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Government pumping up research in alternative medicines, therapies

A *Nutraceutical Business Report* Staff Report

As its revenues balloon ever higher, alternative medicine is attracting more attention – and wanting more respect. Traditional medicine – watching this phenomenon and fearing the competition – is demanding that alternative medicine do more research to get that respect.

Amid the clamor of competing voices, these demands are turning out to be beneficial to both sides. They have improved the chances for integrating the two medical styles and, in more specific terms, they are working to broaden the already vast pharmaceutical research market with new funds. And while the private sector is putting increasing efforts into research, the public sector's growing interest in the industry is bringing both millions in funding and new validity for nutraceuticals in general.

The clearest evidence of this comes from a series of recent new initiatives, ranging from selection of the first permanent head of the National Center for Complementary and Alternative Medicine (NCCAM; see story, p. 3) to the establishment of new centers for research into alternative therapies and new monies to study specific dietary products. And all of the projects are being carried out by some of the most prestigious medical research organizations in the nation.

Dietary Supplements Research Centers launched

The launch of the first Dietary Supplements Research Centers devoted to studying botanicals has just been announced by the National Institutes of Health's (NIH) Office of Dietary Supplements (ODS) in collaboration with NCCAM. Initial awards of $1.5 million per year, for five years, will go to the University of California at Los Angeles (UCLA) and the University of Illinois at Chicago (UIC).

The ODS said in a statement that the new centers "are expected to greatly advance the scientific base of knowledge about botanicals." To address these issues, Congress appropriated additional funds for the ODS in fiscal year 1999 to develop these botanical centers "with major research institutions across the nation."

The research is intended to be interdisciplinary, according to the ODS, and will be designed to identify "potential health benefits and to develop a systematic evaluation of the safety and effectiveness of botanicals, particularly those available as dietary supplements."

The UCLA Center for Dietary Supplements Research on Botanicals will conduct basic and clinical research to explore the potential mechanisms of action of yeast-fermented rice for cholesterol reduction with implications for heart disease prevention, and

Please see GOVERNMENT, page 2

What's Inside

GOVERNMENT

Continued from page 1

green tea extract and soy for inhibition of tumor growth with implications for the treatment of cancer. The center additionally will conduct research on St. John's wort in the treatment of "mild depression," and it will also assess the levels of bioactive compounds in several other botanicals being used as dietary supplements. Its activities will be directed by Dr. David Heber.

The research center at UIC initially will focus on studying 10 herbal supplements described as having "implications" for benefit in women's health issues, including therapies for menopause. Besides conducting basic and clinical research, the UIC group is to support research training in the study of natural products, primarily plants – technically known as pharmacognosy. The UIC group also will provide information on botanicals to consumers and health professionals, with its educational activities to include an interactive web site. The UIC center will be headed by Dr. Norman Farnsworth.

Establishment of the two centers is part of the mission to carry out specific scientific goals outlined in NIH's strategic plan. Besides receiving funding from ODS and NCCAM, the Office of Research on Women's Health and the National Institute of General Medical Sciences are contributing funding to this project.

Aging: a 21st century market driver

Besides the need for validation, NIH's new emphasis on supplements research is being driven by a clear and very pressing demographic trends. These trends are the graying of the world's populations and the growing incidence of associated disorders – especially those of a psychological nature. Looming over the horizon of the new millennium is the pressing need to find treatments with fewer side effects than traditional pharmaceuticals. Thus, NCCAM and the National Institute of Aging (another arm of the NIH) have just announced a multicenter study to test the use of *ginkgo biloba* on older individuals who are at risk for dementia. A six-year, $15 million grant will go to The University of Pittsburgh School of Medicine to coordinate a multicenter study, to be headed by Steven Kosky, MD, professor of psychiatry, neurology and neurobiology, and director of the Alzheimer's Disease Research Center at the medical school.

The clinical centers are a prestigious group: Johns Hopkins School of Medicine's department of radiology; the Alzheimer's Disease Research Center at the University of Pittsburgh School of Medicine; the University of California, Davis; and the Wake Forest University School of Medicine.

The study will enroll a total of 2,000 participants randomly assigned to one of two groups. Primary endpoint of the study will be the onset of any type of dementia, with the secondary endpoint being changes in cognitive function. One group of study participants will be given 240 milligrams of *ginkgo biloba* and will be compared to a second group given a placebo. Study participants, numbering up to 1,500 will be recruited from current participants in a cardiovascular health study who made a clinic visit in 1998-99.

In Asia, standardized extracts from *ginkgo* leaves have been routinely used to treat a wide range of symptoms, including Alzheimer's disease, but there is "no evidence," according to an NIH statement, to validate its use in either prevent or cure this disease. The study also may help identify and standardize the active ingredients of the plant and examine reported side effects.

Arthritic knees, aching backs

NCCAM also announced in mid-September that it would collaborate with another NIH component, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, to study the use of glucosamine and chondroitin sulfate to treat knee osteoarthritis (OA), another problem driven by the aging process. The University of Utah School of Medicine (Salt Lake City) will receive a $6.6 million, four-year grant to conduct a nine-center study of this application in 1,000 participants. Glucosamine and chondroitin sulfate are natural supplements that are receiving increasing publicity for treatment of OA and, according to Harlan, "Providing solid evidence on the benefits and safety of this treatment may help expand health care options for patients challenged with this condition."

Back pain, afflicting all age groups, is the focus of another study recently announced by the NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). This study will compare surgical against non-surgical treatment of three back disorders in 1,450 patients at 11 medical centers. The project, according to NIH, may have "a major impact on clinical practice and on the cost of medical services" related to three back disorders: herniated lumbar disc; spinal stenosis, or narrowing of the canal through which the spinal cord passes; and degenerative spondylolisthesis, where a vertebra in the spine slips forward out of place.

Judi Forman, NIH project coordinator told *NBR* that the study will examine the use of supplements and other alternative medications, along with the full range of non-surgical treatments available to physicians.

