

Chapter 8

Organized Efforts Related to Unconventional Cancer Treatments: Information, Advocacy, and Opposition

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INTRODUCTION

There are organizations that exist solely to advocate “alternative medicine,” or “freedom of choice” in medicine; and there are organizations whose sole goal is to eradicate “health fraud.” Unconventional cancer treatments are major concerns of both types of group. Other organizations, including Federal agencies, engage in activities related to unconventional cancer treatments as part of a broader agenda. The strategies of all these groups vary, but most include some component of providing information to the public or to health professionals; some include lobbying or other political activity; others become involved with private legal actions involving patients, practitioners, and clinics.

This chapter presents the activities of the Federal Government concerning unconventional cancer treatments, through the National Cancer Institute (NCI) and the Food and Drug Administration (FDA), and then discusses the activities of private sector organizations that have taken stands for or against unconventional cancer treatments. Following that, the chapter discusses examples of specialized information services.

FEDERAL GOVERNMENT INFORMATION ON UNCONVENTIONAL CANCER TREATMENTS

The National Cancer Institute (NCI)

NCI has a responsibility to inform the public about cancer. In 1986, NCI staff answered about 400,000 public requests for information (373). The Public Inquiries Office and the Cancer Information Service (CIS), two branches of NCI’s Office of Cancer Communication, supply information to the public about cancer treatments. The Public Inquiries Office and CIS have provided some information on unconventional treatments for several years, and NCI is in the process of developing a more detailed data base on unconventional treatments.

Public Inquiries office

This office is responsible for NCI responses to written inquiries about cancer treatments, including foreign inquiries and legislative requests, and also questions originating within the National Institutes of Health (NIH). Difficult or complex questions from the public may be referred by CIS to the Public Inquiries Office for research and resolution. The staff work with other NCI staff in writing and distributing many treatment-related publications, including the standard response paragraphs used by CIS staff to answer inquiries about unconventional cancer treatments (174).

Cancer Information Service

NCI established the CIS in 1975, as part of a Federal initiative to meet the diverse informational needs of cancer patients. CIS is a telephone network consisting of a national office and 25 regional offices, each covering one or more States or large population areas. Calls coming in after hours or on weekends are transferred to a toll-free 24-hour number answered by the national CIS office, which is run by a private business under contract to NCI. Information on a wide range of cancer-related topics is available to callers through CIS staff, who are health educators and trained volunteers. In response to inquiries, CIS staff may consult a computerized database, their office’s subject matter files (including newspaper and periodical articles), and their reference library. CIS staff also have access to the expertise of NCI physicians and researchers. Followup on telephone inquiries is done by mailing printed materials or a return phone call (306).

Inquiries to CIS about unconventional cancer treatments constitute about 1 percent of all inquiries, and people most frequently ask about these treatments in addition to other cancer-related questions (e.g., clinical trials, treatment in general, coping and counseling, chemotherapy), according to a recent review of 4 years of CIS experience (306). Data on the types of unconventional cancer treatment asked about are not uniformly recorded by CIS staff. However, the Florida regional office of CIS did record this information between September 1982

and February 1983, a period when staff answered 558 telephone inquiries about unconventional cancer treatments. They reported that most of their inquiries concerned Immuno-Augmentative Therapy (probably due at least in part to the proximity of Florida to the Bahamas), other types of "immuno-therapy," Macrobiotic diets, and the use of vitamin C; other inquiries concerned advocacy organizations, home remedies, dimethyl sulfoxide (DMSO), and the Burzynski cancer treatment (781).

According to a recent review of the limited data available, CIS responded to a total of 10,399 inquiries about unconventional cancer treatments during the 4-year period between January 1983 and December 1986. Friends and relatives of cancer patients accounted for just over half these inquiries; cancer patients, 18 percent; the general public, 12 percent; health care professionals, 6 percent; and the media, less than 1 percent. Over the last 4 years, all CIS offices, with the exception of Oklahoma, have recorded some inquiries about unconventional cancer treatments. The six offices reporting the highest percentage of inquiries about unconventional treatments were Tennessee, California, Washington State, New York City, Texas, and Wisconsin (306).

CIS staff read or paraphrase a standard response paragraph to all callers asking about unconventional cancer treatments. This paragraph: 1) urges patients to remain in the care of physicians who use "accepted and proven methods" 2) warns that use of unconventional cancer treatments may result in loss of time and reduce chances for cure or control of disease; 3) points out the availability of experimental forms of treatment for situations where standard therapy is not available or has not been effective; and 4) encourages patients to ask their doctor about their eligibility for clinical trials (306).

When inquiries come in, CIS staff may also read from or paraphrase standard response statements about specific unconventional cancer treatments (see table 8-1), and they may send copies of these statements to callers. These standard response statements are prepared by NCI staff, reviewed by the Office of Cancer Communication, revised as necessary, and then passed through a formal clearance process. In addition to these statements, CIS staff may read, paraphrase, or photocopy other materials collected by individual CIS offices (306).

Table 8-1—Unconventional Cancer Treatments and Practitioners for Which NCI/CIS Has Standard Response Paragraphs

Janker Clinic
Antineoplastons/Dr. Stanislaw Burzynski
Dr. Hariton Alivizatos/Greek Cancer Cure, Inc.
Dr. Albert Szent-Gyorgyi
Laetrile
Hydrazine sulfate
Dr. Harold Manner
Koch synthetic antitoxins
Hoxsey herbs
Krebiozen
Gerson therapy
Lawrence Burton, Ph. D./IAT
Holistic medicine
Macrobiotic diet

SOURCE: V. Friemuth, "The Public's Search for Information on Unorthodox Cancer Treatments: The CIS Experience," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, Feb. 18, 1988.

Most CIS statements about unconventional cancer treatments are several pages long, varying in what they cover. They often identify a major proponent, describe the treatment, and briefly state the claims made. Almost every statement summarizes the evidence available to NCI and draws some conclusion about the treatment, the proponent, or both.

