

DUBIOUS CANCER TREATMENT

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Florida Division, Inc.

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IMMUNO-AUGMENTATIVE THERAPY

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In 1987, immuno-augmentative therapy (IAT) was available only at Immunology Researching Centre, Ltd., an outpatient clinic in the Bahamas. The facility, which opened in 1978, is directed by Lawrence Burton, Ph.D., whose doctoral degree is in zoology. Despite its limited geographic availability, IAT draws many patients and has an active lobby that promotes its use.

IAT literature states that the average length of treatment at Burton's facility is six to eight weeks. In 1987, the estimated clinic fees were \$5,000 for the first four weeks and \$500 per week after that. After the patients returned home, the maintenance program cost \$50 per week.

Dubious Theories

Burton postulates that cancers develop because of a breakdown in the immune system and that IAT restores the body's natural defenses. A 20-page clinic brochure I acquired in 1987 states:

Tumor antibodies are "alerted to the presence" of tumor cells by a protein produced by the tumor cells themselves—tumor complement factor. Tumor complement induces the tumor antibodies to destroy the tumor cells. If the tumor cells are destroyed in an unregulated manner, however, a person's liver may become overburdened. . . . To protect the body, blocking protein factors are produced to shield the tumor cells from attack by the tumor antibodies and thereby regulate the rate of tumor kill. The important balance of tumor kill rate is maintained by yet another blood component—deblocking protein factor . . . which neutralizes the blocking protein and thereby permits antibodies to destroy tumor cells in a regulated manner. At times this

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protein factor exists, along with undersupplies of deblocking protein factors and tumor complement factor. When this imbalance . . . occurs, the individual is said to be immuno-suppressed or immunodeficient.

The brochure describes IAT as a two-step procedure. Each day Burton's laboratory assesses the levels and proportions of "tumor complement," "tumor antibody," "deblocking protein," and "blocking protein." Then the patient is given daily injections of "tumor complement factor" obtained from the serum of persons with cancer and "deblocking protein factor" and "tumor antibody" obtained from the serum of persons without cancer. Dosages are determined by analyzing these data with a computer program developed by Burton and his colleagues. After they consider the patient "stabilized," a computer readout is prepared for a daily program of injections administered to the patient at home.

Burton does not claim that IAT products attack cancers directly. Therefore, failures are attributable not to his treatment but to unresponsiveness of the patient's immune system due to damage by prior treatment or advanced disease. (Burton claims that chemotherapy can reduce tumor complement and that radiation therapy can depress deblocking protein.) He advises patients undergoing IAT to stop other therapies "so as not to confuse other data."

Burton holds several patents for extracting proteins, but his computer program is secret. In 1985, consultants from the Pan American Health Organization asked whether they could observe the preparation and dispensing of his protein fractions. According to their report, Burton replied, "You can go to Washington, pay three dollars, and get a copy of my patent."

Saul Green, Ph.D., a biochemist who worked for many years at Memorial Sloan-Kettering Hospital doing research into the mechanisms and treatment of cancer, has examined the patent applications. Dr. Green, who is renowned for his work in protein chemical analysis, concluded that it is not possible to isolate the substances Burton claims to use by the techniques described in the patents. Dr. Green has noted, for example, that centrifugation using the speeds and times described in the patents is highly unlikely to be able to separate proteins with the molecular weights Burton ascribes to "tumor complement," "tumor antibody," "deblocking protein," and "blocking protein."

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No independent analysis of IAT treatment materials has been carried out on samples provided by Burton himself. Nor has Burton published any results of analyses he has done on the nature and contents of the protein fractions he says he uses to treat patients. However, scientists at the National Cancer Institute have analyzed unopened vials provided by the family of a deceased patient and concluded that they were typical blood proteins and did not contain the components Burton postulates [JAMA 255:505-507, 1986].

Questionable Results

Burton has conducted no controlled trial of his treatment and has not reported detailed case histories of his patients. But claims of IAT success are recorded in other ways. The 20-page clinic brochure contains a chart of about 40 types of cancer in various stages and scores a "+" if half or more "have responded to IAT with long-term regression of tumors and/or remission of symptoms."

This type of presentation may impress laypersons, but it is not a scientific way to assess a cancer treatment. In a 1984 deposition, the clinic's medical director, R. John Clement, M.D., said that the clinic had seen about 2,400 patients and that "if a patient showed an improvement in a matter of two or three weeks, that is regarded as a response for cancer purposes." In a 1987 speech, Dr. Burton said that by monitoring the immune system of patients with his four tests, he can usually determine whether there is a positive response to IAT therapy within three or four days.

In April 1981, while the Florida legislature was considering whether to legalize IAT in Florida, Burton gave each member a 3-inch-thick loose-leaf book entitled *IAT*, which contained documents quoting claims for IAT, as well as a copy of *The Cancer Syndrome* by Ralph Moss.

