



Vol. 52 No. 3

For Everyone Concerned With the Safety of Flight

May–June 2005

Aeromedical Specialists Caution Against Side Effects of Herbs Used for Medicinal Purposes

As the worldwide market for these products increases, civil aviation authorities say that pilots should discuss their use with private physicians and aviation medical examiners.

FSF Editorial Staff

The first use of herbs to prevent and treat human ailments occurred in ancient civilizations; for centuries they were used as integral parts of healing rituals and traditional medical systems.

Even after the advent of antibiotics and other modern drugs in the 1920s, people in many countries continued to use herbs for medicinal purposes (see "Commonly Used Herbal Supplements," page 2) — often in combination with pharmaceutical products. Elsewhere, the medicinal use of herbs declined. In the United States, for example, the decline resulted in part from government requirements for the testing and regulation of all "medicines" — whether sold by prescription or

over the counter; the requirements could not be met without standardization — and standardization often is not a quality of herbal products. The popularity of medicinal herbs waned, and they were not widely available until the mid-1990s, when a change in U.S. laws resulted in the marketing of herbal products as "dietary supplements," which were not subjected to the same scrutiny as medicines.

In 2003, the United Nations World Health Organization (WHO) estimated the world market for herbal supplements at more than US\$60 billion a year, "and growing steadily." Data are incomplete, but in China, between 30 percent and 50 percent of all medicines are herbal products; 90 percent of Germans have used a "natural remedy" at some time in their lives; and in parts of Africa, herbal products are the first line of treatment for 60 percent of children with high fevers caused by malaria.¹

The extent to which pilots and other flight crewmembers are included among those using herbal supplements is unknown,



but aeromedical specialists say that crewmembers' use of herbs may be significant.

"We have no way of knowing how many are taking herbal supplements, but I think it's safe to say that many of them do, based on the huge sales," said Dr. Russell Rayman, executive director of the international Aerospace Medical Association. "We have to assume that a significant number of pilots are self-medicating with herbs."²

A specific mention of herbal medication will be included in the revision by the International Civil Aviation Organization (ICAO) of the medical provisions

of its standards and recommended practices, which will take effect Nov. 24, 2005, and is cited below:³

Any applicant for any class of medical assessment shall be required to be free from ... any effect or side-effect of any prescribed or non-prescribed therapeutic, diagnostic or preventive medication taken ... such as would entail a degree of functional incapacity which is likely to interfere with the safe operation of an aircraft or with the safe performance of duties. *Note: Use of herbal medication and alternative treatment modalities requires particular attention to possible side effects.*" [Italics are included in the ICAO document.]

Dr. Claus Curdt-Christiansen, chief of ICAO's Aviation Medicine Section, said that the note was added because of an increasing awareness of "the danger to flight safety represented by the side effects of these kinds of treatment."⁴

Commonly Used Herbal Supplements

The following are among the most commonly used herbal supplements:^{1,2}

 Chamomile — Typically used for anti-inflammatory, anti-spasmodic or anti-infective purposes; or as a pain-reliever. Studies indicate effectiveness for antiinflammatory and anti-spasmodic purposes.

Known side effects include allergic reaction (among some people with allergies to ragweed, asters or chrysanthemums).

• Echinacea — Typically used to boost the immune system; to relieve symptoms of upper respiratory infection or limit their severity; as an antiseptic; or to treat urinary tract infections, eczema and other skin conditions, and migraine headaches. Studies have resulted in conflicting findings about their effectiveness; in some studies, researchers have concluded that echinacea is effective in stimulating the immune system, and may limit the duration and/or severity of colds.³

Known side effects include, from large doses, nausea or dizziness.

 Ephedra (ma huang) — Typically used as an appetite suppressant; as a nasal decongestant; to enhance strength; or to stimulate circulation. Studies indicate effectiveness as an appetite suppressant and nasal decongestant.

Known side effects have included erythroderma (peeling and reddening of the skin), heart attack, stroke, seizures or death.

