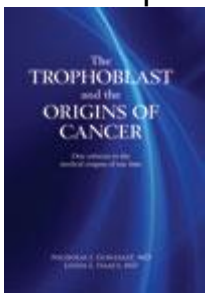
Enzyme Therapy and Cancer

By Nicholas Gonzalez, M.D.

The embryologist Dr. John Beard proposed in 1906 that pancreatic proteolytic digestive enzymes represent the body's main defense against cancer, and that enzyme therapy would be useful as a treatment for all types of cancer. (1) Particularly during the first two decades of the twentieth century, Dr. Beard's thesis attracted some attention in academic circles, and several case reports in the medical literature documented tumor regression and even remission in terminal cancer patients treated with proteolytic enzymes. (2-6) In 1911, Dr. Beard published a monograph entitled **The Enzyme Therapy of Cancer and Its Scientific Basis**, which summarized his therapy and the supporting evidence. (7) In my book **The Trophoblast and the Origins of Cancer** (co-authored with my colleague Dr. Linda L. Isaacs), I review Dr. Beard's work from the perspective of contemporary molecular biology.



After Dr. Beard's death in 1923, the enzyme therapy was largely forgotten. Periodically, other practitioners have rediscovered Dr. Beard's work, and used pancreatic proteolytic enzymes as an alternative cancer treatment. (8)
Dr. Beard believed the enzymes had to be injected, to prevent destruction by hydrochloric acid in the stomach. However, recent evidence demonstrates that orally ingested pancreatic proteolytic enzymes are acid-stable (9), pass intact into the small intestine, and are absorbed through the intestinal mucosa into the blood stream as part of an enteropancreatic recycling process. (10,11)

I began researching the use of oral pancreatic proteolytic enzyme therapy as a treatment for cancer after completion of my second year at Cornell University Medical College in 1981. At that time, I had the opportunity to meet

Dr. William Donald Kelley, the Texas dentist who for twenty years had been treating cancer patients with a complicated nutritional therapy based on Beard's enzyme treatment. Although Kelley had been attacked in the press because of the unorthodox nature of his work, the Dr. Kelley I met was an unassuming man whose primary wish was to have his controversial work fairly evaluated by the academic medical world. I thought his request reasonable. My research advisor at Cornell, Dr. Robert A. Good, at the time President of Sloan-Kettering, agreed to support a case review of Kelley's patients, which I continued despite the rigors of third year medical school. During my fourth year at Cornell, I was given a considerable block of time under Dr. Good's direction to investigate Kelley's work and results in a more structured manner. Eventually, what began as a student project developed into a two-year formal research effort which I pursued during my formal immunology training.

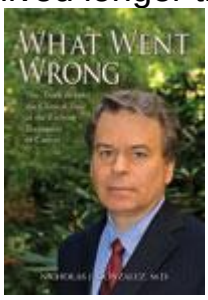
During my study, I reviewed nearly 10,000 of Dr. Kelley's patient records. I interviewed and evaluated intensively over 500 patients with appropriately diagnosed advanced cancer, and summarized my findings in an extended monograph completed in 1986 as partial fulfillment for my fellowship training. This monograph, entitled **One Man Alone: An Investigation of Nutrition, Cancer, and William Donald Kelley**, is now available through **New Spring Press** or on**Amazon**.

The written report consisted of several sections. In addition to outlining Kelley's theoretical approach, I discussed at length 50 of his patients initially diagnosed with 26 different types of poor prognosis cancer, all of whom had enjoyed long-term survival and/or apparent regression of disease while following their nutritional regimen. As a separate chapter, I also evaluated all cases of unresectable pancreatic cancer, both compliant and non-compliant, who had come to see Kelley between 1974 and 1982. I eventually identified 22 patients in this group. For all of these patients, I obtained complete medical records, including death certificates for those who were deceased. I interviewed all surviving patients repeatedly and at length, and in the case of those who had died, I interviewed family members as well as the original attending physicians.