For some treatments (e.g., Antineoplastons, laetrile), the details of evaluation attempts by NCI and other bodies are presented, while for others (e.g., "non-toxic chemicals," Manner therapy), the statements simply state that "no evidence exists that these are effective in cancer treatment." In two cases, the Gerson therapy and Krebiozen, the statements indicate that a record review was conducted by NCI. Although the findings of those reviews are not presented in detail, the statements conclude that these reviews neither established treatment efficacy nor elucidated promise warranting clinical trial investigation. In a few of the statements (e.g., Koch antitoxins, Hoxsey), very little information about the treatment is provided, but actions of FDA, Federal Trade Commission (FTC), State cancer councils, and other governmental agencies related to the treatment or practitioner are described.

In several cases, while the statements report that there is little evidence to support the treatment itself, they acknowledge the potential importance of relevant fields of research, and go on to describe research conducted by NCI or another mainstream medical institution in those fields. For example, the statement on hydrazine sulfate and the statement on

the Gerson therapy acknowledge the potential role of adequate nutrition in cancer treatment and describe the research on nutrients in cancer being conducted by NCI'S Diet, Nutrition, and Cancer program (DNCP). Though the statement on hydrazine sulfate criticizes early published research, it also describes it as "provocative," and goes on to detail current NCI-funded research efforts on this substance and its possible role as an adjuvant cancer treatment (899, 900).

Data Base on Unconventional Treatments

In an effort to provide practitioners with more information about unconventional cancer treatments, in 1987, NCI awarded a contract to Emprise, Inc., a private consulting firm, to prepare information on 26 unconventional cancer treatments. Each entry will include: 1) a statement reviewing the scientific data supporting the treatment, 2) a sample "patient and doctor dialogue" that physicians may find useful in discussing these treatments with patients, and 3) a summary overview and fact sheet about the treatment. NCI has not decided how it will use this information. It may become part of PDQ, an on-line, free, cancer treatment information system targeted to health professionals, in operation by NCI since 1982. Emprise also plans to make versions of the information available in scientific monographs that will be submitted to peer-reviewed journals (631).

The Food and Drug Administration

FDA has statutory authority to regulate the marketing of drugs, devices, and biologics in interstate commerce. Many of the best-known unconventional cancer treatments involve drugs, devices, or biologics unapproved by FDA, and these treatments become FDA's concern when interstate shipment occurs or reports suggest they pose a public health hazard (411). (See ch. 10 for a description of FDA's responsibilities in regulating drugs.) Because FDA's interest arises from these concerns, FDA may provide the public with almost exclusively negative information about unconventional cancer treatments.

To some extent, FDA's Office of Consumer Affairs both initiates public awareness and responds to occasional public inquiries on unconventional cancer treatments. In the last few years, FDA and the Pharmaceutical Advertising Council (PAC) developed a multi-media public service campaign to teach

the public how to recognize, avoid, and help stop what they consider to be 'health fraud,' a term that, as used by the FDA, encompasses some of the treatments covered in this report.¹ In 1986, FDA worked with the National Association of Consumer Agency Administrators (NACAA) to establish an Information Exchange Network. In 1988, the Office of Consumer Affairs contracted with Harris Associates to conduct a national survey (discussed in ch. 7) documenting the extent and impact of what they defined as health fraud on the U.S. public, focusing on use in the treatment of chronic diseases, such as arthritis and cancer.

A few individuals within FDA are knowledgeable about unconventional cancer treatments and may answer specific inquiries or represent the agency on related matters. Staff from the Office of Health Affairs also respond to inquiries from health professionals and organizations regarding unconventional cancer treatments. An FDA historian may respond to public inquiries about unconventional cancer treatments with articles and reprints.

The Office of Regulatory Affairs imposes and publicizes sanctions that may involve unconventional cancer treatments. The office publishes narrative notices of Import Alerts, which have, on occasion, dealt with bans on the importation of unconventional cancer treatments (e.g., IAT, Nieper products). Under the Commissioner of Regulatory Affairs, staff at regional and district offices specifically monitor health fraud and make enforcement efforts. In this vein, the government has sought injunctions against Dr. Stanislaw Burzynski to prevent shipment of unapproved drugs across state lines, and seized some of his records. (See ch. 10 for a full description of this case.)

The Office of Public Affairs prepares "FDA Talk Papers," which are intended to guide FDA personnel in answering questions posed by the public, and are also available to the public directly. A few recent FDA Talk Papers have discussed unconventional cancer treatments (e.g., live cell therapy, homeopathic remedies).

On the agency level, FDA has provided considerable information about some unconventional cancer treatments through sponsorship of health fraud conferences (61 1). In 1985, FDA, FTC, and the U.S. Postal Service cosponsored a National Health Fraud

¹Throughout this section the term "health fraud" is used in the way it is used by FDA.

Conference in Washington, DC. This was the first national conference on health fraud since 1966, and was attended by approximately 250 representatives of Federal, State, and local agencies, independent public interest groups, and industry associations (866). The goal of the conference was to heighten awareness of health fraud in the United States and to facilitate the cooperation of various concerned agencies in the public and private sectors. As a followup to the 1985 national conference, FDA held regional health fraud conferences during 1986 in several cities across the country.

In March 1988, FDA sponsored another national Health Fraud Conference in Kansas City. This 2-day conference, cosponsored by two local hospitals, included speeches and workshops with general and specific information about, among other topics, unconventional cancer treatments and their practitioners. Specific unconventional cancer treatments were highlighted as examples of fraudulent treatments (e.g., laetrile and IAT). Legal, fiscal, and sociological aspects of health fraud were discussed (658,988).