• **Garlic** — Typically used as an antibiotic or a digestive aid, to reduce cholesterol, or to prevent formation of blood clots. Studies indicate effectiveness in reducing cholesterol; garlic also may prevent blood clots and may reduce blood pressure.

No known side effects.

 Ginkgo biloba — Typically used to treat circulatory problems or tinnitus (ringing in the ears), or to improve memory. Studies indicate effectiveness in improving the cognitive behavior of people with Alzheimer's disease. Other studies aimed at assessing cognitive improvement among healthy people have yielded conflicting findings.⁴

Ginkgo biloba can increase the risk of bleeding if it is taken by someone who also is taking medication that has been prescribed to prevent blood clots. Ginkgo also might have an undesired interaction with some psychiatric medications and with some medications that control blood sugar levels. Ginseng (Panax ginseng) — Typically used for a variety of ailments, such as boosting the immune system, increasing mental acuity and improving physical energy. Ginseng often is used in combination with other herbal supplements — a factor that has contributed to difficulty in conducting research on its effectiveness. Nevertheless, some studies of Panax ginseng (also known as Korean ginseng or Asian ginseng, one of several forms of ginseng from the same plant family) have indicated that it can help improve the immune system.⁵

Known side effects may include nervousness, high blood pressure, insomnia, anxiety, euphoria, diarrhea, vomiting or headache. Ginseng also can enhance the stimulant effects of caffeine and can reduce levels of sugar in the blood, which may interfere with diabetes medications.

Saw palmetto — Typically used to treat benign prostatic hyperplasia (enlargement of the prostate gland), which often occurs among men in their 60s and older. In some countries, use of saw palmetto is extensive; for example, in Germany, 90 percent of men being treated for an enlarged prostate gland take saw palmetto. Studies have found the herb effective and safe, with relatively rare, mild side effects.⁶

Known side effects usually involve gastrointestinal disturbances, which are alleviated if the herb is taken with food.

St. John's wort — St. John's wort often is taken for depression, anxiety or sleep disorders. Research has yielded conflicting results. Studies conducted in Europe — where St. John's wort frequently is prescribed to treat mild to moderate depression — have found the herb as effective as conventional antidepressants and with fewer side effects;⁷ in the United States, a National Institutes of Health (NIH) study in 2002 found no such effectiveness.⁸

Known side effects may include a decrease in the effectiveness of several prescribed medications, most notably conventional antidepressants but also birth control pills, and medications to treat the virus that causes acquired immune deficiency syndrome (AIDS) and to prevent the body's rejection of a transplanted organ.⁹♦

Notes

1. Fisher, Charles R.; Véronneau, Stephen J.H. "Herbal Preparations: A Primer for the Aeromedical Physician." *Aviation, Space and Environmental Medicine* Volume 71 (January 2000): 45–60.

- 2. U.S. National Center for Complementary and Alternative Medicine (NCCAM). *What's in the Bottle? An Introduction to Dietary Supplements.* http://nccam.nih.gov.
- Melchart, Dieter, et al. "Echinacea Root Extracts for the Prevention of Upper Respiratory Tract Infections." *Archives of Family Medicine* Volume 7 (November–December 1998): 541–545.
- Sierpina, Victor S.; Wollschlaeger, Bernd; Blumenthal, Mark. "Ginkgo Biloba." *American Family Physician* Volume 68 (Sept. 1, 2003). <www.aafp.org.>
- 5. Kiefer, David; Pantuso, Traci. "Panax Ginseng." *American Family Physician* Volume 68 (Oct. 15, 2003). <www.aafp.org>.

Although some herbal substances may themselves present risks, others are harmless, "and some may even have an effect," Curdt-Christiansen said. "Nevertheless, with effect [even a beneficial effect] usually come side effects and interactions."

In recent years, several civil aviation authorities have adopted provisions that include cautions for pilots who use herbal supplements.

For example, the Civil Aviation Safety Authority (CASA) of Australia says in its *Designated Aviation Medical Examiner's* [*DAME's*] Handbook that flight crewmembers should consider herbal supplements "as they would any other [over-the-counter] medication.⁵

"There is a potential for unforeseen consequences when taking such preparations, and aircrew and ATCs [air traffic controllers] should consult a DAME for advice before taking such medications and performing aviation-related duties. ...

