lutein: Related to beta carotene and promoted for healthy vision by aiding macular pigment in the retina. The supplement is also being looked at as an immune system enhancer.

Source: HealthWorld Online, www.healthy.net; Natural Products Industry Center, www.NPICenter.com; *Alternative Medicine: The Definitive Guide.*

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stipulates the labeling jargon in terms of what a product "may" do or "help" achieve, which is commonly used by manufacturers. (To see the entire set of guidelines, check out the FTC's Web site at www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm.)

Says **Marcia Angell**, MD, executive editor of the *New England Journal of Medicine*, "There cannot be two kinds of medicine, conventional and alternative, only medicine that has been adequately tested or has not, medicine that works or may not work. Once a treatment has been tested rigorously it no longer matters whether it was considered alternative, but it is time for the scientific community to stop giving alternative medicine a free ride."

Drug makers going herbal

Aware that market share is climbing, pharmaceutical companies are not waiting for exhaustive clinical trial results to get into the alternative marketplace. Last year, Warner-Lambert jumped first with its Halls Zinc Defense and Celestial Seasonings Herbal Comfort with Echinacea. This year the company is tapping into two of the most popular supplements with its Quanterra line, highlighted by Quanterra Mental Sharpness, a ginkgo biloba supplement, and Quanterra Prostate from saw palmetto.

Warner-Lambert is using the same carefully worded marketing for the products, which are not tested or regulated by the FDA, but are overseen for advertising content by the Federal Trade Commission to assure no specific medicinal claims are made. Packaging for Warner's ginkgo supplement speaks to the promotion and maintenance of mental sharpness and blood circulation to the brain and extremities, both standard promotions for the product.

The company's saw palmetto offering "helps to maintain healthy urinary flow and supports male prostate health," says Warner-Lambert's **David Barber**. He notes that Warner-Lambert is also attempting to help its traditional industry associates, namely pharmacists and physicians, keep up with their homework on alternative medicine. "We are making a significant commitment to education, and we've already assembled an advisory board across conventional areas of medicine as well as leaders in herbal supplements."

American Home Products is also entering the herbal market with a line of six products called Centrum Herbals that includes ginkgo, saw palmetto, St. John's wort, echinacea, garlic, and ginseng offerings.

The company is co-marketing with the Pharma Print Corp., which has patented a technology that

NIH herbal database goes online

As part of the Congressional Dietary Supplement Health and Education Act of 1994, the National Institutes of Health Office of Dietary Supplements, itself established in 1991, was mandated to create a science-based information bank on alternative medicine.

In January, the Bibliographic Information on Dietary Supplements (IBIDS) database went online, offering published and peer-reviewed literature, with search engines that cover medical, botanical, agricultural, chemical, and pharmaceutical sources.

The database covers more than 10 years of literature on alternative medicines. The NIH plans to update the system monthly or quarterly, depending on the frequency of the literature it draws on. The site is at http://nal.usda.gov/fnic/IBIDS/, while the NIH Center for Complementary and Alternative Medicine is located at http://altmed.od.nih.gov/oam.

Several additional credible Web sites on alternative medicine offer everything from pharmacology and known adverse effects to herb remedy indexes and dosages, FAQs, links, monographs and book reviews, to physician referrals and discussion forums.

The sites have been created by a wide range of groups, from nonprofit organizations and manufacturers to authors and advocacy groups. Some sites visited by *Drug Utilization Review* include: www.medherb.com, www.botanical. com, www.sbherbals.com, www.algy.com, and www.healthy.net/clinic/ therapy/index.html. ■

measures herbal molecular levels to promote specific biological activity and therefore product marketing, which the company says is aimed at furthering scientific standards for the unregulated products. Another large and "traditional" drug maker, Bayer Corp., has also entered the market with a line of One-A-Day Specialized Supplements, while Herbs for Kids, a start-up company based in Bozeman, MT, is offering a line of 31 liquid herbal extracts for children ages 1 and up that also includes St. John's wort and echinacea among its products, as well as white pond lilly, goldenseal, dong quai and chaparral.

More doctors are recommending alternative remedies and more consumers are using them, according to recent surveys. Late last year, the American Academy of Family Physicians published a survey that found one in three physicians recommend herbals to their patients at least once a week, while one in four doctors use the products themselves. The leading product physicians are recommending is St. John's wort, according to the survey, followed by ginkgo biloba. Among consumers, nearly 70% say they use alternative medicines when traditional prescriptions have not cured them, according to a poll conducted by the Stanford University Center for Research in Disease Prevention.

Forty-nine percent said they've detected positive results from the use of herbals and supplements, while 65% said they use the products primarily for prevention. In terms of overall use, 81% said they have used some sort of alternative therapy, ranging from herbals to chiropractors, at some point in their lives.