PRIVATE SECTOR INFORMATION ABOUT UNCONVENTIONAL CANCER TREATMENTS: OPPOSITION

Most information about unconventional cancer treatments, positive and negative, is developed and disseminated through private sector organizations. The most influential of these on the negative side is the American Cancer Society (ACS), through its "Unproven Methods" activities, which are only a small part of the Society's broad agenda. Historically, the American Medical Association (AMA) played a role in fighting what it defined as quackery, which has included a number of specific unconventional cancer treatments, but it has been less active in recent years. The American Society for Clinical Oncology (ASCO), a professional society for oncologists, has had an ongoing interest in unconventional cancer treatments. Other smaller organizations, such as the National Council Against Health Fraud (NCAHF), the National Council on Nutritional Information, and the Quackery Action Coun-

cil, investigate, sometimes litigate, and generally warn the public about the hazards they believe are posed by unconventional cancer treatments. Many of these organizations collaborate, sharing resources and personnel, and have sometimes worked with Federal agencies, such as FTC or FDA, acting against health fraud. These organizations have been termed collectively "quackbusters." Many share information among themselves; and prominent individual "quackbusters" often serve on the committees of several organizations.

This section discusses ACS, AMA, ASCO, and NCAHF and their activities.

The American Cancer Society (ACS)

ACS is headquartered in Atlanta and has 57 divisions throughout the United States. Originally founded in 1913 as the American Society for the Control of Cancer, ACS is a large, voluntary health organization, "dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives from cancer, and diminishing suffering from cancer through research, education, and service" (90). While a strong emphasis is placed on supporting cancer research and training, public and professional education remain important program priorities for ACS (373). An early ACS slogan was "Fight Cancer with Knowledge" (409). The most prominent program relating to unconventional cancer treatments is the long-standing ACS Committee on Unproven Methods of Cancer Management. The Committee and its statements, as well as other relevant ACS activities, are described below.

Committee on Unproven Methods of Cancer Management

The majority of ACS public and professional education activities regarding unconventional cancer treatments originate with the Committee on Unproven Methods of Cancer Management.² Established in 1954, the Committee is administered by the professional staff of the national office, and serves as an information resource for all ACS divisions. The Committee shares information with ASCO, FDA, the U.S. Pharmacopoeia, AMA, and also, on an ad hoc basis, with the unproven methods committee of the European Association of Cancer Societies (373).

²At its Mar. 7 1990 meeting, the Committee on Unproven Methods of Cancer Management proposed a name change to the Committee on Questionable Methods of Cancer Management. This change awaits approval by the Society's House of Delegates in November 1990 (90).

Although the original intent of the Committee was to provide information to physicians on unconventional forms of cancer treatment, more members of the public than physicians currently approach ACS about unproven methods. The main activity of the Committee is “to initiate and approve the preparation of materials for the education of the medical profession and the public concerning unproven methods for treatment and/or diagnosis of cancer” (90). The Committee also funds small research projects, such as two current pilot projects to determine the extent of use of unproven methods of cancer management across the United States.

The Committee meets three times a year to discuss unproven cancer treatments, advocacy organizations for unconventional treatments, and practitioners offering unproven cancer treatments, and to review related projects. Members may be assigned to small working groups for specific projects, such as revising the Unproven Methods statements. The Committee maintains more than 900 information and documentation reference files. ACS states that they gather information by conducting literature searches, reviewing existing files, and inviting proponents of unconventional cancer treatments to submit materials during the drafting and revision processes (287). Statements on unproven methods that appear in the ACS publication *CA-A Cancer Journal for Clinicians* are drafted by a technical writer or by a health professional with interest and knowledge in the topic, and reviewed and approved by the Committee before adoption and public distribution (90).

In an ACS brochure titled ‘Unproven Methods of Cancer Management,’ ACS urges the public not to use “unproven methods,” and to distinguish these from established and investigational mainstream treatments:

Methods of investigation in cancer management research generally include some of the following: observations on the effects of the therapy under study in an adequate number of patients with biopsy-proven cancer; complete evaluation of all clinical and laboratory data including case histories, radiographs, and microscopic slides; reproducible findings; assessment of treatment results as compared with a control group or standard treatment; examination of survival outcome; and consultation with other research groups.

Unproven methods of cancer management differ from standard accepted treatments which have been shown by scientific study to be effective. Standard methods of treatment have undergone study to prove that they are both effective and safe. If methods of therapy have not had careful review by scientists and/or clinicians to show that they are effective, then they are not deemed proven and should not be recommended. (28)

A recent brochure lists 27 individual ACS statements on Unproven Methods of Cancer Management (table 8-2). Most statements describe treatments, but some profile practitioners or advocacy organizations. Some statements open with a standard section that indicates the purpose of the statement and why ACS recommends that unproven methods of cancer management not be used. Additional information varies from statement to statement but may include claimed benefits of treatments, citations from published literature, summary and criticism of available data, examples of legal action, plans for mainstream evaluation of treatments, and biographical information about proponents. All have a strongly negative tone and clearly attempt to dissuade use of unconventional cancer treatments. Some advocates for unconventional cancer treatments term this “the ACS black list.”

In 1988, ACS began the process of updating all of the unproven methods statements. As they are completed and approved by the Committee, they appear in the ACS professional journal, *CA-A Cancer Journal for Clinicians*. In 1989, the new statements on the International Association of Cancer Victors and Friends, Inc. (29), the Revici method (31), and macrobiotic diets (30) were published.

The ACS unproven methods statements are regarded as authoritative by many public and private sector organizations. In addition to their use by patients and their physicians, the statements are also used as reference documents in insurance coverage decisionmaking (577). A recent survey of the commercial health insurance industry by the Association of Community Cancer Centers (ACCC) revealed that ACS Statements on Unproven Methods are one of the five most frequently consulted sources of information used by major insurance companies in their deliberations regarding reimbursement for cancer treatment claims (577).

