

# Unproven Methods of Cancer Management

## Livingston-Wheeler Therapy

*After study of the literature and other available information, the American Cancer Society has found no evidence that therapy offered by the Livingston-Wheeler Clinic results in objective benefit in the treatment of cancer in human beings. Lacking such evidence, the American Cancer Society strongly urges individuals with cancer not to seek treatment at the Livingston-Wheeler Clinic.*

The following is a summary of the material on the Livingston-Wheeler Clinic in the American Cancer Society files as of February 1989. Reference to that material does not imply agreement with its contents.

### Background

The Livingston-Wheeler Clinic in San Diego, California, treats cancer patients with a complex therapy developed by Virginia Livingston-Wheeler, MD. Treatment consists of vaccines, antibiotics, megavitamins and other nutritional supplements, digestive enzymes, enemas, and a strict whole-foods diet that eliminates poultry and eggs.

The clinic (originally called the Livingston Clinic) was established in 1969 by Livingston-Wheeler and her late husband, Dr. A.M. Livingston. Although patients with arthritis, allergies, and AIDS are also treated, the clinic specializes in cancer therapy. The stated purpose of the clinic is to treat ambulatory cancer patients “who have some possibility of remission.”<sup>1</sup>

### Proponents

Virginia Wuerthele Livingston-Wheeler (formerly Virginia Wuerthele-Caspe) was born in 1906. She received her bachelor's degree from Vassar College and her MD from New York University School of Medicine in 1936. After working with women prisoners in New York City, she accepted a position as school physician in Newark, New Jersey. In 1949 she became head of Rutgers-Presbyterian Hospital Laboratory for the Study of Proliferative Diseases. In 1953 she moved to California, eventually settling in San Diego. After the death of her first husband, Dr. Joseph Caspe, she married Livingston, and together they opened the Livingston Medical Clinic in San Diego in 1969. Following the death of her second husband, she married Dr. Owen Wheeler, one of her former cancer patients, and the clinic was renamed the Livingston-Wheeler Clinic in 1976.

Approximately 500 patients are treated annually by the six full-time physicians employed by the clinic. In 1984 Livingston-Wheeler estimated that more than 10,000 people had been treated at the clinic since it first opened in 1969.<sup>2</sup>

### Proponent Claims

The treatment is based on a belief that cancer is caused by a weakened immune system that allows the unchecked growth of a bacterium that Livingston-Wheeler has

named *Progenitor cryptocides*. She describes this as a ubiquitous microorganism that normally lives in humans and animals and becomes pathogenic only when the immune response is inadequate.<sup>2</sup>

Dietary deficiencies weaken the immune system, according to Livingston-Wheeler: "The modern diet is simply deficient in providing the nutrition essentials that maintain a healthy, vital immunity to cancer."<sup>2</sup> She claims to have achieved "remarkable results with human cancer patients by using immunotherapy techniques to help their own bodies ward off tumors and literally destroy them."<sup>2</sup>

In 1947 she published a report of an organism, which she tentatively named *Sclerobacillus Wuerthele-Caspe*, found in scleroderma patients, that was similar to the mycobacteria for tuberculosis.<sup>3</sup> She reported that cultures of this organism produced neoplastic changes when injected into laboratory animals.<sup>4</sup> Subsequently she reported finding a similar bacteria in malignant tissue from humans and animals,<sup>5-7</sup> which she named *Progenitor cryptocides* and classified as a member of the Mycobacterium family, order Actinomycetales.<sup>8</sup> *P. cryptocides* was described as acid-fast (not decolorized by acid-alcohol after having been stained with a dye) and pleomorphic (having more than one form during its life cycle),<sup>8</sup> which she claimed made the organism easily mistaken for other types of bacilli, viruses, and fungi.<sup>9,10</sup>

Based on her research and that of her colleague Dr. Eleanor Alexander-Jackson, Livingston-Wheeler developed the theory that *P. cryptocides* was the cause of cancer. In 1965 they described an experimental treatment against *P. cryptocides* that included an autologous vaccine, a low-carbohydrate diet, antibiotics, and digestive enzymes.<sup>10</sup> This description forms the basis of Livingston-Wheeler's approach to treating cancer.