A similar poll conducted this year by the National Consumers League states that 64% of those queried had taken vitamins in the last 12 months, 39% had taken herbal supplements and 21% had taken mineral supplements. Respondents were also asked if they agreed with a series of statements, from which 46% agreed that herbal supplements are generally safe, 37% found them effective in maintaining overall health and well-being, 36% agreed they were effective in preventing some diseases, 29% thought the products a good value, and 23% agreed they were as effective as prescription or OTC drugs.

For more information on the St. John's wort trial, contact the Wesley Woods Health Center at Emory University, (404) 727-8968. ■

AMA study: Alternative medicine growing rapidly

The total number of visits to alternative medicine providers in the United States increased 47% between 1990 and 1997, according to a yearlong study released by the American Medical Association (AMA) in Chicago and published in the *Journal of the American Medical Association*.

"The trend is clear," says **David Eisenberg**, MD, of Beth Israel Deaconess Medical Center in Boston, who helped design the study. "Alternative therapy in this country has increased dramatically in the last seven years." Eisenberg reports that 83 million Americans — or 2% of the U.S. adult population — reported using an alternative therapy in the last 12 months. By comparison, a 1990 survey used as a benchmark found that 61 million — or 34% of the U.S. adult population — had used an alternative therapy in the last 12 months.

The total number of visits to alternative medicine providers increased from an estimated 427 million in 1990 to 629 million in 1997, according to the study. To put this in perspective, the researchers report an estimated 388 million total visits to primary care physicians in the United States in 1990, compared with 386 million in 1997.

"The number of visits per person did not change significantly — if anything, it decreased in 1997," Eisenberg says, "so these enormous increases have more to do with the overall increase in the overall population using alternative therapy or seeking professional services, as opposed to an increase in the number of visits per person." The 1997 survey found an average of 16 visits per person, compared to 19 per person in the 1990 study.

Spending for alternative medicine increased at least 45% over this period, according to Eisenberg. Expenditures for these services were "conservatively" placed at $21.2 billion in 1997, but the researchers said a "less conservative" estimate would place expenditures as high as $34 billion. More than half of this expense — $12.2 billion — was paid for out of pocket, a number that exceeded out-of-pocket expenses for all hospitalizations in 1997, the researchers noted.

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The study found that almost half of the 629 million visits were for chiropractors (192 million) and massage therapists (114 million). The other most commonly used therapies were herbal remedies and relaxation techniques. The therapies with the most significant increase in usage were relaxation techniques, herbal remedies, massage, spiritual healing, megavitamins, self-help, folk remedies, energy healing, and homeopathy.

Many of the 16 therapies that were examined are deemed "conventional or increasingly mainstream," Eisenberg says. But he adds that the six treatments considered as "more conventional therapies" — biofeedback, hypnosis, guided imagery, lifestyle, diet, relaxation response, and vitamin therapy — accounted for less than 10% of all visits in 1997.

The use of alternative therapies is not confined to any one segment of the population, the study reveals. Use of alternative therapies was significantly more common among women (48.9%) than men (37.8%) and less common among African-Americans (33.1%) than among other racial groups (44.5%).

"The baby boom population was found to use alternative therapy the most," Eisenberg says. Those ages 35 to 49 reported higher rates of use (50.1%) than those older (39.1%) or younger (41.8%). Use was higher among those with college educations (50.6%) than those without (36.4%) and more common among those with annual incomes above $50,000 (48.1%) than those with lower incomes (42.6%). Use was higher in Western states (50.1%) than elsewhere in the country (42.1%).

"In spite of all these dramatic increases in the reach of these alternative medical therapies," he says, "the number of patients that discuss these treatments with their medical physicians remains very low." The number of alternative therapies not discussed with a medical doctor in 1997 was 61%, relatively unchanged from the 60% of alternative therapies that were not discussed with medical doctors in 1990.

"Also troubling is the observation that as many 15 million adults who take prescription medications are also using herbs and high doses of vitamins," Eisenberg adds. "We do not know whether these herbs vitamins and prescriptions interact, so we raise the question of whether 15 million adults are at risk for dangerous interactions.

"The current status quo can easily be described as, 'Don't ask and don't tell,' and that is not in anybody's best interest. Physicians need to ask about their patients' use or interest in alternative therapy, and patients need to discuss this with their physicians."

The majority of alternative therapy in this country continues to be paid for out of pocket entirely, he says, adding that there was no significant change in this over seven years. Because the demand for alternative therapies depends on how much patients must pay out of pocket, he adds, current use is likely to under-represent usage patterns if insurance coverage for alternative medicine increases in the future. The researchers also found that 42% of alternative therapy use is attributed to the treatment of existing illness, while 58% is attributed to prevention and/or health maintenance.