Table 8-2—Treatments and Proponents of Treatments Declared Unproven in ACS Statements on Unproven Methods of Cancer Management, 1987

- Hariton Alivizatos, M.D. (Greek cancer cure, inc.)
- Antonio Agpaoa, the “psychic surgeon”
- Antineoplastons
- Vlastimil (Milan) Brych
- Chaparral tea
- The Committee for Freedom of Choice in Cancer Therapy, Inc.
- Contreras methods
- Dimethyl sulfoxide (DMSO)
- Electronic devices
- Fresh cell therapy
- Gerson method of treatment for cancer
- Hoxsey method or Hoxsey chemotherapy
- Immuno-Augmentative therapy of Lawrence Burton, Ph. D., Bahamas
- Independent Citizens Research Foundation for the Study of Degenerative Diseases
- International Association of Cancer Victors and Friends, Inc.
- Iscador
- Issels combination therapy, proposed by Josef Issels, M.D.
- Kelley malignancy index and ecology therapy
- Koch antitoxins
- Laetrile
- VirginiaWuerthele-Caspe Livingston, M.D. and EleanorAlexander-Jackson, Ph.D.—PPLO vaccine and test
- Macrobiotic diets
- Metabolic cancer therapy of Harold W. Manner, Ph.D.
- National Health Federation
- Carey Reams
- Revici cancer control
- O. Carl Simonton, M.D.

SOURCE: American Cancer Society Inc., “Unproven Methods of Cancer Management,” pamphlet, 87-25M-No. 3028, 1987.

Inquiries to ACS About Unproven Methods of Cancer Management

Depending on whether callers inquire during or after office hours and on the level of information requested, inquiries to ACS about unconventional cancer treatments may be handled by the National Office Professional Education Staff, local Cancer Response System (CRS) staff, or other individuals designated by divisions (373). The Delaware Division, for example, has designated one individual to handle all inquiries from health professionals about unconventional cancer treatments (33).

The ACS National Office received about 800 telephone or written inquiries about unproven methods over the 46-month period from November 1983 through September 1987. (There is no count of

similar inquiries to regional ACS offices.) The inquiries were handled either by the CRS or Unproven Methods Committee staff. Of those inquiring, 415 were patients or their family members, 356 were health professionals, and 33 were from the media. The specific content of the calls is not recorded in sufficient detail to determine patterns of public interest in particular treatments.

Educational Programs

ACS sponsors public service advertisements, health fairs, conferences, and other special programs with, generally, only a minor focus on unconventional cancer treatments. The ACS divisions are independent, however, and some choose to be more active in this area than others (796).

Cancer Response System

Since 1984, ACS has operated the CRS, its telephone “hotline” information service, as a joint educational project between ACS headquarters and regional offices. CRS is operated by ACS volunteers and professional staff, using two toll-free telephone lines, according to prescribed procedures and guidelines (796). A minority of CRS inquiries involve unconventional treatments.³

*Although regional ACS offices may handle inquiries somewhat differently than does the national office, the national office provides the regional offices with most of the information used to respond. Most ACS staff reaming CRS telephone lines read or send standard statements prepared by the Unproven Methods Committee to callers inquiring about specific unconventional cancer treatments. Personnel are asked to emphasize that it is not ACS policy to recommend any specific treatment and urge callers to maintain contact with their mainstream physicians (796). Other reference information may include ACS public education pamphlets; articles from the ACS practitioner journal, *CA-A Cancer Journal for Clinicians*;⁴ FDA Talk Papers; the ACS publication for medical students, *Clinical Oncology*; the *Cancer Manual*, written for a general audience; and articles from other journals. ACS divisions may also develop their own reference materials.*

³In addition to information on unconventional cancer treatments, CRS also maintains materials on more commonly requested information (e.g., causes of cancer, prevention strategies, specific malignancies, orthodox cancer treatments, clinical trials, rehabilitation resources, and other support services for cancer patients).

⁴For example, the May/June 1988 issue of *CA-A Cancer Journal for Clinicians* contains articles on self-help groups, psychosocial issues, and unconventional cancer treatments.

The American Medical Association

AMA is a large trade organization whose membership includes individual physicians, all State and county medical societies, and 70 medical specialty societies throughout the United States. AMA states that it seeks to “promote the art and science of medicine and the betterment of public health,” by “representing the medical profession, providing information about medical matters, upholding professional conduct and performance, and advancing standards of medical education” (47,71). Under this banner, AMA has made efforts to prevent what it considers health fraud and to educate the profession and the public as to the advantages and disadvantages of controversial therapies. In the past, AMA crusaded actively against unconventional cancer treatments (see box 8-A), but in recent years their activity in this area has waned.

Currently, questions concerning unconventional treatments are generally referred to other organizations, such as ACS. AMA does maintain files of published and unpublished literature on unconventional treatments, however, and will respond to questions about them. Responses are provided by staff of the Division of Library and Information Management. In 1989, AMA published a small annotated bibliography of the published, mainstream literature on a group of unconventional treatments, not limited to cancer. AMA itself, however, did not editorialize on the treatments (843). Another AMA activity, the Diagnostic and Therapeutic Technology Assessment (DATTA) Program in the Division of Basic Sciences, Group on Science and Technology, also has become involved, to a limited extent, with unconventional treatments.

Diagnostic and Therapeutic Technology Assessment Program

DATTA was created in 1982 to distill and publicize information for practicing physicians on the safety and clinical efficacy of emerging or controversial medical technologies. DATTA responds to approximately 600 information requests per year with letters, phone calls, and formal DATTA opinions published in the *Journal of the American Medical Association* (71,446,787). Most inquiries are from individual physicians, patients,

and third-party payers. (See ch. 9 for a description of the insurance industry’s use of DATTA opinions.)

Medical technologies may be proposed for DATTA review by the public or by several offices within AMA, but are selected for the formal review process based on the priorities of the Council on Scientific Affairs. In formulating an opinion, DATTA staff review literature from technical journals and then survey assembled panels of experts from relevant medical specialties about the technology’s safety and efficacy. About 10 DATTA opinions are published each year in the *Journal of the American Medical Association*. All DATTA opinions are considered provisional, and may be reassessed upon new findings and information.