"Herbal preparations are widely available in the community and are seen by many as a 'natural' alternative to conventional medicine. Unfortunately, such agents are not always subject to the same stringent regulations that apply to registered medicinal compounds. ... Many of these preparations contain agents that may interact with other drugs and have the potential to cause side effects that are incompatible with flight safety. CASA considers routine use of herbal preparations as being incompatible with flying [duties] or controlling duties."

In Germany, where herbal supplements have been the subject of extensive research and where the government requires that they be registered or licensed,⁶ they must "from an aeromedical view, be treated like medicines," said Cornelia Eichhorn, spokeswoman for the Luftfahrt-Bundesamt (Federal Office of Civil Aviation). "The medical examiners have to examine whether the taken medicines could endanger flight safety or not."⁷

The European Joint Aviation Authorities, in an informational leaflet for pilots about medicine and flying, says that treatments that involve herbal supplements are "developing and gaining

- Gordon, Andrea E.; Shaughnessy, Allen R. "Saw Palmetto for Prostate Disorders." *American Family Physician* Volume 67 (March 15, 2003)
- Vickers, Andrew; Zollman, Catherine. "ABC of Complementary Medicine: Herbal Medicine." *British Medical Journal* Volume 319 (Oct. 16, 1999): 1050–1053.
- 8. NCCAM. *St. John's Wort and the Treatment of Depression.* http://nccam.nih.gov>.
- 9. NCCAM. Questions and Answers: A Trial of St. John's Wort (Hypericum perforatum) for the Treatment of Major Depression. <http://nccam.nih.gov>.

greater credibility. Some such treatments are more acceptable in some states than others. There is a need to ensure that 'other treatments,' as well as the underlying condition, are declared and considered by [aviation medical personnel] when assessing fitness."⁸

The U.S. Federal Aviation Administration (FAA), citing data that show that nearly one-third of Americans take herbal dietary supplements at least once a month, says that their use "while not specifically prohibited by [U.S. Federal Aviation Regulations] ... must be carefully evaluated by the AME [aviation medical examiner]. ...

"Some herbal medications ... have been declared unsafe by the [U.S.] Food and Drug Administration. Other herbal medications may themselves be safe and effective, but the condition being treated contravenes the Federal [Aviation] Regulations."⁹

Rayman said that he considers the positions taken by the civil aviation authorities to be "very reasonable generalizations. It's very difficult to be specific because there are so many herbal substances out there. It's very hard to say, 'This is good, but this isn't good.' What the aviation regulatory agencies in the world seem to be doing is just warning people that there is a possibility that these things have undesirable side effects and that pilots should consult their physicians" (see "Guidelines for Use of Herbal Supplements," page 4).

Herbal supplements vary considerably, depending on where the herbs are grown, how the supplements are prepared and what dosage is administered.

Because some people consider herbs as natural products rather than as chemicals, they often assume that they present no risks to the user. Nevertheless, specialists say that this assumption is incorrect and that herbs have potent pharmaceutical properties and present risks if they are not used properly.

The National Center for Complementary and Alternative Medicine, a branch of the U.S. National Institutes of Health, says, "Just because an herbal supplement is labeled 'natural'

Guidelines for Use of Herbal Supplements

Pilots, or others, who want to use herbal supplements should consider the following guidelines:^{1,2}

- Research the herbal supplements, using wellestablished and reliable sources, including government health authorities;
- Consult with a physician to determine whether the herbal supplement might interact with other medications;
- Buy herbal supplements that are produced by large manufacturers, which some specialists say may be more likely to impose strict quality control measures;
- Use no more than the recommended amount of the herbal supplement. A larger-than-recommended dose could be dangerous;
- Stop using the herbal supplement if side effects occur, and discuss the side effects with a physician.♦

Notes

- 1. U.S. National Center for Complementary and Alternative Medicine. *What's in the Bottle? An Introduction to Dietary Supplements.* http://nccam.nih.gov>.
- 2. Virtual Flight Surgeons. *Herbal Products and Nutritional Supplements.* <www.aviationmedicine.com>.

does not mean it is safe or without any harmful effects. For example, the herbs kava [usually taken for insomnia or short-term stress or anxiety] and comfrey [taken for a variety of problems, including digestive ailments, arthritis, bruises and other injuries] have been linked to serious liver damage.¹⁰

"Herbal supplements can ... cause medical problems if not used correctly or if taken in large amounts. In some cases, people have experienced negative effects even though they followed the instructions on a supplement label."