Ten of these patients had visited Kelley only once and had never followed the protocol: these individuals had been discouraged from proceeding largely because of the negative influence of family and physicians who thought Kelley to be an outright fraud. This population, with a median survival of only 60 days, served as a convenient control. Among the remaining 12 patients, I found a number who had survived far beyond what would be expected for the disease, including one patient with pancreatic cancer to the liver who had, when last contacted, been alive over twenty years from her original diagnosis. (**Discoveries in Medicine review**)
Despite the careful documentation and the five-year investment of time, no one in academic medicine could, at the time, accept that a nutritional therapy might produce positive results with advanced cancer patients.

In 1986, probably as a result of endless pressures, Dr. Kelley gave up research and patient care, and I myself did not speak to him or any of his associates after 1987. He passed away in January 2005. (**Obituary of Dr. Kelley**) In 1987, I decided to move to New York to try and salvage the enzyme approach, and observe for myself the results with poor prognosis cancer patients. My goal throughout has been to generate research support, so that this method, if it indeed proved to have value, could be integrated into general medical treatment.
In July of 1993, the then Associate Director for the Cancer Therapy Evaluation Program at the National Cancer Institute invited me to present selected cases from my own practice as part of an NCI effort to evaluate non-traditional cancer therapies. Dr. Isaacs and I prepared for presentation 25 cases representing a variety of poor prognosis or terminal malignancies who had either enjoyed long term survival or tumor regression while following my program. (**NIH newsletter description**) Included in my presentation were patients diagnosed with advanced breast, lung, prostate and other cancers. After the session, the Associate Director suggested we pursue a pilot study of our methods in ten patients suffering inoperable adenocarcinoma of the pancreas, with survival as the endpoint. He suggested pancreatic cancer because the standard survival for the disease is so poor, and an effect could be seen in a small number of patients in a short period of time. In fact, I was told that if three of ten patients lived a year, that would be considered a positive result. Nestec (the Nestle Corporation) agreed to fund the trial, which began in January 1994. The study has been completed and was published in the June 1999 issue (Volume 33, Number 2) of **Nutrition and Cancer**. Of 11 patients followed in the trial, 8 of 11 suffered stage IV disease. Nine of 11

(81%) lived one year, 5 of 11 lived two years (45%), 4 of 11 lived three years (36%) and two lived longer than four years. In comparison, in a trial of the drug gemcitabine, of 126 patients with pancreatic cancer not a single patient lived longer than 19 months. (12) (**Abstract** of**Nutrition and Cancer** article)



Subsequently, the National Cancer Institute, in conjunction with the National Center for Complementary and Alternative Medicine, approved funding for a large-scale controlled trial evaluating our approach against chemotherapy, again in patients diagnosed with pancreatic cancer. Unfortunately, despite our initial enthusiasm for the project, ultimately it was ineptly managed by the academicians involved. The supervisory personnel at Columbia admitted multiple patients into the nutritional arm of the study whom we believed failed to meet the very specific entry requirements, and who for the most part were far too sick to comply with our treatment. Our multiple complaints were largely ignored. Finally, at our request, the Office of Human Research Protection, an investigative arm of the National Institutes of Health, launched a full scale investigation of those in charge at Columbia. After more than two years, the OHRP determined that the Columbia staff had inappropriately approved 42 of the total of 62 patients entered into the study. More recently, the Food and Drug Administration (FDA) completed its own investigation of the project, confirming my allegations of mismanagement. My book **What Went Wrong** exposes in detail the truth behind this clinical study. A brief summary of the problems with the trial can be found by **clicking here**.

In addition to these clinical trials, we have collaborated with basic science researchers to test our enzyme approach in animal models of pancreatic cancer. In May, 2004, the results of these studies were published in the peer-reviewed journal **Pancreas**. In these experiments, a very aggressive form of pancreatic cancer was induced in mice, then half the animals were given our pancreas product, half were given no therapy. Those treated with our pancreas product showed a significant improvement in survival and behavior compared to animals not receiving the enzymes. In a second experiment, tumor growth was substantially reduced, and survival prolonged again, in animals receiving the pancreas product. (13) (**Abstract of article on enzyme therapy in mice**) We want to emphasize that the results were particularly

significant for a first attempt, since the investigators were using only the pancreas product part of our program, and did not use a variety of doses to determine the most optimal for a mouse. As the principal investigator of the study wrote in the conclusion of the article: “In summary, PPE (porcine pancreatic enzyme) is the first experimentally and clinically proven agent for the effective treatment of PC (pancreatic cancer). The significant advantages of PPE over any other currently available therapeutic modalities include its effects on physical condition, nutrition and lack of toxicity.”