Three unconventional cancer treatments have been evaluated by the DATTA program. The first two were subjects of mainstream research, which were also promoted in the alternative medical community. The third, IAT, exists wholly outside of conventional medicine and research. DATTA assessed *Bacillus Calmette-Guerin* (BCG) vaccine for use in cancer therapy several years ago.⁵ Whole-body hyperthermia was originally assessed in 1983 (466) and rated as “investigational” for use in cancer treatment. DATTA later reassessed whole-body hyperthermia for cancer in 1986 (46) after FDA approved a hyperthermia system for a specific palliative cancer treatment indication. The updated DATTA evaluation states that use of regional or local hyperthermia for the indication approved by FDA represents “established medical practice,” while the use of whole-body hyperthermia, and other applications of local and regional hyperthermia remained “investigational.”

IAT was the subject of a 1988 DATTA evaluation (467). In the published DATTA opinion, panelists had no data from clinical trials or other studies to review; only historical information, descriptive articles, and reports of health hazards were included. The overall opinion was negative (680). (See ch. 6 for a full discussion of the IAT DATTA evaluation.)

The American Society for Clinical Oncology (ASCO)

ASCO has been generally silent about unconventional cancer treatments. Its primary concern is with

⁵BCG is a biologic used in other countries for treatment of tuberculosis, and is sometimes used in the United States as an unconventional treatment for both cancer and AIDS.

Box 8-A—The American Medical Association: Historical View

From the early part of the 20th century through the 1970s, the American Medical Association (AMA) crusaded actively to protect the public from what it considered medical fraud and quackery. In 1906, AMA established a formal department, the Propaganda Department, to confront the issue of health fraud in proprietary medications (649). The Department experienced several name changes, becoming the Bureau of Investigation in 1924 and then the Department of Investigation in 1958, but it retained the same goal: to combat health fraud by evaluating existing medications and technologies and through educating physicians and the lay public about the deceptive practices of quacks. Three mechanisms were used to accomplish this goal: dissemination of information by means of speeches, books (including *Nostrums and Quackery*), school texts, films, and written responses to individual inquiries; distribution of information to State medical boards on the credentials and qualifications of applicants for medical licensing; and cooperation with various Federal agencies, including FDA, FTC, and the U.S. Postal Service, in order to regulate, prevent, and prosecute individuals responsible for health fraud schemes (38,649).

During the 1930s, the peak period for inquiries, 10,000 to 12,000 requests for information on proprietary medicines and cosmetics were submitted each year by physicians and the public. After the passage of the 1938 Food, Drug, and Cosmetic Act, the number of inquiries declined significantly. From 1942 to 1963, an average of 3,000 to 4,000 letters and phone calls were answered each year. During the 1950s and 1960s, questions concerning cancer treatments were the most popular, and a smaller staff in the Department of Investigation continued writing newspaper columns and producing films such as the *Medicine Man* (1958) on the dangers of “quack” treatments.

AMA owed its quackbusting reputation in large part to Morris Fishbein, M.D., editor of the *Journal of the American Medical Association* from the mid-1920s through the 1940s. Fishbein waged public campaigns against well-known unconventional treatments and their purveyors, the most famous being his battle against Harry Hoxsey. In a 1947 editorial called “Hoxsey-Cancer Charlatan,” Fishbein wrote, “[o]f all the ghouls who feed on the bodies of the dead and the dying, the cancer quacks are most vicious and most heartless” (292). The invective that flew between Hoxsey and Fishbein was captured in a recent film, *Hoxsey: Quacks Who Cure Cancer?* In 1949, Hoxsey sued for libel and won a judgment—\$2—against Fishbein, reportedly the only one of the many suits brought against Fishbein that was decided against him (58). Fishbein left the editorship of the journal that same year.

In 1961, AMA’s Department of Investigation and FDA collaborated in sponsoring the first National Congress on Medical Quackery. In this and three subsequent congresses, representatives of AMA, Federal agencies such as FDA and FTC, the Better Business Bureau, State health departments, and private organizations such as ACS, pledged to eradicate “health quacks,” largely through public education campaigns. In the 1960s, the Department of Investigation also participated in the Coordinating Conference on Health Information which met twice annually to “implement and augment various activities against quacks, faddists, cultists, and other aspects of pseudomedicine” (41).

During the 1960s, the Department of Investigation targeted its health fraud prevention efforts on chiropractors; in 1962, it formed the Committee on Quackery, which focused its activities on opposing chiropractors’ efforts to become recognized as legitimate health care providers (40). That episode culminated in a 1987 ruling against AMA and several other professional societies after an n-year lawsuit brought by Chester Wilk and three other chiropractors, who charged that the organizations had engaged in a conspiracy to boycott chiropractors (614,960).

Both the Department of Investigation and the Committee on Quackery were eliminated in a 1975 restructuring of AMA. The Division of Archival Services and Public Affairs assumed some of their functions (42,44,649). Since the restructuring, AMA activities on health fraud and unconventional cancer treatments have greatly diminished (842).

clarifying scientific and political issues germane to the mainstream practice of oncology in the United States. It does, however, have a standing committee concerning unconventional treatments, and has made some efforts to discuss these treatments with their membership and the public. Efforts in this regard have included the 1983 publication of “Ineffective Cancer Therapy: A Guide for the Layperson” (48), and collaboration with NCI in 1980 on a survey of

U.S. oncologists to document their experience with patients who had been treated with IAT.

Public inquiries to ASCO on unconventional cancer treatments are generally referred to ACS or NCI, and the few inquiries received from oncologists are handled by the chairman of the Unorthodox Practices Committee (963). ASCO’s 1989 representative on the ACS Unproven Methods Committee and on AMA’s Cancer Council is an oncologist

known for his negative stance on unconventional cancer treatments. As of 1988, the same individual also was serving on the Committee on Hematology and Oncology in the Scientific Information Section of the United States Pharmacopoeia, which is currently developing information on unproven cancer remedies.

ASCO, along with AMA and ACS, articulates what is considered standard or reasonable cancer treatment in the United States. ASCO is considered highly credible and while, as an organization, it does not do much to influence directly the use of unconventional cancer treatments, its representation on related committees within AMA, ACS, and the United States Pharmacopoeia, and its general lack of public discourse on unconventional cancer treatments conveys a view of these treatments as collectively lacking value. Lack of ASCO endorsement or serious consideration probably influences mainstream oncologists against incorporating these treatments into their practices and, in general, from referring patients to unconventional practitioners.