In 1974 she reported that *P. cryptocides* produces relatively large quantities of human chorionic gonadotropin (HCG), a finding she believed to be unique to this organism and one that might prove useful in the early diagnosis of cancer.<sup>11</sup> She theorized that HCG was responsible for the cachexia

of patients with advanced cancer. Since HCG is produced by the placenta and is involved in the rapid growth of fetal cells, she concluded that bacteria-produced HCG probably accounted for the growth of cancer cells. Vaccination to halt the production of HCG by *P. cryptocides* might therefore provide a basis for treating cancer, she suggested.<sup>11</sup>

Based on earlier research by Alexander-Jackson,<sup>12</sup> Livingston-Wheeler has noted that the Rous virus, which causes neoplastic disease in chickens and other birds, is actually *P. cryptocides*.<sup>2</sup> Because she believes that the bacteria is transmitted to humans by eating chicken and eggs, she advises patients to exclude these items from their diets.<sup>2</sup>

In her 1984 book, *The Conquest of Cancer*,<sup>2</sup> Livingston-Wheeler claimed a success rate of 82 percent (with success defined as either being free of cancer on medical follow-up or "doing well" if cancer was still present), based on 62 case histories out of an original 100 pulled randomly from the clinic's files. She excluded patients with diagnoses other than cancer, those who were "too weak and ill to carry out the program," and those who stopped treatment and continued with traditional therapy. According to the brief descriptions provided in each of the 62 case histories, most of the patients had also undergone surgery, radiation therapy, and/or chemotherapy elsewhere, before, during, and/or after treatment at the Livingston-Wheeler Clinic.

### Investigations of Claims

The idea that cancer is caused by bacteria is not new. It was proposed in 1916 by Leyton and Leyton;<sup>13</sup> Glover claimed to have found the bacteria that causes cancer in 1926<sup>14</sup> and then, in 1930, to have developed a vaccine.<sup>15</sup> Investigators at the National Institutes of Health, however, could neither substantiate the presence of a microbe nor duplicate the vaccine from organisms supplied by Glover.<sup>16</sup> The hypothesis that a bacteria causes cancer was thus discarded by most scientists more than 50 years ago.

Investigators who have attempted to confirm the existence of *P. cryptocides* have concluded that Livingston-Wheeler was in error.<sup>17-21</sup> Her methods for identifying the bacterium were limited, consisting mainly of microscopic examination and culture characteristics. Since many organisms look the same microscopically and behave similarly in culture, such classification errors were common before DNA hybridization techniques and other advances became available.

Even given the limitations of technology, however, Livingston-Wheeler's method of classification contains some remarkable errors. In her 1970 paper enumerating the 24 characteristics of *P. cryptocides*,<sup>9</sup> she notes that the spores are resistant to autoclaving, a characteristic not exhibited by the order Actinomycetales in which she claims the organism belongs. Furthermore, the guanine-cytosine content of *P. cryptocides* was said to be 38 percent,<sup>12</sup> whereas Actinomycetales has a content of about 63 percent. Interestingly, the guanine-cytosine content of *Staphylococcus* is 30 to 40 percent, which is consistent with the conclusions drawn by other researchers who analyzed bacterial strains provided by Livingston-Wheeler (see below).

Technology over the last two decades has allowed more precise characterization of microorganisms. When immunohistochemical techniques were used to analyze *P. cryptocides* cultures supplied by Livingston-Wheeler, all nine of the samples were identified as *Staphylococcus epidermidis*.<sup>17</sup> DNA-DNA hybridization techniques confirmed that several strains of *P. cryptocides* were actually other bacteria that were not related to each other.<sup>18</sup> In subsequent analyses of cultures provided by Livingston-Wheeler, the organisms were found to be several varieties of *Staphylococcus* and *Streptococcus faecalis*.<sup>19-21</sup>

Cultures supplied by Livingston-Wheeler were confirmed to produce HCG.<sup>22,23</sup> Her claim that HCG is a unique product of *P. cryptocides*, however, has been disputed in several studies. Investigators have found that HCG is produced by a

variety of bacteria from both cancer patients<sup>17,20,21,23</sup> and normal human tissue.<sup>24</sup>

