NATIONAL CANCER INSTITUTE

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Cancer Facts

Complementary And Alternative Medicine

Cancell/Entelev: Questions and Answers

Complementary and alternative medicine (CAM)—also referred to as *integrative* medicine—includes a broad range of healing philosophies, approaches, and therapies. A therapy is generally called *complementary* when it is used *in addition to* conventional treatments; it is often called *alternative* when it is used *instead of* conventional treatment. (Conventional treatments are those that are widely accepted and practiced by the mainstream medical community.) Depending on how they are used, some therapies can be considered either complementary or alternative. Complementary and alternative therapies are used in an effort to prevent illness, reduce stress, prevent or reduce side effects and symptoms, or control or cure disease.

Unlike conventional treatments for cancer, complementary and alternative therapies are often not covered by insurance companies. Patients should check with their insurance provider to find out about coverage for complementary and alternative therapies.

Cancer patients considering complementary and alternative therapies should discuss this decision with their doctor or nurse, as they would any therapeutic approach, because some complementary and alternative therapies may interfere with their standard treatment or may be harmful when used with conventional treatment.

1. What is Cancell/Entelev?

Cancell/Entelev, also known as Sheridan's Formula, Jim's Juice, Crocinic Acid, JS–114, JS–101, 126–F, and Cantron, is a liquid that has been distributed as a treatment for cancer and a wide range of other diseases. Cancell/Entelev has been produced in various forms, principally by two manufacturers, since the late 1930s. The U.S. Food and Drug Administration (FDA) has listed the components of Cancell/Entelev as the chemicals inositol, nitric acid, sodium sulfite, potassium

hydroxide, sulfuric acid, and catechol. However, the exact composition of Cancell/Entelev is unknown. Independent tests on one form of Cancell/Entelev found 12 different compounds, none of which are known to be effective in treating any form of cancer.

2. What is the history of the discovery and use of Cancell/Entelev as a complementary or alternative treatment for cancer?

Cancell/Entelev was developed in the late 1930s by a chemist, who called the mixture Entelev and provided it free to cancer patients. In 1984, another manufacturer took over the production of Entelev and distributed the mixture for free under the trademarked name Cancell to patients with cancer, acquired immunodeficiency syndrome (AIDS), and other conditions.

The two principal manufacturers of Cancell/Entelev have offered different explanations for the development of cancer, but their theories about how the mixture works against cancer are similar. According to the original manufacturer, Cancell/Entelev changes cancer cells so they are seen by the body as "foreign" and are destroyed. The second manufacturer states that Cancell/Entelev changes cancer cells so they "self-digest" and are replaced by normal cells. The waste material produced by this self-digestion process is eliminated through urine, perspiration, and other body fluids.

3. How is Cancell/Entelev administered?

Cancell/Entelev can be administered by mouth (orally) or rectally, or it can be applied to the skin of the wrist or the ball of the foot. Cancer patients have been advised to take bromelain, a digestive aid, and to avoid high intakes of vitamins C and E while using Cancell/Entelev.

4. Have any side effects or risks been reported from Cancell/Entelev?

The manufacturer states that the side effects associated with Cancell/Entelev include temporary, moderate fatigue during the first few weeks of treatment. Nausea is also a reported side effect. One patient who exceeded the manufacturer's dose recommendations experienced diarrhea for a few hours, but was reported to be fine the next day.

5. Have any preclinical (laboratory and animal) studies been conducted using Cancell/Entelev?

In 1978 and 1980, the National Cancer Institute (NCI) conducted animal studies on Cancell/Entelev and determined that the mixture lacked substantial anticancer activity. Samples of Cancell/Entelev were also tested under NCI's *In Vitro* (laboratory) Anticancer Drug Discovery Program in 1990 and 1991. On the basis of

negative results from these studies, NCI researchers concluded that no further study of Cancell/Entelev was warranted.

The principal manufacturers of Cancell/Entelev have stated that they have performed many animal experiments with the mixture. None of these studies have been published in peer-reviewed, scientific journals. No information has been provided, beyond stating that some of the experiments tested the toxicity (undesirable and harmful side effects) of Cancell/Entelev.

6. Have any clinical trials (research studies in humans) been conducted with Cancell/Entelev?

No clinical trials of Cancell/Entelev have been reported. The principal manufacturers of Cancell/Entelev have stated that the mixture has been used by more than 15,000 patients and that it is safe and effective in treating 50 percent to 80 percent of all cancers. However, their findings have not been published in peer-reviewed, scientific journals. Only testimonials (information given by people who state that they have been helped by a particular treatment or product) or anecdotal reports (incomplete descriptions of the medical and treatment histories of one or more patients) have been made available.