The National Council Against Health Fraud (NCAHF)

NCAHF describes itself as an organization of "health professionals, educators, researchers, attorneys and concerned citizens, wishing to actively oppose misinformation, fraud, and quackery in the health marketplace" (656). The group was founded in 1977 in California as a local consumer advocacy group for health matters, and became national in 1984. The council "conducts studies and investigations to evaluate claims made for health products and services' educates Americans about "health fraud, misinformation, and quackery"; promotes consumer health laws; and "encourage[s] and aid[s] in legal actions against consumer protection health laws violators." Its newsletter is NCAHF's main means of promoting its cause, but it also has a Resource Center that sells books and articles on health care fraud (656).

Affiliated with NCAHF, the Nutrition Information Center is a non-profit group, based in Arizona, that publicizes negative information about providers of unconventional cancer treatments and specifi-

cally discourages use of what is considered fraudulent or unproven nutritional treatments. It also maintains a speakers' bureau, and sells videotapes, manuals, books, and assorted reprints.

PRIVATE SECTOR INFORMATION ABOUT UNCONVENTIONAL CANCER TREATMENTS: ADVOCACY

Some of the most active organizations providing information to promote the use of unconventional cancer treatments or, more generally, freedom of choice in medicine include the Cancer Control Society (CCS), the International Association of Cancer Victors and Friends (IACVF), the National Health Federation (NHF), the Foundation for Advancement in Cancer Therapies (FACT), the Coalition for Alternatives in Nutrition and Healthcare (CANAH), and the American Quack Association (AQA). There are, in addition, groups formed in support of particular treatments and practitioners, e.g., the IAT Patients' Association (IATPA), the Friends of Dr. Revici, and the Hans Nieper Foundation. A few private information services also provide specialized information about and, in some cases, referrals to unconventional cancer treatments. Examples of these types of organizations are discussed later in this chapter.

The Cancer Control Society (CCS)

CCS, founded in 1973 by two former IACVF members, is currently one of the most active organizations advocating the use of unconventional cancer treatments. Based in California, it has approximately 5,000 members. In a spring 1988 mailing, CCS stated that its purpose is "public education in the prevention and control of cancer and other diseases through nutrition, tests, and non-toxic alternative therapies.' The same flier cites laetrile, Gerson therapy, Hoxsey treatment, Koch enzymes, wheat grass, immunology, mega-vitamins and minerals, detoxification, nutrition, dimethyl sulfoxide (DMSO), and chelation therapy as examples of the treatments considered "non-toxic" by CCS (166).

CCS members receive a journal, the *Cancer Control Journal*, and may be eligible for discounts at selected treatment-related supply houses (270). CCS provides free lists of practitioners and clinics offering unconventional treatments, in addition to selling books, informational pamphlets, cassette tapes, self-help materials, and specific treatment-related products directly to the public. CCS holds an annual convention on unconventional cancer treatments, attended by approximately 1,000 people per year, at which 50 to 100 practitioners of unconventional cancer treatments, many of whom practice in Mexico, discuss and promote their services (764). Treated patients also participate in the CCS annual convention and may offer testimonials in support of practitioners.

In order to respond to public inquiries, CCS maintains a 24-hour telephone hotline and sends out information (including names and addresses) about unconventional practitioners and clinics; mailings also include names and addresses of patients who have used unconventional treatments (163,164,166). In at least some cases, CCS specifically recommends practitioners and types of unconventional cancer treatment based on the inquiring patient's diagnosis and any expressed preferences. Aside from periodic updating of their membership list and letters to members asking their permission to be contacted by other patients, no formal effort is made to follow up on patients referred by CCS to unconventional practitioners (764).

CCS assists cancer patients in looking into unconventional treatment options by providing prospective patients with a list of patients who have used various unconventional treatments and their telephone numbers. CCS also arranges "Cancer Clinic Tours," consisting of guided bus trips to Mexican clinics that offer unconventional treatments. Commentary by CCS bus tour guides about the clinics and practitioners may influence patient decisionmaking, as may the comments made by the practitioners and patients they meet at each clinic. Approximately 200 people per year take the CCS trip to Mexican cancer clinics (764).

The International Association of Cancer Victors and Friends (IACVF)

IACVF, founded in 1963 by a cancer patient, currently has approximately 4,000 members. Headquartered in California, IACVF has chapters in

Florida, Illinois, New York, Texas, Washington State, and affiliates in Canada and Australia. One IACVF goal is "to continually collect, research, analyze, evaluate, and disseminate new information concerning alternative non-toxic treatments, therapeutic agents, vaccines, pharmaceuticals, nutritional aids and clinics in the United States and abroad" (29).

IACVF facilitates person-to-person networking by providing a list of "recovered patients" and encouraging contact by potential patients. IACVF's publication, *Cancer Victors Journal*, focuses on unconventional and occasionally conventional approaches to cancer prevention and treatment, nutrition, interviews with researchers and practitioners, and personal case histories of cancer "victors." IACVF runs an informational telephone hotline through its national and regional offices. Its national office reports an average of 5 to 10 calls per day concerning unconventional cancer treatments, with some regional offices receiving more (192). In response to inquiries, IACVF provides supportive telephone counseling and, at the volunteer's discretion, general discussion of available unconventional cancer treatments. As followup, callers may be sent written materials advocating a wide variety of unconventional cancer treatments. IACVF's National Office develops and distributes sample informational packets, also distributed by regional chapters, along with supplemental information relevant to each area of the country. Regional chapters also sponsor seminars on topics related to cancer and cancer treatment.

IACVF cooperates with CCS in developing and publishing listings of alternative cancer treatments, practitioners, treatment supplies, clinics, and support groups. The Association also participates in the CCS annual convention.

The National Health Federation (NHF)

NHF was established in 1955 and provides generally positive information about unconventional medical treatments (not limited to cancer) coupled with consistent criticism of mainstream medicine. NHF also acts politically, attempting to effect legislative change to deregulate practitioners and enhance "freedom of choice" in health care. It is based in California, with 82 chapters in 32 states (389).