The five-year, $13.5 million study will be directed by James Weinstein, DO, professor in the department of community and family medicine, Center for the Evaluative Clinical Sciences, and professor of surgery at Dartmouth Medical School. Participating centers include: Case Western Reserve University (Cleveland, Ohio), Dartmouth Medical School (Hanover, New Hampshire), Emory Spine Center (Decatur, Georgia),

the Hospital for Special Surgery (New York), Rothman Institute (Philadelphia, Pennsylvania), Nebraska Spine Surgeons, PC (Omaha, Nebraska), Rush-Presbyterian-St. Luke Medical Center (Chicago), University of California (San Francisco), The Hospital for Joint Diseases (New York), Washington University (St. Louis, Missouri) and William Beaumont Hospital (Royal Oak, Michigan).

Dr. Stephen Katz, director of the NIAMS, said, "Based on this trial, we shall, for the first time, have scientific evidence regarding the relative effectiveness of surgical versus non-surgical treatment of these commonly diagnosed lumbar spine conditions."

The NIH Office of Research on Women's Health and the National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention are also contributing funding for the study.

New emphasis

Perhaps the most far-reaching and innovative initiative launched by the NIH, however, is the recent funding of five centers to study "mind-body interactions and health." While these centers will not be looking specifically at the use of medications, the thrust of the studies clearly will promote the importance of alternative strategies in health and healing.

The centers, according to an NIH statement, "will focus on research that seeks to understand how beliefs, attitudes, values and stress affect physical and mental health . . . [and] how beliefs, attitudes, and values that affect health are developed, maintained, and changed."

The initiative also appears to suggest broad underlying support for looking at alternative healing since the effort is driven by a congressional mandate. The Office of Behavioral and Social Sciences Research (OBSSR) was directed to lead efforts at the NIH to develop a mind-body initiative, and 12 NIH institutes are cosponsoring the initiative.

The five centers include the department of psychiatry and Carnegie Mellon Humanities and Social Sciences department of psychology at the University of Pittsburgh Medical Center (Pittsburgh, Pennsylvania); the department of epidemiology at the University of Michigan School of Public Health (Ann Arbor, Michigan); the department of psychology at the University of Wisconsin (Madison, Wisconsin); the department of psychology at the University of Miami (Coral Gables, Florida); and the department of microbiology and immunology at the College of medicine and Public Health at Ohio State University (Columbus, Ohio).

"These new research centers," according to Dr. Norman Anderson, Director of the OBSSR, "represent innovations in the integration of behavioral, social, and biomedical research. It is hoped that the findings they produce will accelerate our understanding of mind/body interactions, and lead to more effective approaches for the treatment and prevention of disease."

First NCCAM director named at NIH

Stephen Straus, MD, has been named as the first director for the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH). In announcing the appointment, Health and Human Services Director Donna Shalala called Strauss a "nationally and internationally recognized expert in clinical research and clinical trials." Since 1991 he has served as the chief for the Laboratory of Clinical Investigation at NIH's National Institute of Allergy and Infectious Diseases (NIAID).

"Dr. Straus brings exceptional expertise and leadership to this position and will continue to ensure high-quality complementary and alternative medicine treatments and modalities," Shalala said. "I look forward to the light he and his colleagues will shed on various alternative approaches to maintaining good health and treating disease."

"The American public is increasingly interested in complementary and alternative therapies, and it is critical that NIH put its scientific expertise to work to help determine which therapies are safe and effective," said Harold Varmus, MD, director of NIH. "The appointment of Dr. Straus, with his experience in alternative therapies and his expertise in clinical evidence, will result in significant expansion of clinical research in this field. He brings to this position a clear sense of leadership, strong management and organizational expertise, and superb communications skills."

Straus has broad basic and clinical research experience related to many diseases for which there are alternative remedies, including chronic fatigue syndrome (CFS), Lyme disease, AIDS/HIV, chronic hepatitis B virus and genital herpes infections and chronic post-herpetic pain. He is known for his wide-ranging studies involving patients with CFS, which began in 1979, before the syndrome was named. These studies ranged from efforts to identify viral etiologies in the syndrome to his more recent immunologic, neuroendocrine and neuropsychologic studies of the disorder. He also has a strong background in investigations of the molecular biology, pathogenesis, treatment and prevention of human viral infections.

Straus received his medical degree from the Columbia University College of Physicians and Surgeons. After his internship at Barnes Hospital in St. Louis, Mo., Straus' first NIH experience began in 1973, when he accepted a research associate position in NIAID's Laboratory of the Biology of Viruses. Returning to Barnes for his residency, he earned a fellowship in infectious diseases at St. Louis Washington University, which he completed before he returned to NIAID as a senior investigator.

William Harlan, MD, has been serving as acting director of NCCAM, and will return to his position as director of the NIH Office of Disease Prevention.

Frutarom acquires Baltimore Spice in move to expand

By RAE FISHMAN
***NBR* Correspondent**

HAIFA, Israel – Frutarom, Israel's leading flavor and fragrance manufacturer, valued at about $31.2 million, is actively seeking to raise its annual turnover from about $75 million to $300 million by the year 2005.

A producer of raw materials, seasoning mixtures, aroma chemicals and flavorings for the food, beverage, cosmetics, detergents, specialty chemicals and pharmaceuticals industries, the company in late September acquired full ownership of Baltimore Spice Israel Ltd. (Acre) for $3 million in cash and a pledge to release Baltimore's former owners from guarantees worth $2.5 million. Baltimore's annual sales are estimated at from $5 million to $6 million.

Ori Yehudai, Frutarom's president and chief executive, said that "Buying Baltimore, which has been developing new products for some 21 years, will bolster the company's research and development infrastructure and bring a new range of technological know-how, which will immediately benefit Frutarom's subsidiaries in Russia, Turkey and China."

Baltimore's products are expected to meld with Frutarom's compounds division, its most profitable activity, anticipated to eventually contribute 60% of the company's gross profit. Frutarom plans to boost its raw materials division's profitability by launching several new products for the fragrance, food, and pharma-cosmetics-sunscreen industries.

Yehudai says Frutarom is considering further acquisitions of foreign companies "to reach a critical mass" and to expand into markets such as Turkey and China, where the company can enjoy a relative advantage compared with rival multinationals.