Side effects vary widely, but those most frequently reported include mild digestive problems, increased urine flow, allergic reactions, dizziness, headache, fluid retention, sleepiness and hallucinations.¹¹

Some of the most serious problems have resulted from the incorrect use of traditional herbal medicines, WHO said.

"For instance, the herb ma huang (ephedra) is traditionally used in China to treat short-term respiratory congestion," WHO said. "In the United States, the herb was marketed as a dietary aid, whose long-term use led to at least a dozen deaths, heart attacks and strokes. In Belgium, at least 70 people required renal [kidney] transplant or dialysis ... after taking the wrong herb ... as a dietary aid."¹²

Other reports, including one from the Natural Health Products Directorate of Health Canada, said that the Belgian incident resulted from a mix-up of two herbal supplements with similarsounding Chinese names. Guan fang ji (guan fang chi, known scientifically as *Aristolochia* westlandii), which contains a nephrotoxin — a natural chemical that may cause kidney damage — was used in place of han fang ji (han fang chi, known scientifically as *Stephania* tetrandra).¹³

Because of the assumption that herbal supplements are natural and without risk, many people who take the supplements do so without the advice of their physicians — and often, without mentioning to their physicians that they are using the herbs.

Medical specialists say that a physician or other health care provider should be consulted before an herbal supplement is used because of the possibility that the herb might interact with other medications. For example, ginkgo biloba — often taken to improve memory — can increase the risk of bleeding if it is taken by someone who also is taking medication that has been prescribed to prevent blood clots,¹⁴ and St. John's wort — often prescribed for depression — may decrease the effectiveness of some prescribed antidepressants and several other types of medication.¹⁵

Aeromedical specialists say that they are concerned that, in addition to failing to discuss use of herbal supplements with private physicians, some pilots fail to disclose use of herbs to aviation medical examiners.

"I think many pilots and other license holders do not consider herbal medicines as something they have to disclose to the [civil aviation] authority, either on forms they fill out about their health or when interviewed by their medical examiner," Curdt-Christiansen said. "But the use of such medications is important and should be disclosed and discussed with the AME."

Aeromedical specialists said that such disclosures should be made not only because of the possible interactions of herbal supplements with other medications and because of their possible side effects, but also because their use may indicate that the pilot has an underlying medical condition that might interfere with performance of flight duties.

"It is the medical condition, not necessarily the treatment (herbal or otherwise), that may influence the safety of flight," said Dr. Donato J. Borillo, an FAA aviation medical examiner writing in the *Federal Air Surgeon's Medical Bulletin*. ¹⁶ The AME should not debate the 'medical legitimacy' of an herbal medication but should consider the possible underlying disease."

Borillo said that, for example, a pilot who takes an herbal supplement such as ginseng — often used to improve physical

energy and mental energy — should be asked why he or she is fatigued.

"A flier that is tired may have a chronic illness or depression," he said. "In addition, ginseng should be avoided by [people with high blood pressure] and can cause anxiety, irritability, nervousness and insomnia."

AMEs should use similar reasoning in evaluating pilots who report using other herbal supplements, FAA says.

Medical specialists throughout the world, including aeromedical specialists, continue to examine the role of herbal supplements in health.

Dr. Yasuhiro Suzuki, WHO executive director for health technology and pharmaceuticals, said that herbs — along with other components of traditional medicine, also known as complementary/alternative medicine (TM/CAM)¹⁷ — are "victim of both uncritical enthusiasts and uninformed skeptics."¹⁸

A more appropriate approach to the use of herbal medicines and TM/CAM would "tap into [the] real potential for people's health and well being, while minimizing the risks of unproven or misused remedies," Suzuki said.

