
Chapter 2

Patients, Science, and Alternative Cancer Therapies

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The percentage of the U.S. population that was expected to develop invasive cancer at some point in their lifetime was 38% for women and 48% for men in the 1991–1993 period (Parker et al. 1997). Another way of expressing the magnitude of the cancer epidemic is that one and a quarter million persons in the United States are diagnosed with cancer per year, and another 800,000 persons are diagnosed with basal cell and squamous cell skin cancers. About half a million people die from cancer each year, making the disease the second leading cause of death.

The problem is not solely one of magnitude: conventional therapies have an unsatisfactory track record. Five-year survival rates have remained largely static during the decades subsequent to President Richard Nixon's declaration of the war on cancer. As pathologist and environmental cancer expert Samuel Epstein comments,

According to the NCI's [National Cancer Institute's] own statistics, overall five-year survival rates for cancers in all ages and races improved marginally from 49.1% to 51.1% from 1974 to 1987—the rates for African Americans during this period actually dropped from 38.6% to 38.4%. Even this minuscule improvement in overall “cure” rates may be little more than statistical artifact: earlier diagnosis, for example, may extend the period between diagnosis and death, leading to the conclusion that the patient has survived longer, when the cancer may have proved fatal regardless of when it was diagnosed (1992, 234).

Likewise, according to veteran cancer activist and researcher Ralph Moss, the list of cancers responsive to chemotherapy was almost the same in the 1990s as in 1971, notwithstanding a quarter-century of research and the expenditure of tens of billions of dollars on research (1995, 81).

Given the dismal picture in terms of the size of the cancer epidemic and

the poor chances for long-term survival that many cancer patients face, it is not surprising that they have turned to various alternative and complementary cancer therapies (ACCTs). An often-quoted survey in the *New England Journal of Medicine* suggests that more than 34% of the American people had resorted to at least one unconventional therapy during the year prior to the survey (Eisenberg et al. 1993). Estimates for the use of alternative therapies for cancer in the United States run from 10 to 50% of cancer patients; even the conservative end of the estimates suggests that at minimum the number of cancer patients in this category is probably between half a million and a million people (McGinnis 1991). Survey data suggest that users of ACCTs tend to be better educated than the population as a whole (Cassileth et al. 1984; Sharma 1992; Furnham and Forey 1994), although the data do not take into account variations within the population that might be associated with linkages between ethnic groups and traditional ethnic medicine. It is therefore likely that as the population becomes more educated about treatment options, cancer patients will tend to use more alternative and complementary therapies. As the number of patients using ACCTs grows, their views will have an increasing impact on regulatory policy and research agendas. This study will describe some of the major contours of the ACCT movement in the United States and their implications for the prevention and control of cancer in North America.

BACKGROUND

Let us estimate that over one million Americans are using ACCTs in some way for the treatment of cancer. Probably the bulk of those patients could be described as minimal users of complementary therapies. The use of the term "complementary" raises the vexed issue of the politics of terminology. A number of charged terms, such as "quack," "unproven," "questionable," and "unconventional" therapies, appear in the literature, usually employed by persons who do not have adequate credentials in the social sciences and have no interest in developing an accurate portrayal of the ACCT movement as a social phenomenon. Likewise, the idea that there is "no alternative medicine, only medical alternatives," which one sometimes hears from opponents of ACCTs, suggests a political naivete, which this chapter will question. The terminology is therefore highly charged and warrants some clarification.

I use the terms "alternative" and "complementary" as sociocultural descriptors of differences in usage patterns. The term "alternative" denotes a usage in place of such conventional therapies as surgery, radiation, and chemotherapy; "complementary" denotes usage alongside conventional therapies as adjuvants (British Medical Association 1993). The same therapeutic intervention, such as vitamin C, can be either alternative or complementary, depending on how it is used. It is probable that the bulk of patients who might be classified as users of ACCTs are using them as complementary interventions. For example, instead of taking high doses of intravenous vitamin C infusions as part of an alternative protocol, most patients are probably taking some oral supplement as an adjuvant to conventional methods.