The Botanicare activity of Frutarom's fully owned American subsidiary, Frutarom Incorporated Botanicare, a natural products manufacturer located in New Jersey, is another focus of increased activity.

The American market for nutraceuticals – or for drugs based on natural herbal ingredients – is estimated at $3.5 billion to $4 billion a year. Botanicare is targeting a market estimated at $500 to $600 million a year.

Frutarom ended the second quarter of 1999 with a net profit of $963,000 on turnover of $18.1 million, a relative decline from $1.2 million on turnover of $19.3 million in 2Q98, in part due to Botanicare's lowered profits due to an overstock of kava-kava, marketed as a natural tranquilizer.

Personnel File

• Janice Thompson, PhD, has been named president and CEO of **Ancile Pharmaceuticals** (San Diego, California), developer of botanical drugs for the prescription and self-medication markets. Thompson, a natural products expert, has been vice president, scientific affairs at Ancile since its founding in February 1998. In her new posts, she succeeds Kevin Kinsella, who had held those positions since co-founding the company. He will remain as board chairman.

• David Lumley has been named president and CEO of **Experimental and Applied Sciences** (EAS; Golden, Colorado), a distributor of sports nutritional supplements. Lumley replaces EAS founder Bill Phillips, who has been CEO since the company's inception. Phillips takes on the new position of director of Value Creation and he remains a member of the EAS board of directors. Prior to joining EAS, Lumley was president of Brunswick Bicycles.

• Susan Alpert, PhD, MD, has been appointed director of food safety at the **Food and Drug Administration**'s **Center for Food Safety and Applied Nutrition**, effective Oct. 25. Alpert has been with the FDA since 1987, and currently serves as director of the Office of Device Evaluation at the agency's Center for Devices and Radiological Health. She previously held the position of supervisory medical officer in the FDA's Center for Drug Evaluation and Research.

• Robert Burgess has announced his retirement as president/chief operating officer of **PharmaPrint** (Irvine, California), a developer of pharmaceuticals and dietary supplements from natural plant extracts. Elliott Friedman, PharmaPrint's chairman and CEO, said that a search is under way for a successor to Burgess, and that the company hopes to announce the successor within the coming weeks. PharmaPrint develops, manufactures and markets pharmaceuticals and dietary supplements derived from natural plant extracts.

• Roger Williams, MD, has been named executive vice president and chief executive officer-designate of the **United States Pharmacopeia Convention** (USP; Rockville, Maryland), effective Jan. 4, 2000. Williams will succeed Jerome Halperin, who has announced his intention to resign. Williams will officially assume all responsibilities of the position on April 16, 2000, at USP's quinquennial meeting. Williams comes to USP after nine years with the U.S. Food and Drug Administration's Center for Drug Evaluation and Research.

Market Updates

Herbal supplements nearing saturation?

The consulting group ExperTeam (Irvine, California) has issued a report indicating that saturation of the market for herbal supplements is not too far away. That market "has been growing at an annual rate of 25% to $4 billion," according to Herbert Loveless, a health care analyst with the group, adding that this market sector "is reaching its inflection point and will likely peak at $6 to $8 billion in two to three years." He estimated the "comparable market" in Europe at about $6 billion. He noted that herbals have reached perhaps greatest acceptance in Germany which has a formal regulatory process and where they have long been an accepted part of German medical practice. "It's difficult to imagine the U.S. herbal market will markedly outperform such a mature market as Europe's," according to the ExperTeam report. Loveless also predicted a plateau in generic drugs "with 8% of the $80 billion U.S. retail pharmaceutical market." Loveless said that there has been a trend for many supplement companies "to go the new drug application route in order to penetrate the prescription market. However, both Shaman and Pharmanex have abandoned this strategy. Funding, patentability and competition from dietary supplements have proven difficult problems to overcome."

"The supplement industry's only hope for continued growth is new federal legislation that will establish a separate track for herbal medications that will give some type of exclusivity," Loveless said. "Unfortunately, ephedra, a stimulant in many herbal preparations, is an example of how serious problems are between the agency and the industry. . . . The needed legislation will be extremely complex, and virtually impossible to enact without some degree of agency cooperation. It's difficult to see how any scenario can be worked out in the near to medium term."

Dr. Atkins criticizes AHA drug focus

In the wake of the recent Fall Conference and Scientific Sessions of the Council for High Blood Pressure, held in Orlando, Florida, Robert Atkins, MD, developer of the well-known Atkins Diet, criticized the gathering for "ignoring the increasing success of diet and nutritional supplementation when treating high blood pressure patients." Physicians continue to focus on drug treatments for heart disease, but drugs, "merely mask symptoms," according to Atkins, a trained cardiologist and founder of The Atkins Center for Complementary Medicine. "Most cardiovascular drugs not only fail to deal with heart problems like hardening of the arteries, but in some cases compound those problems, exposing people to even greater perils."

Atkins reports that his center has produced an 85% success rate in treating hypertension patients and weaning them from medications, using a combination of low-carbohydrate diet and a protocol emphasizing nutritional supplements. A combination of "mainstream" and alternative techniques "helps personalize medical treatment and provide the most effective solution for each patient," according to a statement from the Atkins Center. "The Atkins Diet is a key treatment component in reducing hypertension. A high-protein, low-carbohydrate diet, paired with nutritional supplementation, can be helpful in normalizing blood sugar, promoting weight loss and reducing other cardiovascular risk factors associated with this condition," says Patrick Fratellone, MD, head of cardiology at The Atkins Center. "Nothing is more consistently and rapidly observed on the Atkins Diet than the normalization of blood pressure,"

The Atkins Center physicians also use chelation therapy, a non-surgical process for removing harmful metals from the body and helping to restore blood flow. Chelation therapy intravenously administers a mixture of vitamins and minerals, called ethylene diaminetetra-acetic acid, which helps improve calcium and cholesterol metabolism. Another treatment option used at the center is personalized nutritional supplementation, which includes a broad base of vitamins and supplements.