NHF advocates the use of unconventional treatments through its journal, *Health Freedom News*, which contains articles and advertisements for treatment-related supply houses, clinics, and practitioners offering unconventional cancer treatments. NHF also sells books, reprints, and pamphlets that advocate specific unconventional cancer treatments. One of the most vocal advocacy organizations in the United States, NHF uses its journal to seek both financial and political support from its readership for "freedom of choice" causes.

The main issue around which NHF frames most of its goals is its belief that many government actions in the health area are invasions of personal freedom and civil liberties. The organization's role is to fight for an individual's right to choose their health care, a liberty they feel is restricted by the health industry as it exists presently.

Coalition for Alternatives in Nutrition and Healthcare (CANAH)

CANAH is a coalition, based in Pennsylvania, that has as its main goal the enactment of a Healthcare Rights Amendment to the U.S. Constitution and similar amendments to the constitution of each state, but the group involves itself in a wide variety of health issues, including access to unconventional cancer treatments. Like NHF, CANAH argues that conventional medicine controls health care in the United States, suppressing other types of care (such as homeopathic, naturopathic, etc.) to which people should have access. CANAH presents its stands on various issues through its newsletter, *Healthcare Rights Advocate*, and other publications (205).

The Foundation for Advancement in Cancer Therapies (FACT)

FACT is a New York-based educational organization, founded in 1977, with chapters in Detroit, Boston, and Philadelphia. It distributes information about cancer treatments it considers "nontoxic." Based on a belief that cancer is a sign of systemic dysfunction or imbalance in a person, FACT advocates cancer treatments that purport to enhance patients' resistance. The group focuses on "early non-invasive diagnosis, nutrition, detoxification, structural balance, and mind-body connection" (298). FACT only advocates cancer treatments that

it deems "holistic," "host-oriented," and "nontoxic." Treatments meeting FACT's nontoxic criteria are fever therapy, immunotherapy, cellular therapy and botanicals (298). In addition to the many unconventional cancer treatments advocated in FACT literature, a few innovative cancer treatments from mainstream research institutions are also advocated.

In its effort to educate the public, FACT responds to requests by sending out books, article reprints, and cassette tapes. Their publication, *Cancer Forum*, has a circulation of approximately 5,000. FACT volunteers respond to telephone inquiries by "assessing patients' physical, financial, and geographic needs" (770). In addition, FACT's public education activities have included a conference in Philadelphia on nutritional and psychoneuroimmunologic cancer treatments, attended by patients and professionals.

The group makes treatment referrals almost exclusively to "metabolic" practitioners. Referred patients are asked to report back to FACT on their treatment experiences and their comments are considered by FACT staff in making future referrals. FACT had planned to undertake a structured evaluation of the treatment experiences of their callers in 1987, but the project has been delayed indefinitely (770).

American Quack Association (AQA)

AQA, a small organization founded in 1985 and based in Florida, views both patient and practitioner use of unconventional health care treatments as "freedom of choice" prerogatives. Its membership includes both professionals in the health field and lay practitioners. The AQA publication, the *Journal of the American Quack Association*, which is published with *Health Consciousness*, contains articles and letters to the editor from practitioners and patients advocating the use of unconventional medical treatments. AQA invites its members and readers of its journal to share "descriptions of their experiences with Quack Remedies which they have found effective" (498). There are currently more than 350 members of AQA (497).

AQA sponsors an annual "Quality Care With Kindness" conference at which the availability and practices of numerous unconventional practitioners are publicized (497).

Project Cure and the Center for Alternative Cancer Research

Project Cure, established in 1979 by a former cancer patient and businessman, describes itself as “the first citizens’ lobby group acting on behalf of cancer patients and their non-toxic treatment alternatives” (280). According to its literature, Project Cure’s primary goal is to “encourage Congress and the medical community to evaluate and employ nutritional, non-toxic cancer therapies” (731).

Toward its stated goals, Project Cure provides the public with petitions and postcards to express their sentiments directly to legislators. Topics of recent Project Cure write-in campaigns include: supporting legislation to prohibit food irradiation, advocating increased nutritional education in medical school curricula, opposing licensing of dietitians, advocating that NCI spend more of its research budget on nutritional treatments and prevention of cancer, and urging Congress to “protect OTA from biasing influences’ in this assessment of unconventional cancer treatments. In addition to postcard campaigns, Project Cure personnel contact congressional staff directly, and have collaborated with other advocacy organizations in efforts to influence public opinion.

Project Cure also created a Center for Alternative Cancer Research (CACR) (732). CACR’S primary service is the provision of free packets of information in response to inquiries about unconventional cancer treatments. CACR reports sending out more than 300,000 such packets between 1987 and 1989 (280), each including a 1986 article from the *New England Journal of Medicine* (65), a 1987 study by the General Accounting Office (862), and a reprint of the Fitzgerald Congressional Hearings of 1953 (294)-three documents that question the degree of success of current conventional approaches to cancer treatment.

Although Project Cure literature disavows advocating “a specific therapy or practitioner” (731), CACR provides the public with information on various alternative cancer treatments, clinics, and practitioners, and also refers patients to specific support groups or information services that provide “additional counseling and direction.’ Project Cure tries to educate the public about non-toxic alternative cancer treatments by distributing free copies of a recently published international guide to alterna-

tive cancer treatments (289), publishing a quarterly newsletter, *The Turning Point*, and publishing a brochure summarizing their view of state-of-the-art mainstream cancer treatments and “alternatives” (280).

Committee for Freedom of Choice in Medicine (CFCM)

Formerly known as the Committee for Freedom of Choice in Cancer Therapy, CFCM, a California-based organization, describes itself as “committed to freedom of choice with informed consent for physicians and patients in medicine’ (365). CFCM sponsors informational seminars on alternative cancer treatments and distributes generally positive information about specific treatments. CFCM is one of the oldest politically-active advocacy organizations in this field, beginning in the 1970s with lobbying efforts to legalize laetrile (365). At one time, there were 500 CFCM chapters nationwide; now there are approximately 50, the decrease due apparently to changes in the legal status and waning popularity of laetrile (54).