### The Livingston-Wheeler Regimen

The majority of patients seeking treatment at the Livingston-Wheeler Clinic have already received standard treatment with surgery, radiation therapy, and/or chemotherapy, and many continue these treatments while receiving therapy at the clinic. Some patients in remission seek treatment at the clinic to prevent a recurrence. Despite her disparaging remarks about orthodox treatment,<sup>2</sup> Livingston-Wheeler refers patients to other physicians for conventional therapy.<sup>25</sup>

### Immune System Enhancement

The Livingston-Wheeler *Physicians Handbook*<sup>1</sup> describes the purpose of the treatment as stimulation of the patient's immune system to produce antibodies against *P. cryptocides*. The basis of this treatment is an autogenous vaccine made from each patient's individual strain of bacteria. The bacteria, which is usually obtained from a urine specimen (although blood or tumor tissue is also used), is grown in culture, killed, and processed to produce a vaccine. The autogenous vaccine is administered twice weekly, alternating between injections and oral doses. Patients are advised that they must continue taking the vaccine for the rest of their lives.

Because the autogenous vaccine takes about three weeks to manufacture, treatment is started with several vaccines to stimulate the immune system immediately but nonspecifically. Bacillus Calmette-Guérin (BCG), a vaccine against tuberculosis, is given because of the purported similarity between the tuberculosis bacteria and *P. cryptocides*. Patients are first given a skin test using purified protein derivative (PPD) to determine whether they are immune to the tuberculosis bacteria. Patients who test negative lack immunity to the bacteria, which is considered an indication that their immune systems are depressed, and are given BCG.

Other vaccines are also used, although when or how they are administered is not specified. In an affidavit submitted to the US Department of Health and Human Services (HHS) in 1986,<sup>25</sup> Livingston-Wheeler noted the following: "purified antigen," described as a purified extract of a fraction of the cell wall of *P. cryptocides*; and Mixed Respiratory Bacterial Vaccine, manufactured by Hollister-Stier, administered on the theory that cancer patients have continuous chronic inflammation. This vaccine produces antibodies to secondary infections and, it is claimed, helps raise the immune level. In addition to the PPD skin tests, "red" and "green" vaccines (manufactured by Pharma-Selz in West Germany) are sometimes administered. Both are described as "nonspecific vaccines" that stimulate the reticuloendothelial system to form antibodies.<sup>25</sup>

Various other agents described as enhancing the immune response are used, including injections of gamma globulin once a week, injections of sheep spleen extract one to two times a week, "Custom Formula" (described as spleen and liver extracts from sheep—it is unclear whether this is an oral or injectable preparation), and injections of crude liver extract and vitamin B<sub>12</sub> one to several times a week.

According to Livingston-Wheeler, routine antibiotic therapy is important to reduce the *P. cryptocides* population. Drug selection is based on the patient's bacterial cultures, and therapy is continued for several months. Penicillin, erythromycin, cephalixin, tetracycline, furazolidone, and methenamine mandelate are prescribed.

#### Adjuvant Therapy

Levamisole (an anthelmintic) is given in doses of 50 mg each, three times a day for three days on alternate weeks. Fresh whole blood transfusions—from a family member whenever possible—are also sometimes administered.

To rid the intestinal tract of *P. cryptocides*, the bowel is cleansed with castor oil, epsom salt, or a Fleet's enema. Thereafter, daily enemas with coffee, lemon juice, or

plain hot water are used for the purpose of keeping bacterial growth low and removing toxins. Lactic acid bacillus is prescribed for the purpose of maintaining a desirable intestinal flora.

*P. cryptocides* is said to require an alkaline environment for optimal growth. Digestive enzymes (hydrochloric acid, chymotrypsin, and pineapple and papaya enzymes) are prescribed to help maintain blood and urine pH (acidity) at 6 or lower. Patients are instructed to test the pH of their urine several times a day using nitrazine paper and to increase the dosage of digestive enzymes if the pH rises above 6.

Megadoses of vitamins and minerals, given both by injection and orally, are used for all patients, on the assumption that cancer causes vitamin deficiencies. Vitamins A, C, D, and E and the individual B vitamins are prescribed, as well as calcium, magnesium, selenium, and iodine. Debilitated patients are given as much as 30 g of vitamin C a day intravenously.