Naturopathic licensing sought in California

The California Association of Naturopathic Physicians (CANP; San Francisco) recently launched a campaign for licensing of naturopathic doctors in that state. "California has long held the image of the bellwether for the country. Yet the state is seriously lagging in providing qualified naturopathic health care to consumers," said CANP President David Field, ND, LAc. "Licensing will allow consumers to select from a broader range of responsible health care professionals," Field said. "Patients deserve qualified, competent, safe choices for their personal health care. California has fallen behind the rest of the country in this area, and the state's residents face a major dilemma when they seek natural health care."

Naturopathic medicine emphasizes use of both time-tested and newer natural treatments, according to the CANP. These include clinical nutrition, botanical medicine, homeopathic medicine, physical medicine and lifestyle counseling. Naturopathic physicians are graduates of four-year accredited naturopathic medical schools recognized by the U.S. Department of Education. Like MDs, they study basic sciences for the first two years, but they then focus for the next two years on the use of natural therapeutics.

Sally LaMont, ND, LAc and vice president of the CANP, called Californians among "the most savvy health care consumers in the nation." But, she said that in order to natural treatment, "they have to piece together information from what they read or hear on a hit-or-miss basis. That's because California is one of the only Western states that has not yet licensed naturopathic physicians."

Naturopathic physicians are currently licensed in Arizona, Oregon, Washington, Alaska, Hawaii, Utah, Montana, Connecticut, New Hampshire, Vermont and Maine. The requirements for licensure in those states include: Graduating from a four-year postgraduate naturopathic medical school; passing a comprehensive state naturopathic board exam; maintaining a requisite number of Continuing Education credits; and adhering to codes of ethics and conduct.

CANP's parent organization is the American Association of Naturopathic Physicians. Recently, two licensed naturopathic physicians were appointed to the Complementary Alternative Medicine Program Advisory Council at the National Institute of Health by the Secretary of the U.S. Department of Health and Human Services.

Alternatives get heavy use for arthritis sufferers

A new study indicates that many people with arthritis use alternative medicines to treat their problem, and that the number is larger than generally estimated. Additionally, the study suggests that more of these people are discussing with their doctors the alternatives they are using, and they generally have little concern about their physicians disapproving of the practice. Dr. Jaya Rao is lead author of the study, published in the Sept. 21 *Annals of Internal Medicine*, which surveyed more than 200 arthritis patients in Indianapolis, Indiana. Rao reported that 56% of those surveyed were using some form of alternative medication, a finding he said that "most surprised us." Another surprise: 24% were using more than one form of alternative treatment.

Of those who did not tell their doctor about the alternative treatments, only 15% said they failed to do so because they feared the doctor would disapprove; 55% said the doctor did not ask, and 49% said they meant to tell the doctor but forgot. Among those who did tell their doctor about using alternative medication, 71% said their doctors told them it was acceptable to keep using the alternative treatments, while 14% said their doctors told them to stop.

Among one of the more interesting findings of the study was that college-educated patients were more likely to use alternative treatments than those without degrees.

Rao's study examined 232 patients who saw rheumatologists at six different clinical settings that were varied in type. The study did not examine the attitudes of people who rely exclusively on alternative healing and avoid physicians altogether.

Focus on Foods

Pharmanex, Purdue to research green tea as a cancer fighter

Pharmanex (San Francisco) said that it has formed a research collaboration with Purdue University to explore the possible therapeutic effects of green tea in relation to cancer. Pharmanex produces Tegreen 97 (pronounced "tea green"), an extract of green tea, which will be used in the study as a standardized, caffeine-free source of catechins. The study is being led by cancer researchers Dorothy Morre and D. James Morre. "Bringing together the talents and resources of Purdue and Pharmanex in this joint study is very exciting," said Dr. Dorothy Morre, professor of foods and nutrition in Purdue's School of Consumer and Family Sciences. "We have a vital interest in green tea research and this further exploration will hopefully bring us closer to validating a link." Bill McGlashan, Jr., president of Pharmanex, said, "The Morres' earlier findings on green tea have given us tantalizing clues. We are pleased that the standardized qualities of our green tea extract may help provide additional answers in the areas of cancer prevention and treatment."

Scientists from Pharmanex will be involved in the study on a consulting basis. The collaboration builds on earlier research reported last year at the 38th annual meeting of the American Society for Cell Biology in San Francisco. That laboratory study revealed how biologically relevant concentrations of epigallocatechin gallate (EGCg), the key catechin found naturally in green tea, effectively slowed the growth of tNOX, an overactive form of quinol oxidase (NOX). The Morre's earlier research has suggested that NOX – an enzyme expressed on the surface of cancer cells – facilitates aggressive cell multiplication, linking tNOX to tumor growth and development. The collaborative study with Tegreen 97 will try to define whether a consistent level of EGCg and related catechins delivered to cancer cells will achieve an anticancer effect.

Another antioxidant source: Kiwifruit

A new report from the California Kiwifruit Commission (Sacramento, California) is promoting the benefits of kiwifruit, particular as an excellent source of antioxidants including lutein and vitamins E and C. Lutein is a phytochemical found in both green

fruits and leafy greens, and it has been credited as an antioxidant in reducing the risk of cancer and heart disease, and in protecting against age-related macular degeneration, the leading cause of legal blindness in people over age 65. A serving of kiwifruit contains about twice as much vitamin C (250 milligrams) as an orange and more than twice the recommended vitamin C daily intake. As reported in the *Journal of the National Cancer Institute*, male smokers aged 50 to 69 who consumed vitamin E achieved a 32% decrease in the incidence of prostate cancer and a 41% decrease in deaths compared to men not taking vitamin E. Kiwifruit also contains copper, a critical mineral for bone growth and brain development in children.

Maureen Ternus, MS, RD, said that kiwifruit may be one of the best food sources for good health at all stages of the life cycle. "They should be front and center in consumers' minds as they choose winter fruits," Ternus said. California kiwifruit represents 95% of all kiwifruit grown in the U.S., with peak season for California's kiwifruit crop from October through March.