The group of therapies in the ACCT range can be classified in different ways. In readings and conferences, the following categories were used: psychospiritual interventions, dietary programs, supplements, nontoxic pharmacological and immunological modalities, and herbs. Many of the psychospiritual interventions, such as group psychotherapy, have now achieved acceptance in the medical community as valuable adjunctive therapies. Some aspects of dietary programs, supplements, and herbs have also been integrated into conventional protocols in hospitals in the United States, again as adjunctive therapies. However, when those modalities are combined and offered as alternatives to conventional therapies, they remain controversial. Likewise, the nontoxic pharmacological and immunological modalities tend to be offered as alternatives and to be highly controversial. Those modalities include immunotherapies (such as bacterial vaccines), peptides (known as antineoplastons), blood fractions (known as immuno-augmentative therapy), a nontoxic chemotherapeutic substance (known as laetrile), oxygen therapies such as ozone and hydrogen peroxide, and a product designed to control cachexia (known as hydrazine sulfate).

The research presented herein is based on interviews with opinion leaders of the ACCT movement. Those interviews are broken down into two groups of roughly equivalent size. The first group includes about two dozen of the leading clinicians, researchers, journalists, and heads of information-providing organizations. The interviews in this group are the topic of a book (Hess 1999). The second group involves women patients, mostly breast cancer patients, who have used ACCTs and have subsequently become involved as leaders of the movement to open up medical treatments for women cancer patients. Most of the women have written books on the topic; others have volunteered as workers in patient support organizations. The interviews in this group and discussion of general themes and policy issues were published in the book *Women Confront Cancer* (Wooddell and Hess 1998) and will not be discussed here.

THE STRUCTURE OF THE ALTERNATIVE CANCER THERAPY MOVEMENT

The ACCT movement today in North America has changed dramatically since the 1970s. Social science reports of the ACCT movement of the 1970s described the political mobilization surrounding laetrile and the divisions within the movement, between groups associated with right-wing politics and those with a more liberal or left-wing political orientation (e.g., Peterson and Markle 1979a, 1979b). Today, the ACCT movement is much more diverse, both in terms of the number of major organizations involved and the number of therapies offered.

Although there are no adequate quantitative measures of the growth of the ACCT movement, the number of publications, institutions, clinicians, and patient support organizations has grown substantially since the 1970s. Several background social changes suggest that the pattern of growth is long-term and systemic:

1. the globalization of medical care through the institutionalization of alternative clinics in Mexico and Europe, and the movement of thousands of patients per year

- across international borders, such that a de facto deregulation has occurred as a result of globalization;
2. the growth of health maintenance organizations that are beginning to accept less-expensive alternative therapies in response to cost-benefit analysis and patient demand (although funding for ACCTs may prove much more difficult to achieve than for other chronic diseases and conditions);
 3. the widespread dissemination of information through decentralized mass media (health-food books, small magazines, direct mail campaigns, and the Internet); and
 4. the growth and professionalization of such alternative health care providers as naturopaths and specialists in Chinese traditional medicine.

In addition, epidemiological data suggest that age-standardized incidence rates have climbed steadily at a rate of about 1% per year, at least until recently; thus there has been a long-term increase in the patient population in the United States (Davis et al. 1994, 431).

American patients who pursue ACCTs are sometimes able to find a medical doctor, naturopathic doctor, or other health-care provider who is willing to supervise the case locally. However, each year thousands also go to foreign clinics and hospitals. The best known are the Lukas and Janker clinics in central Europe, the immuno-augmentative therapy (Burton) clinic in the Bahamas, and the dozens of clinics and hospitals in Mexico, principally Tijuana. The growth of ACCTs in Tijuana has been phenomenal, from just a few clinics in the early 1970s to over thirty clinics and hospitals in the 1990s.

Patients learn about ACCTs through access to a network of support organizations, usually led by former patients or family members of former patients. Those organizations provide information about a wide range of therapies. Many of the alternative therapies were founded by scientists or clinicians who had credentials and work experience that could have located them, or did locate them for some time, within the medical and scientific establishment but who because of their choice to pioneer alternatives, became controversial. Examples of researchers and clinicians who fit that category include Stanislaw Burzynski (antineoplastons), the late Lawrence Burton (immuno-augmentative therapy), Ernesto Contreras (laetrile, etc.), Joseph Gold (hydrazine sulfate), the late Virginia Livingston (autogenous bacterial vaccines), the late Harold Manner (laetrile, enzymes, and vitamin A), the late Linus Pauling (vitamin C), and the late Eli Jordon Tucker (DMSO and hematoxylon).

The controversies surrounding their research could be conceptualized in terms of the social studies of science literature as controversies within the scientific and medical communities between orthodox and unorthodox members (Hess 1997b). However, the research controversies are also connected to patients, via clinical applications, and patients and their friends have organized into a social movement. Therefore, the ACCT community is sociologically a combination of a network of researchers in a series of linked scientific controversies, a new social movement, and an incipient heterodox scientific community in which activist patients and unorthodox clinicians and researchers are working synergetically.