WHO said in 2003 that although about 70 countries regulated herbal supplements, there was no single model for regulation. Herbal medicines are defined differently in different countries, and different methods have been adopted for licensing, dispensing, manufacturing and trading these medicines, WHO said.

Establishment of policies that integrate the use of herbal medicine into existing health care systems is intended to promote the rational use of safe and effective herbal medicines.

Nevertheless, as use of herbal supplements continues to increase, flight crewmembers should be especially aware of the effects of these supplements and should discuss their use with their private physicians and AMEs.◆

Notes

- 1. United Nations World Health Organization (WHO). Fact Sheet No. 134, *Traditional Medicine*. <www.who.int>.
- 2. Rayman, Russell. Telephone interview by Werfelman, Linda. Alexandria, Virginia, U.S., April 29, 2005. Flight Safety Foundation, Alexandria, Virginia, U.S.
- Curdt-Christiansen, Claus. E-mail communication with Werfelman, Linda. Alexandria, Virginia, U.S., April 26, 2005; April 28, 2005; June 7, 2005. Flight Safety Foundation, Alexandria, Virginia, U.S. Curdt-Christiansen is the chief of the Aviation Medicine Section of the International Civil Aviation Organization (ICAO).

Before the revision, ICAO said (in *International Standards and Recommended Practices*; Annex 1, *Personnel Licensing;* Standard 6.2.2, "Physical and Mental Requirements," "Any applicant for any

class of medical assessment shall be required to be free from ... any effect or side effect of any prescribed or non-prescribed therapeutic medication taken ... such as would entail a degree of functional incapacity which is likely to interfere with the safe operation of an aircraft or with the safe performance of duties."

- 4. Ibid.
- Civil Aviation Safety Authority of Australia. *Designated Aviation Medical Examiner's Handbook*. Section 2.13, "Medication Drugs and Flying/Controlling." Version 3.0, December 2003.
- 6. German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Midizinprodukte [BfArM]). *The BfArM and its Tasks.* <www.farm.de>.
- Eichhorn, Cornelia. E-mail communication with Werfelman, Linda. Alexandria, Virginia, U.S., June 1, 2005. Flight Safety Foundation, Alexandria, Virginia, U.S.
- European Joint Aviation Authorities. Joint Aviation Requirements, Interpretive Explanatory Material, Flight Crew Licensing (IEM FCL) 3.040, "Use of Medication, Drugs, Other Treatments and Alcohol."
- U.S. Federal Aviation Administration Civil Aeromedical Institute (CAMI; now the Civil Aerospace Medical Institute). *CAMI Training Manual: Clinical Aerospace Physiology Review for Aviation Medical Examiners — Self-study Correspondence*. Lesson 9G, "Alternative Medicine." April 1999.
- U.S. National Center for Complementary and Alternative Medicine (NCCAM). *Herbal Supplements: Consider Safety, Too.* http://nccam.nih.gov>.
- Fisher, Charles R. Jr.; Véronneau, Stephen J.H. "Herbal Preparations: A Primer for the Aeromedical Physician." *Aviation, Space, and Environmental Medicine* Volume 71 (January 2000): 45–60.
- 12. WHO. WHO Launches the First Global Strategy on Traditional and Alternative Medicines. <www.who.int>.
- McCutcheon, Allison R. An Exploration of Current Issues in Botanical Quality: A Discussion Paper, prepared for the Natural Health Products Directorate of Health Canada. December 2002. <www.hc-sc.gc.ca>.
- 14. NCCAM. What's in the Bottle? An Introduction to Dietary Supplements. http://nccam.nih.gov.
- 15. NCCAM. Questions and Answers: A Trial of St. John's Wort (Hypericum perforatum) for the Treatment of Major Depression. <http://nccam.nih.gov>.
- 16. Borillo, Donato J. "Herbal Medication and Flying." *Federal Air Surgeon's Medical Bulletin.* Spring 1999.
- 17. "Traditional medicine" (TM) refers to therapies, including herbal medicines, used in native cultures. In industrialized countries, use of the same therapies is known as "complementary/alternative medicine" (CAM). In 2002, WHO announced a traditional medicine strategy intended to help countries "develop national policies on the evaluation and regulation of TM/CAM practices; create a stronger evidence base on the safety, efficacy and quality of the TM/CAM products and practices; ensure availability and affordability of TM/ CAM, including essential herbal medicines; promote therapeutically sound use of TM/CAM by providers and consumers; and document traditional medicines and remedies."
- WHO. WHO Launches the First Global Strategy on Traditional and Alternative Medicine. News release, May 16, 2002. <