Ocean Spray pushing cranberries

Ocean Spray (Lakeville-Middleboro, Massachusetts) is perhaps the best-known brand in cranberries, but the company is pumping up its marketing efforts even further with an increasing focus on the berry's nutritional properties. "There's more and more evidence that women and families are looking for healthy products that give them great taste and refreshment," said Don Hattoon, Ocean Spray's board chairman. "That's exactly what Ocean Spray and cranberry is known for. We're going after the untapped potential in the market with a full slate of promotional programs and new advertising as part of one of the most aggressive marketing campaigns we've ever executed." The company will reportedly spend up to $100 million this year in its promotional efforts, focusing much of that effort on various new products it recently has rolled out.

The company recently rolled out its Cranberry Juice Cocktail PLUS, calling it a "supercharged" juice that contains 130% of the recommended daily requirement of vitamin C, plus vitamins A and E and calcium. The company also in May renamed its line of 100% juices as Ocean Spray premium 100% Juices to emphasize their healthful value. Additionally, it added two flavors to the line: cranberry and concord grape, and cranberry and Pacific raspberry. The company's marketing efforts could be bolstered by two years of cranberry surplus and what is estimated to be a bumper crop in year 2000.

Beta-carotene benefits downgraded

New research by a team at Brigham and Women's Hospital and Harvard Medical School (Boston) indicates that taking supplements of beta-carotene taken every other day does not reduce a man's risk of developing type 2 diabetes. Beta-carotene is found frequently in orange and yellow fruits and vegetables and some green vegetables and, once consumed, converts to vitamin A. The study, headed by Dr. Simin Liu and conducted over 12 years, would appear to contradict previous research indicating that beta-carotene can fight off non-insulin-dependent diabetes. Researchers followed more than 20,000 men who took either a 50 milligram supplement of beta-carotene or a placebo pill over the 12-year period. In the beta-carotene group 396 men developed type 2 diabetes, compared to 402 in the placebo group, a difference with no statistical significance. In an interview, Liu told Reuters that the study showed "no effect, either beneficial or harmful." Despite this conclusion, Lieu did not rule out the ability of other compounds in fruits and vegetables to protect against diabetes. "Vitamin E and other types of carotenoids may play a role," he said. "we still need to evaluate their efficacy."

Sorbitol warning sought

The Center for Science in the Public Interest (CSPI; Washington) has petitioned the FDA to beef up the existing warning label on processed foods that contain the sugar substitute sorbitol, a sweet-tasting sugar alcohol product. Sorbitol is used in many sugar-free or "dietetic" candies, cake mixes, syrups, and other foods, as well as in some medicines. Because it is poorly absorbed by the body, it provides fewer calories than regular sugars. However, CSPI says that studies have proven that sorbitol can cause gastrointestinal symptoms ranging from mild discomfort to severe diarrhea when adults consume 10 grams to 50 grams of the additive. Children may be affected by even smaller amounts, according to the CSPI. Currently, the FDA requires a laxative notice only on the few products that may lead to the consumption of 50 grams or more of sorbitol daily, though some companies voluntarily label additional products.

"The FDA should require a better label notice on sorbitol-containing products," said Michael Jacobson, PhD, executive director of CSPI. "The FDA has known for years that sorbitol can cause severe diarrhea. It's high time that the agency required a strong label notice on all products that might cause problems."

The group said that the warning was especially important before Halloween because so many candies contain sorbitol. CSPI recommends that the labels state: "NOTICE: This product contains sorbitol, which may cause diarrhea, bloating, and abdominal pain. Not suitable for consumption by children. To protect yourself, start by eating no more than one serving at a time."

Supplement News

B vitamin family making headlines

Recent news has highlighted the varied and important roles of certain members of the B family of vitamins. These products range from folic acid, which is essential for cell growth and reproduction – and which has until now been most publicized for its role in preventing neural tube birth defects – to B6, which aids in the formation of many amino acids and several neurotransmitters, and which now has been shown to reduce nausea and vomiting in pregnancy.

A study funded by the FDA's Office of Women's Health has found that increasing folate, or folic acid, levels in women prior to conception may reduce the incidence of Down's syndrome, a genetic disorder that combines mental retardation with physical abnormalities. The study, published in the *American Journal of Clinical Nutrition*, found that mothers of babies with Down's syndrome often have the same genetic abnormality in folate metabolism as that associated with the neural tube birth defect spina bifida, according to a statement from the Public Information Committee for the American Society for Nutritional Sciences and the American Society for Clinical Nutrition. Mothers with the abnormality were 2.6 times more likely to have a child with Down's syndrome than mothers without the genetic defect, the study found.

Researchers for the University of Maryland (Baltimore) measured levels of homocysteine in the blood of 167 women aged 15 to 44 who had suffered a stroke, and also in 328 stroke-free controls. After factors known to affects stroke risk, such as cigarette smoking and socieoeconomic status, had been accounted for, women with the highest blood levels of homocysteine were 60% more likely to suffer a stroke than those with the lowest levels, the study showed.

The report may indicate important opportunities for nutritional intervention, since folic acid and other B vitamins are believed to lower blood levels of homocysteine. The next step is to embark on a study to see if stroke can be prevented with high doses of B vitamins, said Dr. Steven Kittner, the study's lead researcher and professor of neurology, epidemiology and preventive medicine at the University of Maryland School of Medicine.

Another study, presented recently at the 68th annual meeting of the Royal College of Physicians and Surgeons of Canada, found still more good news related to B family intake, this time specifically with B6. The research suggested that taking a multivitamin containing at least 10 milligrams of the vitamin before and after conception may help reduce the severity of nausea and vomiting during pregnancy. Dr. Svetlana Emelianova and colleagues from the Motherisk Program at the Hospital for Sick Children (Toronto, Ontario, Canada) conducted the study.

Nandrolone still IOC-banned

The heads of 27 International Olympic Committee (IOC)-accredited "doping" laboratories said after their annual meeting recently that they had reaffirmed that the anabolic steroid nandrolone will remain on the IOC's list of banned substances, and urged governments to ban the sale, manufacture and imports of nutritional supplements that could contain banned substances. Several British athletes, including former world and Olympic sprint champion Linford Christie, have tested positive for nandrolone but have been cleared by the UK Athletics governing body of taking performance-enhancing drugs. Several athletes have questioned the reliability of drug testing, particularly for nandrolone. The lab chiefs, however, are standing behind the effectiveness of the methods used to detect nandrolone. "The use of anabolic steroids and related substances is prohibited by the IOC. Nandrolone and the related substances norandrostenedione and norandrostenediol are specifically included in the list of prohibited substances," the laboratory heads said. The British sports body is reportedly on a collision course with the International Amateur Athletics Federation, the sport's world governing body, over the nandrolone issue.