The relations among the scientific researchers, patients, and the leaders of

patient support and referral organizations are further complicated by biographical trajectories that result in a change of roles over time. The interviews identified a pattern whereby people tended to progress from naive patient to dissatisfied user of conventional therapies, to informed consumer of ACCTs, and on to referral or support-group person. In some cases they earn advanced degrees in nutrition or a biomedical field and achieve professional positions. The trajectory is similar to those found in other biomedical social movements, such as AIDS activism (Epstein 1996).

Likewise, there are cases of clinicians who have become dissatisfied with their conventional medical practices or who have sought ACCTs in response to their own cancer or that of a family member and become journalists or writers, publicizing the cause of ACCTs. The movement back-and-forth among patients, clinicians, and researchers—mediated by journalists and patient-support organization leaders—creates a dynamic interchange that is part scientific research community and part social movement.

POSITIONS: THE POLITICS OF EVALUATION

Interviews with the researchers, clinicians, and leaders of information-providing organizations focused on the question of evaluation. The main questions in the one-to-two-hour semistructured telephone interviews were what evaluation criteria they used and which ACCTs they thought most and least promising. Over the course of the interviews I learned to distinguish various types of evaluation: (1) the patient's needs at all levels, including financial, social, spiritual, and of course biomedical; (2) referral and patient support organizations; (3) clinicians and clinical organizations (including quality of service delivery); (4) the therapies themselves; (5) a meta-level involving criteria for evaluating therapies (such as randomized, controlled trials); and (6) policies and politics of research, funding, and regulation. The themes that emerged regarding the evaluation of therapies and criteria for evaluating therapies are reviewed elsewhere (Hess 1998). This section will summarize some of the views regarding methodology.

Many of the interviewees were well aware of the politics of randomized, controlled trials for ACCTs, including documented cases of design modifications that introduced biases against ACCTs (Houston 1989; Moss 1996). A critical, sociological, and historical literature on randomized, controlled trials is now beginning to emerge (e.g., Coulter 1991; Epstein 1996; Marks 1997). One set of criticisms in our interviews focused on the economic issues that exclude small-scale clinicians from pursuing the "gold standard" of randomized, controlled trials. Likewise, the unpatentable nature of most of the ACCTs implies that pharmaceutical companies are unlikely to invest the funds required to achieve FDA approval. Since the late 1980s the FDA has approved some conventional cancer drugs without randomized, controlled trials; however, the gold standard is often demanded for nontoxic, nonpatentable therapies. As journalist Robert Houston commented in one interview (Hess 1998), the gold standard is therefore a double standard.

Other criticisms focused on the problem of how placebo controls were impossible for such therapies as the Gerson dietary program, which involves coffee

enemas and a dozen glasses of juice per day. Some interviewees suggested testing clinicians and clinics as total units rather than specific therapeutic modalities, as tends to occur in conventional medicine. Others questioned the ethics of running any randomized clinical trials for late-stage cancer patients, who often request a clinical strategy of switching therapeutic modalities if the ones first attempted show no short-term benefit.

Interviewees were well aware of the hierarchy of evaluation methods and the difficulties of using retrospective outcomes analysis, case study reviews, and subclinical data as a basis for making decisions. However, notwithstanding the biopolitical situation, they often looked at all data and attempted to arrive at a holistic calculation that took into account legality, cost, ease of use, and safety. Several interviewees pointed to the outcomes analyses of Hildenbrand and colleagues (1995, 1996) as a possible model for future research and evaluation that does not compromise clinical ethics but allows for some of the rigor associated with controlled trials. In some cases, clinicians were willing to use substances that had support only at the lower rungs of the ladder of evidence if they appeared relatively safe and nontoxic, but they wanted higher levels of evidence for more toxic substances.

CONCLUSIONS

From the public understanding of science—in this case, the understanding that patients have of cancer—is still based on the transmission model. In other words, we (the medical community) know what science is, we do it, and we transmit it to you, the public and the patients, either directly (such as via the NCI website on ACCTs or the media) or indirectly (through your doctor). In its more democratic guises, the transmission model is linked to public education policies that attempt to transmit science to the “great unwashed.” A less democratic guise is a policy of suppression of ACCTs and their advocates. The politics of suppression can involve FDA raids on supplements firms and clinicians, FDA refusal to approve nonpatentable and nontoxic natural substances for cancer treatment, loss of medical licenses, prosecution of holistic doctors for involvement in alleged illegal medical practices, denial of grants to researchers who go outside the mainstream, and refusal to publish research. The effects of suppression can extend to social scientists who document the suppression, under the pretense that their work is not objective or value neutral.