What can you do to improve aviation safety?

Join Flight Safety Foundation.

Your organization on the FSF membership list and Internet site presents your commitment to safety to the world.

- Receive 54 issues of FSF periodicals including Accident Prevention, Cabin Crew Safety and Flight Safety Digest that members may reproduce and use in their own publications.
- Receive discounts to attend well-established safety seminars for airline and corporate aviation managers.
- Receive member-only mailings of special reports on important safety issues such as controlled flight into terrain (CFIT), approach-and-landing accidents, human factors, and fatigue countermeasures.
- Receive discounts on Safety Services including operational safety audits.

Want more information about Flight Safety Foundation?

Contact Ann Hill, director, membership and development, by e-mail: hill@flightsafety.org or by telephone: +1 (703) 739-6700, ext. 105.

Visit our Internet site at <www.flightsafety.org>.

We Encourage Reprints

Articles in this publication, in the interest of aviation safety, may be reprinted, in whole or in part, but may not be offered for sale, used commercially or distributed electronically on the Internet or on any other electronic media without the express written permission of Flight Safety Foundation's director of publications. All uses must credit Flight Safety Foundation, *Human Factors & Aviation Medicine*, the specific article(s) and the author(s). Please send two copies of the reprinted material to the director of publications. These restrictions apply to all Flight Safety Foundation publications. Reprints must be ordered from the Foundation.

What's Your Input?

In keeping with the Foundation's independent and nonpartisan mission to disseminate objective safety information, FSF publications solicit credible contributions that foster thought-provoking discussion of aviation safety issues. If you have an article proposal, a completed manuscript or a technical paper that may be appropriate for *Human Factors & Aviation Medicine*, please contact the director of publications. Reasonable care will be taken in handling a manuscript, but Flight Safety Foundation assumes no responsibility for material submitted. The publications staff reserves the right to edit all published submissions. The Foundation buys all rights to manuscripts and payment is made to authors upon publication. Contact the Publications Department for more information.

Human Factors & Aviation Medicine

Copyright © 2005 by Flight Safety Foundation Inc. All rights reserved. ISSN 1057-5545

Suggestions and opinions expressed in FSF publications belong to the author(s) and are not necessarily endorsed by Flight Safety Foundation. This information is not intended to supersede operators'/manufacturers' policies, practices or requirements, or to supersede government regulations.

Staff: Roger Rozelle, director of publications; Mark Lacagnina, senior editor; Wayne Rosenkrans, senior editor; Linda Werfelman, senior editor; Rick Darby, associate editor; Karen K. Ehrlich, web and print production coordinator; Ann L. Mullikin, production designer; Susan D. Reed, production specialist; and Patricia Setze, librarian, Jerry Lederer Aviation Safety Library

Subscriptions: One year subscription for six issues includes postage and handling: US\$160 for members/US\$280 for nonmembers. Include old and new addresses when requesting address change. • Attention: Ahlam Wahdan, membership services coordinator, Flight Safety Foundation, Suite 300, 601 Madison Street, Alexandria, VA 22314 U.S. • Telephone: +1 (703) 739-6700 • Fax: +1 (703) 739-6708.

Flight Safety Foundation An independent, industry-supported, nonprofit organization for the exchange of safety information

for more than 50 years

FLIGHT SAFETY FOUNDATION • HUMAN FACTORS & AVIATION MEDICINE • MAY-JUNE 2005