At lunch with my good friend Bob Houston in April, he showed me an article from the latest issue of the American Cancer Society's pseudo-scientific monthly, Ca, a Journal for Clinicians. The article was a tedious put-down of nonconventional cancer therapy, written by a junior associate of Dr. Barrie Cassileth, the director of the integrative treatment program at Memorial Sloan-Kettering Cancer Center, New York.

My nose told me that the contents were ripe with age; the misinformation about the late Dr. Emanuel Revici, which I turned to first, dated from the mid-1960's. I know a thing or two about Revici's treatment; the few sentences which the writer allotted to it revealed total ignorance. Bob advised me that the rest of the article showed the same rot, so I read no further.

I take Bob Houston's advice seriously. He's been publishing articles and letters in magazines and medical journals since the late 1960s. One of his specialties is nutritional therapies. He also admits to a fair amount of knowledge about the design and conduct of clinical trials, particularly the ways in which they can be jiggled to give optimal results in mainstream studies and minimal or no positive findings in studies on alternative medicine.

When Congress authorized the late Office of Technology Assessment to report on unconventional cancer treatment in 1987, the alternative "camp" chose Houston to write its position paper. Then, they split over what they felt the paper should say. Bob wrote a large part of what he had in mind anyway, and two patients on alternative therapy modestly compensated him for his independent labor. Issued as a reduced typescript by the Immuno Augmentative Therapy Patients Association (IATPA) in 1987 under the title, Repression and Reform in the Evaluation of Alternative Cancer Therapies, Houston's monograph still applies. Its insights into how the evaluative process is biased against unconventional treatments are just as true today.

These days, though, Bob prefers to write music, a muse-driven activity practiced from childhood -- decades before he joined the front rank of the defenders of CAM. But he keeps up with CAM developments, occasionally sticking a figurative finger in the air to catch which way the wind blows in the world of health care. At our April lunch, I interviewed him between mouthfuls of Chinese food. The broad subject: Changes in clinical trial design that might speed up the evaluation of unconventional approaches to treatment for a range of diseases.

Interview with Robert G. Houston

"The OTA published its report in September 1990," I led, following with two questions: "Did evaluative criteria for trials at the National Cancer Institute (NCI) change afterward? Did the FDA relax its criteria for the approval of new drugs?"

"In 1989, even before the OTA report came out," Houston recalled, "Dr. Frank Young, the FDA commissioner, initiated a fast-track system for approvals. It bypassed large-scale, randomized trials where smaller, less rigorous trials gave dramatic results. The system was mainly for AIDS drugs. A few new cancer drugs got market approvals, too. Young was responding primarily to political activism by AIDS patients. Breast cancer patients played a lesser role."

Houston continued: "Back in 1990, some cancer activists joined the AIDS patients in calling for more flexible criteria for approval of new treatments. In the context of therapies based on natural substances, flexibility made sense; these substances generally have a high safety factor. In relation to such toxic drugs as AZT for AIDS, though, putting hugely toxic drugs on the fast track was disastrous! Remember that AZT was first tested at NCI, where it proved too toxic for further trials. AZT can cause or exacerbate immune deficiencies in humans. It causes immune deficiency in healthy animals."

"So your conclusion about fast tracking? I broke in.
"It killed thousands of AIDS patients," Houston said. "With a fast-track system, there has to be far more concern for safety issues."

I touched on the NCI reaction to the OTA study. "Did the OTA report have any effect?"

Houston drew on his memory again: "The OTA recommended a best case study of at least ten patients as a feasible first step in evaluating unconventional cancer treatments. But the NCI offered no promises to follow up, no guarantees that successful best case studies would lead to clinical trials -- or to any interest by the government in these cases. Intrinsically, it was a risky step for unconventional innovators who might submit treatment data. Placing all their paperwork on record exposed them to prosecution, invited reprisal by the FDA."

Houston looked at his wristwatch at this point, excusing himself to do an errand. He directed me to Frank Wiewel, in Iowa. "We're getting political," Bob said, "and Frank's the best person to speak to about government involvement in alternative cancer treatment."

Wiewel is also a musician. He played with a rock band in the early 1980s, before his father-in-law developed cancer and sought immuno-augmentative treatment at the Burton clinic in the Bahamas. Closure of the Burton clinic in 1985 by the Bahamian government turned him into a performer on the congressional stage. (According to Bob Houston in Repression and Reform, the NCI and other US agencies instigated that temporary shut-down.)

From 1985 to 1990, Wiewel led Burton's support group, and was a key player in convincing Congress to authorize the OTA study. (Originally, the study was to focus on Burton's therapy.) Since then, Wiewel has been a major voice in urging government evaluation of nonconventional cancer treatment. He now directs People Against Cancer (PAC), headquartered in Otho, Iowa, a
grass roots organization that remains at the forefront of political activities to obtain clinical trials of nonconventional medical approaches. PAC also provides information on cancer treatment on a fee basis.

Interview with Frank Wiewel

I reached Frank Wiewel by phone a few days later. "There's definitely something happening here in Iowa," he remarked. "We've got Senator Tom Harkin, a liberal Democrat, and Senator Chuck Grassley, a conservative Republican with libertarian leanings in health care. Both are statesmen who can be counted on to do the right thing. Both support alternative medicine and use it. Then, there's former Congressman Berkeley Bedell, who's been taking unconventional therapies for years: he's established a foundation devoted to alternative medicine."