Notwithstanding the strong support of the transmission model in scientific and medical communities, social scientists have increasingly documented the ways in which the understandings of patients and other publics differ from those of the expert producers whose knowledges and technologies they consume (Hess 1995, ch. 5; Irwin and Wynne 1996). The alternative that emerges from research on both sides of the Atlantic is the “reconstruction model”—that is, patients (or other public groups and social movements) operate as active agents who reinterpret and question expert knowledge. However, the mere recognition that lay understandings are different from those of the experts is only half the picture. Patients not only

have different understandings from those of doctors and researchers (see also Hunt, in this volume) but occasionally challenge research agendas and regulatory policies. A viable alternative to the transmission model needs to take into account not only the activity of patients and the public in their reception of expertise but also the ways in which the public shapes that expertise. It is therefore necessary to extend the reconstruction model to describe how pockets of the public coalesce into social movements and organizations that go beyond the reconstruction of expert authority. In some cases, public organizations develop their own research (such as lay epidemiology) and become involved in reshaping the research and regulatory agendas of the experts, often via alliances with unorthodox members of scientific research communities.

Consequently, a more accurate model of the relationship between the science and the public, at least for the case of ACCTs, is what I term the "public shaping of science" model. In this model, citizen groups coalesce from the public, and out of them emerge leaders who question the expertise of research establishments, produce alternative knowledge, and challenge research agendas. The process has been documented in other patient activist movements, such as repetitive-strain injury (Arksey 1994) and AIDS activism (Epstein 1996; Treichler 1991), and it is an extension of more general ways in which citizen groups affect the policy process (Peterson 1984). The case of ACCTs is distinctive, however, because of its emphasis on changing the research agenda toward the evaluation of less toxic therapies and diagnostic procedures, and because of the sophisticated quality of some of the research that has been produced.

As patients who use alternative and complementary therapies become more organized and more sophisticated about the biomedical politics of research and regulation, they have begun to have a policy impact. Such legislative reforms as the "Access to Medical Treatments" bill, which in 1999 was still pending approval in Congress, promise to give doctors and their patients the right to experiment with safe alternative therapies under conditions of informed consent. Versions of that legislation and related laws have already been passed in several state legislatures. A number of other policy reforms merit consideration and have been discussed elsewhere (Hess 1997a; Houston 1989).

Perhaps the most complicated issue of policy reform is the problem of evaluating ACCTs. As the medical community learns that the biopolitical landscape has been permanently altered, that patients and the public at large are demanding an increasing role in the shaping of scientific research agendas, the policy of suppression will be replaced by one of evaluation. In other words, whereas the transmission model leads to a policy of suppression, the model of public shaping of science suggests an alternative policy, evaluation. However, that policy cannot be embraced naively. The collective wisdom and experience of the leaders of the ACCT community note that in the cases where public support has led to clinical trials of ACCTs, trial designs have been manipulated to produce failures for ACCTs (Houston 1989; Moss 1996). Given the experience with prejudicial design alterations in trials for laetrile, vitamin C, hydrazine sulfate, and most recently anti-neoplastons (which Burzynski found out about during the trial, thus forcing can-

cellation), the interviewees were very skeptical that the major organizations associated with the cancer establishment could produce unbiased evaluations of ACCTs.

Accordingly, a policy of evaluation begins to replace a policy of suppression, there needs to be an awareness of the history of trials funded to end controversy that end up fueling it. Key figures from the ACCT community, such as Gar Hildenbrand, Robert Houston, and Ralph Moss—as well as moderate, mediating leaders such as Michael Lerner and Keith Block—need to be included in consultations over design. A number of policy checks needs to be implemented in the evaluation process. One example is the inclusion of multiple sites, including non-establishment organizations. The design of trials might even include site as a variable, employing such major alternative institutions as Tijuana hospitals or naturopathic universities. Another policy check is to give coprincipal investigator status to the ACCT advocate of a therapy, allowing that person complete access to the test site and protocols, to ensure that protocols are not altered after being implemented.

The question of preventing and controlling cancer in North America is therefore a complicated political issue. Clearly, more research and funding needs to be devoted to prevention, and those funds should be protected from being siphoned off into such projects as trials of preventive chemotherapy. The control of cancer, however, may ultimately rest on the public control of cancer politics and research.

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