The researchers surveyed 2,055 adults by telephone in 1997 and compared those data with the results of a 1990 telephone survey of 1,539 adults. The 1990 survey used a national random sample and had a response rate of 67%. The 1997 survey also used a national random sample and had a response rate of 60%. "We made no mention of the term 'alternative medicine,'" Eisenberg says. "It is not important to mention it, because patients don't see it that way."

An increasing number of U.S. insurance companies and managed care organizations now offer some alternative medicine programs and benefits, and the majority of U.S. medical schools now offer courses in alternative therapies. "In light of these observations," the authors conclude, "we suggest that federal agencies, private corporations, and foundations and academic institutions adopt a more proactive posture concerning the implementation of clinical and basic science research, the development of relevant educational curricula, credentialing and referral guidelines, improved quality control of dietary supplements, and the establishment of postmarket surveillance of drug-herb (and drug-supplement) interactions."

"When it comes to alternative therapies, the AMA has a common-sense message," says **Yank Coble**, MD, a trustee of the association who presented the AMA's position on this growing trend. "Either a therapy works and can be proven to work, or it's untested, unproven and risky."

The AMA's latest policies on alternative medicine were released as a result of an extensive 1997 Council on Scientific Affairs study, according to Coble. From this study, the AMA concluded: "There is little evidence to confirm the safety or efficacy of most alternative therapies.

Well-designed, stringently controlled research should be done to evaluate the efficacy of alternative therapies."

"Make no mistake, some alternative therapies and herbal remedies are quackery," Coble says. "They are unproven and ineffective. At best, they are a waste of time and money and, at worst, dangerous and even deadly. Sometimes the alternative therapy itself is dangerous, and other times the delay in getting a proven medicine proves deadly."

Coble adds that, given the growing public interest in alternative medicine as illustrated by the AMA statistics, "accurate, even-handed education about alternative medicine is vital." The bottom line, he says, "is that if standing on your head and rubbing your stomach can be scientifically proven to cure a person's ills without unacceptable side effects, then there is no reason why that technique cannot or should not be used by the patients and the physicians of America."

Coble notes that 94% of primary care physicians indicate a willingness to refer for at least one alternative therapy, according to a 1996 survey of referral patterns by board-certified family physicians and internists. The therapies most commonly mentioned, he says, were relaxation techniques, biofeedback, and therapeutic massage. "It is a mistake for patients to think a physician would automatically disapprove of a treatment outside the mainstream, but it is critical that care be coordinated," he says. "This can only be done if the physician is informed of other therapies being used." ■

Medication Error Update

ISMP, FDA launch labeling, education programs

The nonprofit Institute for Safe Medication Practices (ISMP) in Warminster, PA, and the FDA have unveiled new medication programs aimed at brand name labeling, patient education, and post-market surveillance. Backed by internal research showing that 25% of all medication errors result from "confusing or misleading naming, labeling, and packaging," says ISMP President **Michael Cohen**, MS, FASHP, the organization has developed a software program that can analyze and predict potential problems when new brand names come to market. The ISMP is offering this confidential service to pharmaceutical companies during marketing development. The ISMP is launching the program as a corporate subsidiary named the Medical Error Recognition and Revision Strategies (MED-ERRS) program. The computer program evaluates similarities between word pairs of proposed and existing brand names. In addition, software can be installed into hospital pharmacy systems that can flag similar drug names.

Cohen has consistently faulted drug makers for lacking the initiative to undertake this type of review on their own, and hopes the confidentiality of the MED-ERRS offer will prompt pharmaceutical companies to get involved. One spokesman for a large drug manufacturer responds, "Money is always a factor for our industry, and budgeting for these kinds of systematic or exhaustive reviews has always fallen off the books. If this program can be used efficiently and if it's coming from a nonprofit and can be confidential, I don't see why the industry can't take a look at it." A new FDA regulation taking effect June 1 demands the attention of drug makers on the issue of patient education.

The agency's *MedGuide* rule requires that patient information leaflets be supplied to dispensing pharmacists, and that pharmacists include them in prescription packaging. The FDA is defining which classes of drugs must be covered by the regulation, which will largely effect new drugs coming to market. Overall, the regulation will affect drugs carrying potentially serious adverse effects and when "serious risk-to-benefit

ratios" are present. The ruling also affects new and refill prescriptions. The agency will approve the content of the leaflets, and will allow manufacturers to supply the information to unit dose or bulk containers, which pharmacies must then adapt to individual patients.

The FDA has also announced the formation of a new regulatory Office of Post Marketing Drug Risk Assessment. The office will concentrate on designing post market approval studies, assessing the risks of new drugs, overseeing manufacturers' observational studies, and dealing with post-marketing errors.