The lab chiefs also called on all governments to clamp down on nutritional supplements that some experts say may contain substances that produce or promote nandrolone "whether labeled or not."

Extracts improve cholesterol levels

Results from recent studies in the U.S. and Australia show extracts from rice bran and red clover extract may prove to be new ammunition in the battle to keep cholesterol LDL levels low and HDL levels high. A study at the K. L. Jordan Heart Research Foundation (Montclair, New Jersey) demonstrated that tocotrienol-rich vitamin E extracted from rice bran oil has been found to improve significantly total cholesterol levels in patients with high cholesterol. The extract reduced total cholesterol 14.1% and LDL, or "bad," cholesterol by 20.6%. It also raised HDL, or "good," cholesterol and lowered triglyceride levels. The researchers additionally saw a substantial reduction in TBARS, a test that measures oxidation. The findings were published in September in the *Journal of Environmental and Nutritional Interactions*. "Dietary change has met with limited success, and many pharmaceuticals, although effective in modulating cholesterol levels, are fraught with negative side effects. The tocotrienol-rich extract from rice bran oil appears to offer a safe and effective way to improve the cholesterol profile and reduce the risk of coronary heart disease," said cardiologist Marvin Bierenbaum, director of the K. L. Jordan foundation.

Business Developments

Kellogg is seeking EU harmonization on 'fortified foods'

Kellogg Co. (Battle Creek, Michigan), a producer of vitamin-fortified foods for more than 50 years, has called for harmonized European rules on fortified foods, saying disparate national laws create an unfair barrier to trade in Europe's single market. The company said it wants to take "a leading role" in the effort to standardize laws in the 15-nation European Union (EU) to allow manufacturers to sell their products without facing varying restrictions from country to country. Because standards are so different within the EU, it has been forced to tailor its recipes to individual markets, according to Kellogg. The wide variations are both complex and unnecessary, according to Anne-Laure Gassin, the company's nutrition affairs manager for Europe. "We're here to satisfy consumer needs and we want the ability to be able to add nutrients to foods in our markets and let the consumer choose," Gassin said in an interview with Reuters news services.

Reuters reported that the European Commission is due to decide later this month whether to take the Dutch government to the European Court of Justice after Kellogg complained its ban on breakfast cereals fortified with folic acid, vitamin D and zinc was an illegal trade barrier. Gissin said restrictions such as this get in the way of innovation because it blocks marketing of a "common brand profile" across the entire European area. "Our underlying philosophy is that we've been adding nutrients to foods for decades now because we believe it adds nutritional value to the products and that's been confirmed by science."

Gissin chairs a committee within the Confederation of the Food and Drink Industry of the EU, that committee lobbying for the unified vitamin standards. Currently those standards range from highly restrictive – in the Nordic countries – to extremely liberal – in Britain and Ireland. Gissin noted that attempts to get approval for mutual recognition of standards among these countries has failed and so a single standard is required. She said that in order to achieve that single standard, the food industry would be willing to consider "maximum levels" of nutrients to satisfy those EU member states with the most stringent standards.

Metabolife on the offensive

Rather than waiting for what it expects to be negative publicity, Metabolife launched a PR offensive this month, criticizing a television report on its product before the piece aired. Metabolife International (San Diego) posted on the Internet a videotape of an ABC News "20/20" interview with its chief executive, Michael Ellis, and says it will spend at least $1.5 million in advertising to call attention to the web site. Ellis said he is worried that the story – on its Metabolife supplement product – will be negative. Additionally, he said that such a report is a reaction by ABC to a lawsuit the company recently filed against an ABC affiliate. Ellis said "20/20" requested the interview 10 days after MetaboLife filed suit against WCVB-TV in Boston after it ran a story about the alleged harmful side effects of the company's products. The story – and a potential negative slant – would be a matter of "retaliation" for that legal action, Ellis said. ABC officials have rejected Ellis' accusations, saying that the report will be both objective and fair. A date for the story hasn't yet been released.

Metabolife reportedly has hired the same lawyers and public relations firm that worked for Food Lion, a North Carolina-based supermarket, which won its case against ABC News for a report on that company. In 1992, ABC's "PrimeTime Live" aired videos implicating the supermarket in selling spoiled food, using as the basis for the story video taken secretly.

Whole Foods spins off e-grocery business

Natural foods store chain Whole Foods (Austin, Texas) said late last month that it will sell off its Internet grocery business. Whole Foods said it has already sold a 13.5% share in the venture and within the year will sell shares to the public. The company – to be called WholePeople.com – will be led by Whole Foods founder John Mackey. Whole Foods operates in 20 states and Washington, D.C., and, with more than 90 stores, is considered the country's largest natural food chain. Brands include Whole Foods Market, Bread & Circus, Bread of Life, Fresh Fields, Merchant of Vine and Wellspring Grocery. The company also has product lines in coffee roasting and nutritional supplements.

'China Odyssey' to be on web

Two American manufacturers of Chinese herbal formulas, Neo Concept and Pharma Botanixx, recently sponsored what they termed a "China Odyssey," an investigation of Chinese culture and its use of herbs in that culture, both ancient and contemporary. Michael Rand and Vitus Shum were sent to the eastern coast of China and their results will be posted on the "China Odyssey" section of MotherNature.com (Concord, Massachusetts).The new section will include herbal formulas and information about their history and uses, photographs and stories about the Chinese people and places visited, and a Q&A section, the answers provid-

ed by the president of the Beijing Herbal Medicine and Acupuncture Institute and chief physician of the Beijing Municipal Hospital of Traditional Chinese Medicine.