In recent years, CFCM has begun to advocate “metabolic therapy and general freedom of choice in health care” and currently provides a referral service to more than 500 ‘holistic’ doctors in North America and abroad. CFCM frequently collaborates with other advocacy organizations (280).

Through their magazine, *The Choice*, CFCM consistently criticizes new and established mainstream cancer treatments, oncologists, and cancer treatment institutions and encourages the exclusive use of unconventional metabolic treatments for cancer (and other diseases). This journal contains advertisements for mail-order “metabolic products,’ ‘ and books advocating unconventional cancer treatments (sold by CFCM), as well as for the two treatment clinics run by CFCM leaders.

The Coalition, Alliance, and Foundation

Over the last few years, individuals from several advocacy organizations have collaborated to advance the interests of alternative medicine in the United States. The ‘Coalition for Alternative Medicine’ was formed in the spring of 1986 by individuals from IATPA, CCS, CFCM, IACVF, NHF, People Against Cancer, and Project Cure. The Coalition cited a short-term goal of winningapolitical support for a congressionally mandated OTA evalu-

ation of IAT and a long-range goal of establishing ‘a permanent mechanism in government for the evaluation of alternative therapies that show promise’ (206). The Coalition met again in November 1986 and January 1987, but eventually disbanded due to internal conflicts and financial problems (595).

A few individuals from the defunct Coalition regrouped in late 1987 to form two new allied organizations—the Alliance for Alternative Medicine (AAM) and the Foundation for Alternative Medicine (FAM). AAM’s literature states that it is composed of “organizations, physicians, and other professionals in the medical field, as well as alternative therapy practitioners. Alternately, FAM, whose goals are the same as AAM, is an organization open to the public (456).

AAM’s primary goal “is to assist government agencies in developing an efficient and cost-effective evaluation method for both orthodox and alternative cancer therapy” (17). AAM anticipates that, as one outcome, such a government organized evaluation program will “serve to separate the ‘quacks’ and ‘opportunists’ from the genuine researchers and practitioners” (19). **As one of their first major efforts**, AAM sponsored a spring 1988 showing of the film Hoxsey: *Quacks Who Cure Cancer?* for congressional staff, intended to increase awareness of the politics surrounding alternative medicine (18). In contrast, FAM’s role is “to support the educational and research goals” (299).

Patient Associations

Immuno-Augmentative Therapy Patients’ Association

IATPA was founded in July 1985 with the single goal of reopening the Immunology Researching Centre (IRC), a clinic in the Bahamas at which Lawrence Burton offers IAT. IRC had been closed by the Bahamian Ministry of Health following a site visit by representatives of the Centers for Disease Control (CDC) and other consultants, prompted by much-disputed reports that IAT treatment materials were contaminated with Human Immunodeficiency Virus (HIV, the AIDS virus) and hepatitis B virus. (See ch. 6 for a complete discussion.) In order to facilitate the clinic’s reopening, the IATPA offered to purchase laboratory equipment so that the IAT clinic could test for these two viruses (553) (the clinic itself actually purchased the equipment). The leadership of IATPA also persuaded then-

Congressman Guy Molinari to hold public hearings on IAT. Although Burton’s clinic was allowed to reopen, **an IATPA member indicated, “in the course of these events, we [IATPA] became convinced that a conspiracy exists which suppresses evaluation of unconventional treatments and have** become more broadly politically active in response to this” (455).

Since the reopening of the IAT clinic in March 1986, IATPA leaders and a member of then-Congressman Molinari’s staff, acting as principal members of the Coalition (and later the Alliance for Alternative Medicine), helped to rally congressional interest, culminating in the request for OTA’s case study of IAT. In addition to political activity, IATPA members share information, emotional support, and assistance (e.g., discount lodging, arrangement for meals and transportation, legal assistance, insurance advice, customs tips, storage, and long-term access to medications) through a periodic newsletter and person-to-person networking. The IATPA also publishes *a Patient’s Handbook* and informally provides information and support to new and potential IAT patients.

Hans Nieper Foundation (HNF)

In 1985, HNF was established to advocate the unconventional cancer treatments developed and provided by Hans Nieper, a German physician practicing in Hannover, Germany, where some U.S. patients are treated. In addition to publishing a newsletter, providing informational support to potential patients, and selling books and written materials about Dr. Nieper’s treatment, HNF arranges for Nieper to speak in the United States (376,378,379). FDA has imposed an import ban on Nieper products because of inadequate labeling or misbranding and seizures have intermittently been made (678,892). HNF expresses concern about this and the problems it creates for Nieper patients in the United States, though they have taken no formal actions to alter the ban (377).

Friends of Dr. Revici

The Friends of Dr. Revici is a network of individuals who support Dr. Emanuel Revici’s unconventional cancer treatment. The group is based in New York, with local groups in several cities across the United States. It states that its goal is to share information with new and current patients concerning all aspects of Revici treatment. Members assist each other in obtaining necessary medical

records; arranging for lodging, food, and transportation to Dr. Revici's office in New York; and in acquisition, storage, and appropriate use of the prescribed medications (9). Like the Hans Nieper Foundation, this organization also provides financial support to assist with Dr. Revici's legal expenses.

Specialized Commercial Information Services

A few commercial information services offer to act as personal treatment information "brokers" for cancer patients. They assist in identifying conventional and unconventional treatments and providers. Can Help, one such service, provides patients with

customized literature on both mainstream and unconventional cancer treatment options, but will also review medical records, obtain second opinions from selected medical advisers, and provide cancer patients with an independent synthesis and interpretation of all the information (595).

Another commercial information service, the Health Resource, provides cancer patients with reports containing a literature review for both conventional and unconventional treatments, and offers patient vignettes and patient contacts, all based on the client's diagnosis and interests (365).