Cutting in, I said, "Let's return to 1990, Frank. What's happened of consequence politically after publication of the OTA report? What did you hope the report would accomplish?"

"We thought the OTA report would help codify studies of alternative cancer treatment. There was a need for that in the early 1990s. When Congress established the Office of Alternative Medicine (OAM) in the NIH in 1992, largely through the efforts of Harkin and Bedell, we felt it might promote the organized evaluation of alternative cancer therapies, might broaden the base for later evaluations. Harkin, with Grassley and Bedell pitching in, worked on the NIH to help the OAM set up pilot trials. Ralph Moss and I spent six years in Washington pushing for such trials, but the NIH never gave the centers the OAM started in different areas of medicine a chance to do a real study."

Wiewel went on with the history lesson: "When Congress created the National Center for Complementary and Alternative Medicine (NCCAM) in 1997, enlarging its budget and providing greater autonomy within the NIH, the NIH frustrated attempts to make NCCAM an effective substitute for the OAM. Referring the projects planned by NCCAM, which the NIH showed no real interest in backing, the NIH said, 'We do things in different ways.' One sensed, however, that the NIH didn't want even the preliminary best case studies of alternative cancer treatment to get off the ground, because they might find something positive."

"We told them, 'Look, it's a win-win situation. If these studies point to promising alternative treatment, everybody wins - the public most of all. If nothing effective comes out of the preliminary trials on unconventional care, you win.' The NIH wouldn't budge!"

"Senator Harkin hauled the NIH director, then Dr. Harold Varmus, into his office and for two hours he tried to convince Varmus to do the right thing with NCCAM. Varmus refused, later quiting the NIH to become director of Memorial Sloan-Kettering. His successor at NIH have also stalled."

"So where do we go from here, Frank?"

"Back to square 1, back to grass roots calls for change, back to individual alternative cancer therapists seeking funds for pilot studies on their own."

Wiewel paused to tell me about a recent meeting with Grassley, who chairs the Senate Finance Committee: "I suggested to the Senator that the weight of the whole, insane system of testing new drug treatments might soon bring about its collapse. The cost of researching and developing a single drug through the FDA's safety and efficacy requirements, through clinical trials, is now 700 million dollars," I told him. He replied, 'Think 1 billion, Frank.'"

Interview with Mark Noble, PhD

I phoned Dr. Mark Noble at the University of Rochester, New York. Noble, a cell biologist, specializes in research on the development of cancers of the nervous system. The government research institutions clearly had no appetite for nonconventional approaches to cancer treatment. I wanted to know if the mainstream had been pursuing any new, truly promising, exciting avenues of investigation. Noble keeps an open mind about alternative medicine. He's familiar with therapies pioneered by a number of alternative physicians, Emanuel Revici among them.

"Generally," he said, "there have been advances in treatment for low-grade tumors, really solid progress, but advances in therapy for high-grade cancers have just been incremental."

"What about Dr. Judah Folkman and his colleagues, studying angiogenesis factors?" I asked. "At one time the potential of these agents interested you."

(Angiogenesis is a process through which cancers form blood vessels that supply them with nourishment. Folkman’s "factors," isolated by him over 20 years of research, are various substances that tumors produce which can promote or inhibit tumor and metastatic growth.)

"A wide range of antiangiogenesis drugs are under investigation, still in the first stages of testing," he said. "The final results of these trials are not yet in."

"Can you give me an example of a hot new chemotherapy, one more effective and less toxic than standard chemo?"

"Yes," he said. "Gleevec, in chronic myelogenous leukemia (CML). It's been tested for about three years, and in CML that hasn't reached blast crisis the results have been fantastic. An enormous number of patients go into remission. Once the leukemia goes into blast crisis, though, Gleevec hasn't been very useful. It has shown less toxicity, so far, than earlier chemotherapy, cisplatin, for instance."

("Blast Crisis" or "cycle" refers to the phase of CML in which the number of immature, abnormal white blood cells in bone marrow and blood is extremely high. It is the terminal event in the clinical course of CML.)

"Who developed Gleevec? How does it work?"

"Oregon Health Sciences," Noble answered. "Gleevec emerged from NCI research on signaling pathways involved in cell division, and, by extension, abnormal cell division."

"Anything else noteworthy in the mainstream?" I asked.

"Some members of the CAM community have used low-dose chemotherapy for years. Now, many trials of low-dose therapy are underway at mainstream institutions. It seems a promising, less toxic method of treatment. Its major site of action, like Folkman's angiogenesis agents, are endothelial cells."

(Endothelial cells make blood vessels.)

"Does it have a name?"

"Metronomic Therapy."

"Meaning?"

"The ability to give frequent exposures in low doses."

In a future column, I'll interview Peter Barry Chowka, an independent investigative journalist who has published articles on nonconventional therapies since the 1970s; Michael Lerner, PhD, director of Commonweal (Bolinas, California), a special consultant to the OTA during its study of unconventional cancer treatment; and Ralph Moss, PhD, author of The Cancer Industry (and numerous other books on cancer), whose on-line service (www.cancerdecisions.com) provides information on alternatives to conventional care for a fee.

All three are veterans of the cancer wars and may have hopeful news about action along the battlefield to share with readers of the Townsend Letter.