7. Has the Food and Drug Administration (FDA) approved Cancell/Entelev for use in the United States?

To conduct clinical drug research with humans in the United States, researchers must file an Investigational New Drug (IND) application with the FDA. Entelev, the original name of the mixture, was assigned an IND number by the FDA in 1982. This IND is inactive, because information about the product's composition and studies showing its therapeutic effectiveness in animals have not been submitted to the FDA. In 1989, the principal manufacturers of Cancell/Entelev were permanently prohibited from distributing the mixture, which was judged to be an unapproved new drug by the FDA. Therefore, Cancell/Entelev is not approved for use in the United States.

8. When considering complementary and alternative therapies, what questions should patients ask their health care provider?

- What benefits can be expected from this therapy?
- What are the risks associated with this therapy?
- Do the known benefits outweigh the risks?
- What side effects can be expected?
- Will the therapy interfere with conventional treatment?
- Is this therapy part of a clinical trial? If so, who is sponsoring the trial?
- Will the therapy be covered by health insurance?

9. How are complementary and alternative approaches evaluated?

It is important that the same scientific evaluation that is used to assess conventional approaches be used to evaluate complementary and alternative therapies. A number of medical centers are evaluating complementary and alternative therapies by developing clinical trials to test them.

More information about how CAM approaches are evaluated can be found in the National Cancer Institute (NCI) fact sheet *Complementary and Alternative Medicine in Cancer Treatment: Questions and Answers*. This fact sheet can be accessed at http://cis.nci.nih.gov/fact/9_14.htm on the Internet, or by calling the Cancer Information Service (CIS) at 1–800–422–6237.

10. How can patients and their health care providers learn more about complementary and alternative therapies?

Patients and their doctor or nurse can learn about complementary and alternative therapies from the following Government agencies:

The **NIH National Center for Complementary and Alternative Medicine** (NCCAM) facilitates research and evaluation of complementary and alternative practices, and provides information about a variety of approaches to health professionals and the public.

NCCAM Clearinghouse
Post Office Box 7923
Gaithersburg, MD 20898–7923
Telephone: 1–888–644–6226 (toll free)
301–519–3153 (for International callers)
TTY (for deaf and hard of hearing callers): 1–866–464–3615
Fax: 1–866–464–3616
E-mail: info@nccam.nih.gov
Web site: http://nccam.nih.gov

NCCAM and the **NIH National Library of Medicine** (NLM) jointly developed **CAM on PubMed**, a free and easy-to-use search tool for finding CAM-related journal citations. As a subset of the NLM's PubMed bibliographic database, CAM on PubMed features more than 230,000 references and abstracts for CAM-related articles from scientific journals. This database also provides links to the Web sites of over 1,800 journals, allowing users to view articles in full-text. (A subscription or other fee may be required to access full-text articles.) CAM on PubMed is available through the NCCAM Web site at http://nccam.nih.gov. It can also be accessed at http://www.ncbi.nlm.nih.gov/PubMed by selecting "Limits" and choosing "Complementary Medicine" as a subset.

The NCI **Office of Cancer Complementary and Alternative Medicine** (OCCAM) coordinates the activities of the NCI in the area of complementary and alternative medicine (CAM). OCCAM supports CAM cancer research and provides information about cancer-related CAM to health providers and the general public via its Web site http://cancer.gov/cam on the Internet.

The **Food and Drug Administration** (FDA) regulates drugs and medical devices to ensure that they are safe and effective.

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Telephone: 1–888–463–6332 (toll free)
Web site: http://www.fda.gov/

The **Federal Trade Commission** (FTC) enforces consumer protection laws. Publications available from the FTC include:

- "Who Cares: Sources of Information About Health Care Products and Services"
- "Fraudulent Health Claims: Don't Be Fooled"

Consumer Response Center
Federal Trade Commission
CRC–240
Washington, DC 20580
Telephone: 1–877–FTC–HELP (1–877–382–4357) (toll free)
TTY (for deaf and hard of hearing callers): 202–326–2502
Web site: http://www.ftc.gov/

The information in this fact sheet was adapted from the NCI's PDQ® summary Cancell/Entelev. *Full reference citations are listed at the end of the PDQ summary, which can be accessed at http://cancer.gov/cancerinfo/pdq/cam/cancell on the Internet. The PDQ summary can also be obtained by calling the Cancer Information Service (CIS). The CIS, a national information and education network, is a free public service of the NCI, the Nation's primary agency for cancer research. The toll-free phone number for the CIS is 1–800–4–CANCER (1–800–422–6237). For deaf and hard of hearing callers with TTY equipment, the number is 1–800–332–8615.*

The information in this fact sheet is not presented as a substitute for informed medical advice. If you have any questions about your individual medical situation, please contact your doctor.

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