For more information, contact ISMP at (301) 497-2375, and the FDA's Office of Drug Standards at (301) 594-5443. ■

Computer systems fail to spot harmful interactions

ISMP surveys error alerts

Computer software integrated into hospital pharmacy systems to flag potential medication errors failed by a wide margin to detect a sample of 10 error-types in a field survey of 307 hospital systems conducted by the Institute for Safe Medication Practices. The ISMP used errors that had been previously reported to its Medication Errors Reporting Program as the way to test computer programs, covering aspects such as potentially harmful drug interactions, labeling concerns, and dosage alerts.

Overall the field survey found that only four of the 307 systems tested caught potential problems with all 10 medication orders. The survey found that a variety of computer system vendors are being used in hospital pharmacies, including (in descending order of frequency) HBOC, Meditec, Cerner, SMS, Pharmacon, and Digimedics, as well as drug information providers such as First Data Bank, Medispan, and Medicom. (Overall the survey found no discernible differences among the systems and did not evaluate or rank them as part of the survey.) In other words, all of the systems equally flagged, or failed to flag, the same types or number of potential error alerts.

The survey found that 87% of the systems failed to detect toxic doses of antibiotics for patients with renal impairment; 87% did not detect single or cumulative lethal doses of colchicine; 65% did not detect potentially toxic drug ingredient duplication with acetaminophen and Percocet; 62% did not detect lethal overdoses of cisplatin or vincristine; 61% did not flag an order when an oral suspension was ordered for IV use; and 58% did not link pharmacies and labs.

"It's frightening to believe that the vast majority of pharmacy computer systems may be incapable of preventing lethal errors," says ISMP president **Michael Cohen**, who stresses that computer systems cannot be blindly relied upon.

The institute historically has recommended hospitals install systems that allow for routine manual updating of new error alerts, and that systems should be installed that can be tailored to specific types of alerts matched with the medicine being practiced by an institution or to errors commonly unique to an institution.

The survey did find that 54% of the hospitals, which voluntarily agreed to be part of the testing, do integrate drug information updates into their systems at least quarterly.

And not all of the survey results were bad. Of the systems tested, 88% did detect a ketorolac-aspirin cross allergy; 85% detected interactions between ketoconazole and cisapride; and 69% of the systems do provide for updated inclusion of specific medication alerts.

Complete survey results can be found at http://www.ismp.org. ■

HIV research highlights conference on infections

A new protease inhibitor for pediatric therapy, drugs for resistant HIV strains, and combination therapy aimed at reduced drug regimens were announced at the 6th Conference on Retroviruses and Opportunistic Infections held in February in Chicago.

Phase III trials of the protease inhibitor Agenerase (amprenavir) combined with two nucleoside reverse transcriptase inhibitors (NRTIs) reduced viral load to below 400 copies in 15 of

37 pediatric patients at eight weeks, according to research presented by manufacturer Glaxo Wellcome. The drug has been formulated as a twice daily dosage, and proved equally successful when given in 50 mg tablets or as an oral solution. If approved for marketing, the protease inhibitor would join two others approved for children now on the market. Side effects from trials included nausea, diarrhea, rash, oral paresthesia, and headache.

Preliminary NNRTI results presented

Glaxo also submitted research on the drug's preliminary ability to reduce HIV levels in seminal fluid when taken as a monotherapy or in combination with NRTIs, findings the company will pursue in terms of anti-resistance therapy and transmission prevention.

Also submitted at the conference were preliminary study results on a pair of investigational non-nucleoside reverse transcriptase inhibitors (NNRTIs) and their activity against strains of HIV proving resistant to NNRTI therapy, presented by DuPont Pharmaceuticals.

Activity has been found in vitro when compared to existing NNRTIs, according to DuPont, when tested against five mutated viruses. Simian research has shown a half-life of the drug of between 20 and 76 hours at a 2 mg/kg dose, making researchers hopeful that a once daily dose could be produced as human trials are pursued.

And finally, GCI Healthcare/Roxane presented research it says shows that therapy using nucleoside analogues, specifically ddI and d4T, as a base treatment, then combined with either an NNRTI, 3TC, or protease inhibitor as the third combination element, produce equally effective treatment results in terms of plasma loads.

The company pursued the research to show that its NNRTI Viramune (nevirapine), already on the market, could be a successful substitute for protease inhibitors in terms of decreasing the number of drugs needed in a therapeutic regimen.

The study included the protease inhibitor indinavir, which, when taken as part of the combination therapy described above, totals 12 pills three times a day. By substituting the NNRTI, the regimen fell to eight pills twice daily, according to the submitted research. Comparable plasma loads were detected during randomized trials of 298 patients. ■

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