The legislators also were given a binder containing testimonials. The first section included 142 "cancer victims whose immune systems have responded successfully to IAT." Two of these patients did not have cancer, and six did not specify when their treatment began or the date the testimonial was signed. Of the remaining 134 patients, 39 (29%) had begun treatment less than two months before their testimonial had been obtained, and 50 (37%) had given their testimonial between two and six months after starting treatment. This is hardly sufficient time to evaluate a cancer treatment.

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Quite by chance, I learned that two of these patients had died at least two months before Burton presented their testimonials to the legislature. Both had had breast cancer. One was a woman whose affidavit—obtained less than four months after she began IAT—stated, “Improvement in bone metastases confirmed by a bone scan.” She died of her disease two months after signing her affidavit. The “improved” bone scan (of a rib) had actually been due to *progression* of her disease. Ordinary x-ray films showed that metastatic tumor had completely destroyed the rib, so there were no radioactive bone cells in that area for the scanner to detect. The other patient had signed her affidavit five weeks after beginning IAT treatment. Eight days after the signing, she became comatose and was admitted to a Miami hospital. She died five days later, and the autopsy showed extensive metastatic disease.

In July 1981, Kenneth Monson, M.D., a radiation therapist in Pompano Beach, released the following statement at a press conference on behalf of the Florida Society of Clinical Oncology:

I have had first-hand experience with Dr. Burton and his patients, having treated 13 of his patients, consulted on two more, and visited his clinic. Dr. Burton and his associate were quite open with me in regards to their experience and theories, but documentation was poor to nonexistent. I left with the impression that he gives tender loving care, but I could not evaluate the effectiveness of his treatment. Subsequent to that visit, my experiences with his patients have been nothing short of disastrous. . . . To the best of my knowledge, only one of the fifteen patients is alive, and he is on conventional treatment.

The MetPath Contract

In 1979, Burton entered a contract with MetPath, the nation’s largest biomedical laboratory. The material he presented to the Florida legislature claimed that this contract provided “another practical validation of the principles on which IAT is based.” It also stated:

MetPath thoroughly investigated the IAT early detection test . . . In the process of its investigation, MetPath sent 193

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numbered vials of blood samples to the IAT lab in Freeport, Bahamas, and requested that the blood samples be tested.

The results . . . were spectacular. The IAT early cancer detection test proved to be so sensitive and accurate that it identified the blood samples of 6 persons out of the 193 samples as persons who were highly likely to contract cancer in the future. The identification of future cancer victims also proved to be 100% accurate since all 6 persons contracted cancer within two to six months later!

—MetPath's successful testing of the IAT early detection test validates the principles on which IAT is based. In addition . . . MetPath has recently purchased a license to adapt and use the IAT early cancer detection test for its mass-testing requirements. Thus, the . . . test may soon be marketed nationwide by MetPath to hospitals, clinics and physicians for testing the millions of persons who would like to know if they either have cancer now, or if they are likely to contract cancer in the near future.

In October 1981, I asked MetPath's board chairman Paul A. Brown, M.D., whether Burton's account was accurate. He replied that Dr. Burton and MetPath had entered an agreement with a 4-part protocol:

The first phase . . . was to verify the existence and determine the measurability of the substance in serum said by Dr. Burton to be related to the presence or absence of cancer. Secondly, we proposed to develop a commercially viable technique to measure this substance. . . .

Based on . . . the information furnished by Dr. Burton and extensive laboratory testing we have concluded that there exists a substance in serum the level of which is related to the presence or absence of malignant carcinoma. We were, however, unable to develop a sufficiently reliable technique to measure or identify this substance. In fact, we obtained 25% false positives in patients known to be free of cancer and 25% false negatives in patients known to have cancer.

Based on our inability to discover a sufficiently reliable test, we were not able to proceed with phases three and four of our protocol and, accordingly, our agreement with Dr. Burton was terminated in December 1980.

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Notwithstanding Dr. Burton's assertions to the contrary, our contract was not "another practical validation of the principles upon which IAT is based". . . . MetPath no longer has any relationship with Dr. Burton and, accordingly, MetPath has no plans to market the Burton test. We are quite distressed about assertions being made by Dr. Burton and hope this letter will put any misconceptions to rest.

Note that the contract was terminated four months before Burton acclaimed it to the Florida legislature.

Legislative Action

Despite criticism by the scientific community, many Florida legislators were sympathetic to the idea of legalizing IAT within the state. But first the bill to accomplish this was amended to permit the use of any unproven therapy for which a protocol and periodic data were presented to a patient qualification review board. This bill was passed in 1981, but was vetoed by the governor amidst cries that "Florida will become the quackery capital of the world!" During 1982, the legislature passed the bill again and overrode the governor's veto. But two years later, after Burton had shown no interest in operating within Florida and no one else had utilized the act's provisions, it was repealed.