Abscisic acid (or Dormin), a derivative of vitamin A and carotene from plants, is emphasized in the program. Livingston-Wheeler describes abscisic acid as inhibiting tumor growth and destroying HCG.<sup>2</sup> A computer search of the scientific literature, however, found no reports of any studies of abscisic acid.

#### Diet

Livingston-Wheeler describes the anti-cancer diet as "not intended as a treatment for cancer, but rather as a way of raising immunity and increasing the patient's resistance to disease."<sup>2</sup> Based on the theory that *P. cryptocides* enters the body via infected foods—especially poultry and other meat—she prescribes a strict vegetarian diet that is 75 percent raw fruits and vegetables. Poultry, meat, eggs, milk, sugar, processed foods, food additives, alcohol, caffeine, and fluoridated water are all eliminated from the diet. After the patient is in remission, a less strict "maintenance diet" is permitted that allows fish (but not shellfish), lamb, and a greater proportion of grains.

### Adverse Effects

The Livingston-Wheeler *Physicians Handbook*<sup>1</sup> states that "the autogenous vaccines have never been shown to be toxic . . . however, reactions occur." Reactions are described as malaise, aching, slight fever, and tenderness at the injection site. No information is given about the frequency of these reactions.

### Legal and Regulatory Status

The Livingston-Wheeler Clinic and the physicians employed by the clinic are licensed legally under the California Board of Medical Quality Assurance. Although a spokesperson for the State Health Department agrees that the clinic "is probably in violation" of the 1959 California Cancer Act, no action has been taken against Livingston-Wheeler or the clinic. Lack of staff and funds was cited as the reason for the board's inaction.<sup>26</sup> The state Cancer Act makes it unlawful to sell, give away, prescribe, or administer any medicine to be used in the treatment of cancer unless it has been approved by the US Food and Drug Administration or the California Health Department. Livingston-Wheeler has not sought FDA approval for her vaccine.

In the history of the clinic, only one known lawsuit has been filed. Legal action was taken by a family whose relative refused conventional medical treatment for lung cancer, visited the Livingston-Wheeler Clinic, and later died. The case was settled out of court with no admission of guilt.<sup>26</sup>

In 1986 HHS ruled that the Livingston-Wheeler Clinic and its employees were excluded from participating in the Medicare program. A corresponding ruling from the California Department of Health Services suspended the clinic from participation in the Medicaid (Medi-Cal) program. This action was taken after an audit determined that services rendered by the clinic did not meet the professional recommended standard of health care considered to be usual and customary treatment for a patient with cancer.

A peer review instigated by HHS doc-

umented several serious deficiencies in the clinic operations that were submitted as exhibits in the prehearing memorandum. A detailed review of patient medical records revealed poor data collection of patient histories, physical examinations, and histology to confirm or deny the presence of cancer; lack of follow-up on abnormal results of laboratory tests; lack of follow-up on complications; and lack of informed consent. Patients made excessive, often daily, visits to the clinic, even when there was no problem or evidence of disease. In addition, the same treatment was given for every patient, regardless of the type of cancer or stage of disease.<sup>27</sup>

In 1983 Livingston-Wheeler was granted a patent on a vaccine to prevent Marek's disease in chickens and formed Imutek, Inc., a company to manufacture and distribute the vaccine.<sup>27</sup> The efficacy of this vaccine remains undocumented.

### Summary

Livingston-Wheeler's cancer treatment is based on the belief that cancer is caused by a bacterium she has named *Progenitor cryptocides*. Careful research using modern techniques, however, has shown that there is no such organism and that Livingston-Wheeler has apparently mistaken several different types of bacteria, both rare and common, for a unique microbe. In spite of diligent research to isolate a cancer-causing microorganism, none has been found. Similarly, Livingston-Wheeler's autologous vaccine cannot be considered an effective treatment for cancer. While many oncologists have expressed the hope that someday a vaccine will be developed against cancer, the cause(s) of cancer must be determined before research can be directed toward developing a vaccine.

The rationale for other facets of the Livingston-Wheeler cancer therapy is similarly faulty. No evidence supports her contention that cancer results from a defective immune system, that a whole-foods diet restores immune system deficiencies, that abscisic acid slows tumor growth, or that cancer is transmitted to humans by chickens. ©

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