Michael Barach, president and CEO of MotherNature.com, said the company previously sent similar teams to India and Peru to gain first-hand knowledge of those countries' practices in the use of herbals and other therapies. "We will continue to send our contributors in search of practices and experiences to add to the World Medicine section of MotherNature.com," he said.

VitaminShoppe IPO raises $50 million

In its initial public offering, VitaminShoppe.com (North Bergen, New Jersey), an online retailer of vitamins, nutritional supplements and minerals, has raised $50 million. The company sold 4,545,455 shares of Class A common stock at $11 per share, with the trading launched Oct. 8 on the Nasdaq National Market. Vitaminshoppe.com, a majority-owned subsidiary of Vitamin Shoppe Industries, is a leading online source for products and content related to vitamins, nutritional supplements and minerals. Its offerings include its own branded products plus about 400 other brands representing more than 18,000 items.

The offering was managed by Thomas Weisel Partners LLC, William Blair & Company and PaineWebber Incorporated. Vitaminshoppe.com has granted the underwriters an over-allotment option to purchase up to an additional 681,818 shares of Class A common stock for 30 days following the pricing of the offering.

Galaxy on Amex, awaits FDA word on soy

Galaxy Foods (Orlando, Florida), a producer of nutraceutical soy-based dairy and dairy-related alternatives, began trading on the American Stock Exchange on Oct. 6 under the symbol GXY. The company already has been traded as GALX on the Nasdaq Stock Market. The company recently said it is expect FDA approval of a health claim for soy that will boost consumer acceptance of a variety of new products: FDA announcement will further advance Galaxy's already popular line of soy-based dairy alternatives by increasing consumer awareness of soy foods. The new products, all high in soy protein, are Veggie Milk, The Ultimate Smoothie and Veggie Soy Protein Powder. The FDA announcement is expected to state that 25 grams of soy protein per day, included in a diet low in saturated fat and cholesterol, may reduce the risk of coronary heart disease. In order for a soy food product to make the claim, each serving must contain at least 6.25 grams of soy protein, or one-fourth of the daily requirement of 25 grams of soy protein.

Angelo Morini, Galaxy's president and CEO, said that as the company approaches the year 2000, it "plans to introduce a variety of new soy products including sport and diet smoothies, protein mixes and protein bars that will make a positive contribution to consumers' health."

Product Briefs

GM tomato gets EU 'amber light'

A genetically modified (GM) tomato from pharmaceutical manufacturer **Zeneca** has passed one of the stages toward winning approval for release on European Union (EU) markets. The European Commission announced Oct. 11 that its Scientific Committee on Food had expressed a favorable opinion on the safety of products derived from the tomato. **Zeneca** had sought approval under the EU Novel Food Regulation for this tomato variety intended solely for processing. When ripe, the tomato softens less quickly than its conventional counterparts, thus conferring better processing properties. The fruit is reported to be unpalatable and therefore is not intended to be consumed raw. It is processed, using heat treatment, for products like diced canned tomatoes, juice, and puree. This heat treatment biologically inactivates the modified genes and their protein products.

The committee concluded that, from the consumer health point of view, processed foods derived from these tomatoes are as safe as products from conventional fruit. However, it also acknowledged that "the question whether genetic modification results in modification of the existing proteins cannot be totally answered. This question would apply equally to other GM foods as well as to new strains developed by traditional crosses not involving GM technology." The European Commission will take the opinion into account in deciding on the conditions for the product's authorization, and on the labeling requirements for it.

The product already is authorized in the U.S., Canada, Mexico and the U.K., and it has already received clearance from the EU's Scientific Committee on Plants. But some EU member states have raised objections about marker genes it carries, and have urged that the product should also be cleared through the EU's 1990 general rules on release of biotechnology products.

Elsewhere in the product pipeline:

• **Aquasearch** (Kailua-Kona, Hawaii), a marine biotechnology company that develops and commercializes products from microalgae, has begun a safety clinical trial of its astaxanthin-rich dietary supplement. Thirty volunteers will receive either the anticipated recommended dose of the nutraceutical or a dose that is five times higher, for a period of 28 days. The participants then will receive a series of physicals

and clinical analyses to confirm that the product is safe. Astaxanthin's potential utility is as an antioxidant. It has demonstrated 100 times the antioxidant activity of vitamin E and 10 times the activity of beta carotene in experimental models, Aquasearch said. The company expects to submit an application to the FDA for marketing allowance during the fourth quarter of this year.

• Prostatonin, a supplement distributed nationally by **Boehringer Ingelheim Pharmaceuticals**' (Ridgefield, Connecticut) **Pharmaton Natural Health Products** division, has proven in clinical trials to be safe and effective in helping men manage frequent urination, promoting normal urinary patterns and supporting prostate health. The supplement contains proprietary, standardized extracts from African plum tree bark (*Pygeum africanum*, PY102) and nettle root (*Urtica Dioica*, UR102), each of which has been clinically shown to independently reduce urinary frequency during the day and night, reduce urgency and improve urine flow, the company said. The extracts, approved for use in a number of European countries since as early as 1988, inhibit the enzymes 5 alpha-reductase and aromatase, which affect testosterone metabolism and prostate health.

• **Bristol-Myers Squibb** (Princeton, New Jersey) has added Theragran Heart Right to its line of Theragran multivitamins. In addition to essential vitamins and minerals, the new product has a combination of micronutrients that medical research suggests may have cardiovascular benefits: vitamins C, E, B6 and B12, folic acid, carotenoids, selenium and magnesium.

• **CV Technologies** (Edmonton, Alberta, Canada) said the FDA has cleared its investigational new drug application for a formal Phase II study of its lead herbal extract product, CVT-E002, a multicomponent phytopharmaceutical extracted from North American ginseng. The product is intended for use as a prophylactic against acute respiratory infection in the cold and flu market. The clinical project is expected to begin in October and will be conducted through the Eastern Virginia Medical School. The investigational new drug application is the company's first, CV said.