Bahamian Apathy

To me the most disturbing aspect of the IAT situation is the role of the Bahamian government, especially its Ministry of Health. The Immunology Researching Centre began operating in the Bahamas in 1977. During the following year, representatives of Bahamian Ministry of Health and the Pan American Health Organization visited the facility and reported:

Forty-nine charts were reviewed, which were selected by the center's staff, to represent patients who had what this staff considered to be encouraging results. These included patients who allegedly had regression of disease or stability of disease. In the majority of these cases, the best that could be said is that there was insufficient information to reach any

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be said is that there was insufficient information to reach any kind of judgment. . . . The charts of the patients who had been in the program and who had died were not reviewed.

With regard to the laboratory evaluation and treatment, the report stated:

Insufficient data were presented to make it possible to determine whether any of the laboratory tests being performed are reproducible. . . . It is therefore impossible to determine whether this test is a test for anything, and if in any way the information being used to calculate the doses of the material administered to the patients has any validity whatsoever. The material being used to treat the patients simply is a totally unknown quantity.

The report concluded:

The present procedures of the center do not permit any meaningful evaluation and it is highly unlikely that any changes in the procedures will make the treatments valuable. Further, it is emphatically stated that no consistent treatment effect has been achieved when assessed by objective criteria. It is recommended, therefore, to close the Immunology Researching Centre.

In June 1984, Gregory N. Curt, M.D., a National Cancer Institute official, notified Dr. Burton of the results of his studies of IAT materials that had been given to Burton patients. He noted that eight IAT fractions from two patients were contaminated with bacteria, and that one patient's materials were positive for hepatitis, suggesting that a hepatitis carrier inadvertently had been used to derive treatment materials. When Burton did not respond, Dr. Curt asked Dr. V.T. Allen, chief medical officer of the Bahamian Ministry of Health, for help in suggesting that Burton institute verifiable quality control procedures. A few weeks later, Dr. Allen replied, "I have taken another step to attempt to assure some degree of control of exercise at the institute in Freeport."

Dr. Curt then complained that another case of hepatitis had appeared, and that a patient on IAT had developed a fulminating *Pseudomonas* infection. He asked Dr. Allen to provide a list of

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patients with their addresses so that potential problems of infection could be controlled. Dr. Allen suggested that Dr. Curt address his concerns to Dr. Clement, which he did. Dr. Clement did not reply.

During 1985, public health officials found antibodies to the AIDS virus in vials of serum obtained from several patients—suggesting that blood infected with the AIDS virus had been used to prepare IAT treatment materials. Antibodies to hepatitis B (a serious liver infection) have also been found in IAT serum, and several cases of this disease have occurred following treatment at Burton's clinic.

Because of the public health risk involved, the Bahamian health authorities asked the Pan American Health Organization to send consultants to inspect Burton's clinic again. The consultants reported:

The visit to the clinic was essentially unproductive. . . . Some miscellaneous information was obtained, such as the fact that the clinic has treated AIDS patients . . . The overall impression [of the report's writer] was one of dismay and concern for the lack of scientific knowledge displayed by the clinic staff, including the director, the unscientific atmosphere in the laboratories and the considerable potential for harm.

The consultants advised the Ministry of Health to close the clinic. It was closed in July 1985, but was allowed to reopen in March 1986. In April, as chairman of the Florida Cancer Control and Research Advisory Board, I asked Dr. Allen for detailed information about what measures were being taken to assure that IAT materials were safe. He answered:

The Centre resumed its operation under conditions set out by the Ministry of Health which are designed to eliminate the health hazards to staff and client. The materials as well as the final product to be administered must be certified as free from contaminants, both chemical and microbiological. The Ministry of Health may authorize its representatives or agents to carry out inspections and reviews in order to ascertain compliance by the Centre. Such agents may include international investigators.

I wrote again to get more specific information and offered to send a Florida Health Department team to make an inspection. This

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time Dr. Allen did not respond. In August 1986, the FDA issued an Import Alert advising U.S. Customs and the Postal Service authorities to stop the importation of IAT materials into the United States. But Burton is still very much in business and has opened clinics in Mexico and Germany.

The OTA Study

The Office of Technology Assessment (OTA) is a nonpartisan support agency which provides congressional committees with analyses of emerging, difficult, and highly technical issues. In 1986 U.S. Representative Guy V. Molinari (R-NY) held a hearing after which he and about 40 other congressional representatives asked OTA to evaluate immuno-augmentative therapy. Subsequently, Representative John Dingell, chairman of the House Energy and Commerce Committee, asked OTA to study unconventional cancer treatments, with IAT included as a case study. OTA then appointed a working group composed of technical experts and representatives of Burton to try to design a protocol with which IAT could be properly evaluated. However, in December 1989, the effort was abandoned because final agreement could not be reached about certain details. OTA's account of what happened is included in a lengthy report that was released in September 1990.*

A scientifically run clinical trial would certainly help the general public place IAT in perspective. But it remains to be seen whether Burton will ever conduct or cooperate with such a test.

*The 312-page OTA report (*Unconventional Cancer Treatments*—GPO stock #052-003-01207-3) is available for \$14 from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.