• The **Daily Wellness Company** (Mountain View, California) has released results of a double-blind, placebo-controlled clinical study of ArginMax for Male Sexual Fitness, a nutritional supplement for enhancement of sexual performance. The data were scheduled to be presented Sept. 28 at a meeting of the American Urological Association in Carmel, California. The study used the International Index of Erectile Function and was performed in collaboration with physicians affiliated with the **University of Hawaii School of Medicine** (Honolulu, Hawaii) and **Albany Medical College** (Albany, New York). Following a four-week daily regimen of ArginMax, the Daily Wellness Company said, 87.5% of the men demonstrated improved ability to maintain an erection during sexual intercourse, while 75% of the men reported improved satisfaction with their overall sex life. There were no reported side effects. ArginMax is based on the observation that certain botanical extracts may facilitate the conversion of the amino acid L-arginine into nitric oxide, a molecule involved in circulation, erection and arousal. The supplement contains L-arginine, ginseng, ginkgo, antioxidants and a multivitamin. The Daily Wellness Company also makes a formulation designed to improve sexual performance in women.

• A study at the K. L. Jordan Heart Research Foundation (Montclair, New Jersey) demonstrated that tocotrienol-rich vitamin E extracted from rice bran oil has been found to improve significantly total cholesterol levels in patients with high cholesterol. The extract reduced total cholesterol 14.1% and LDL, or "bad," cholesterol by 20.6%. It also raised HDL, or "good," cholesterol and lowered triglyceride levels. The researchers additionally saw a substantial reduction in TBARS, a test that measures oxidation. The findings were published in September in the *Journal of Environmental and Nutritional Interactions*. The five-year, placebo-controlled clinical trial, expected to be completed by the end of 1999, involved 50 blinded subjects diagnosed with stenosis of the carotid artery. **Eastman Chemical Company** (Kingsport, Tennessee), maker of NuTriene tocotrienols derived from rice bran oil, has been donating supplements to the heart research facility for the past two years.

• Pharma Green has launched a $1 million advertising campaign to promote **Gum Tech International**'s (Phoenix, Arizona) Double Gum line of eight functional chewing gums in Israel. One of the highlights of the campaign, according to Pharma Green General Manager Motti Cohen, will be the launch of Gum Tech's Children's Dental Gum in cooperation with McDonald's, which will include pieces of the gum in its kid's meals. Pharma Green, the functional food division of the Pharm Up Group, a conglomerate of pharmaceutical and health product distributors in Israel and abroad, has been distributing functional gums that have been exclusively developed and manufactured for it by Gum Tech since September 1998.

• Pycnogenol, a nutritional supplement extracted from the bark of the French maritime pine tree (*Pinus maritimus*) and distributed exclusively in North America by **Henkel Nutrition and Health Group**, has been shown in a study to significantly reduce platelet aggregation, which can lead to heart attack and stroke. The study compared the product to aspirin, long-term use of which may lead to side effects such as stomach problems and increased bleeding time. Thirty-eight smokers at the **University of Munster** (Munster, Germany) and the **University of Arizona** (Tucson, Arizona) were given either a

single dose of 100 milligrams to 120 milligrams of Pycnogenol or 500 milligrams of aspirin, then were instructed to smoke so as to increase platelet aggregation. Within two hours after smoking, the effects of the two products in reducing platelet clumping were then measured. A single dose of Pycnogenol proved as effective as the aspirin dose five times its size, and Pycnogenol did not increase bleeding time. "Our research shows that Pycnogenol is a safe and natural option, especially for those who cannot tolerate the adverse effects of aspirin," said Ronald Watson, PhD, a professor of public health research at the **University of Arizona School of Medicine** (Tucson) and one of the study's lead authors. The product, a water-soluble flavonoid complex, also has demonstrated antioxidant properties. The study was published in a recent issue of *Thrombosis Research* .

• **Novogen** (Sydney, Australia) said its Rimostil dietary supplement increased bone density and HDL cholesterol levels in a nine-month clinical study of 50 postmenopausal women. Rimostil, derived from isoflavins (plant estrogens), increased cortical bone mass an average 4% after six months. It also raised HDL levels an average 28%, restoring women to premenopausal levels, Novogen said. The product showed none of the side effects often associated with hormone replacement therapy, such as bleeding and hot flashes, according to Graham Kelly, chairman and founder of Novogen. The study results were presented in New York at the annual conference of the North American Menopause Society. Kelly said he expects the company to launch the dietary supplement worldwide in 2000.

• **Nutrition for Life International** (Houston, Texas) has launched Kholesterol Blocker, a chewable, soybean-derived phytosterol dietary supplement targeted at heart health-conscious consumers. Phytosterols, or plant sterols, are almost identical to cholesterol in molecular structure, according to David Bertrand, Nutrition for Life's president, and have become popular since several research studies have documented their ability to maintain healthy cholesterol levels. "The body can't tell the difference [between cholesterol and phytosterol]," Bertrand said. "Thus, the phytosterols compete for and attach to absorption sites, resulting in regulated cholesterol levels in the blood." Phytosterols up to now have most often been added to margarines, or sold as tablets that must be taken 30 minutes prior to mealtime. Kholesterol Blocker, however, is taken at the beginning of each meal, three times daily. Each tropical-flavored tablet contains400 milligrams of phytosterols.

• **PharmaPrint** (Irvine, California), a developer of dietary supplements, functional foods and pharmaceuticals from natural plant extracts, and **HealthQuick.com**, an Internet health care site, have signed an agreement under which the latter will distribute PharmaPrint's new line of combination vitamin/herbal products containing echinacea, garlic, ginkgo biloba, ginseng, saw palmetto and St. John's wort. HealthQuick.com also will carry product information on PharmaPrint's other proprietary products.

• The **Quigley Corporation** (Doylestown, Pennsylvania), a natural health and homeopathic drug company, has increased the national distribution network for its BodyMate nutrition and weight management program. The company plans to launch a radio advertising campaign in early January to further support expanded distribution. BodyMate lozenges are all-natural and nutritional and contain garcinia cambogia and chromium polynicotinate for weight management. The program also includes weight maintenance suggestions, food recommendations and exercise guidelines. Quigley said that 90% of the 74 retailers at the Vitamin, Diet and Nutrition Conference, held in late August in West Palm Beach, Florida, agreed to carry BodyMate throughout the upcoming year.

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