In addition to the financial support from Nestle, from 1995-1998, Procter & Gamble invested considerable resources helping us refine our therapy. You can review **statements of support** from Pierre Guesry, M.D., former Vice President for Research at Nestle, and J.P. Jones, Ph.D., the retired Vice President for Health Care at P&G.

In January 2007, we published a lengthy article about our **results** in the peer reviewed journal **Alternative Therapies in Health and Medicine**. (14) Here, we discussed 36 patients diagnosed with a variety of advanced and poor prognosis cancer who responded to our treatment with exceptional survival and in many cases evidence of tumor reduction. We intend eventually to publish in book form 100 such cases, with supporting medical documentation. Please subscribe to our **announcement list** for updates on book projects currently in progress.

We also want to emphasize that in our practice we prescribe, and in the pilot study and in the animal experiments we used a formulation of pancreas product made to our strict specifications. In our experience, quality, manufacturing methods, and composition vary widely among commercially available preparations of pancreas product and/or proteolytic enzymes. The results of our studies cannot be used as validation for any other product, whether obtained from a health food store, a pharmacy or an Internet source.

Although our published research deals with pancreatic cancer, in our office we treat patients with all types of cancers. We also treat patients with a variety of other problems, ranging from chronic fatigue syndrome to multiple sclerosis. Each treatment protocol is individualized for each patient, regardless of the underlying problem.

The therapy itself is quite complex, but basically involves three components: diet, aggressive supplementation with nutrients and pancreas product (containing naturally occurring enzymes), and detoxification. The protocols are individualized and each patient receives a diet designed for his or her specific

needs. The diets are quite variable, ranging from a pure vegetarian program to a diet requiring fatty red meat 2-3 times a day.
The supplement regimens are also individualized, and intense: each cancer patient consumes between 130 and 175 capsules daily. Non-cancer patients will require considerably fewer supplements per day. The supplement regimens include a range of vitamins, minerals, trace elements, anti-oxidants and animal glandular products, prescribed according to the particular patient's needs and cancer type. These nutrients do not, we believe, have a direct anti-cancer effect, but instead serve to improve overall metabolic function. In addition to these supplements, every cancer patient takes large quantities of pancreas product in capsule form, which we believe provide the main anti-cancer action.
The animal glandular products and pancreas product that we use are derived from animals raised in Australia and New Zealand, where there has been no history of BSE (mad cow disease) or other prion diseases such as scrapie. The animal husbandry regulations in Australia and New Zealand are the strictest in the world, and prohibit the feeding practices that have caused problems in other countries.
The third component of the protocol involves what we call “detoxification” routines. On this therapy, we find that as patients repair and rebuild, large amounts of metabolic wastes and stored toxins are released. As a result, patients routinely develop a variety of symptoms, most commonly described as “flu-like,” such as low grade fevers, muscle aches and pains, even rashes that we hypothesize result from low grade tumor lysis. “Detoxification” refers to procedures such as the coffee enema, which are believed by alternative practitioners to enhance liver function and in turn, the processing and excretion of metabolic wastes. The coffee enemas are done twice daily, and patients most commonly report symptomatic relief. (**Click here** for Dr. Isaacs' article about these procedures.)

Coffee enemas have been discussed in the orthodox medical literature for the better part of this century. Many nursing texts routinely recommended coffee enemas (15), and the **Merck Manual** advocated coffee enemas as a stimulant in all editions from the first in 1898 through 1977. During the 1920s and 30s, coffee enemas were prescribed for a variety of conditions. (16-20) In terms of their physiological effect, studies have shown that the rectal instillation of fluids will stimulate gallbladder contraction and emptying. (21)
Of the hundreds of Kelley patients I interviewed during my research study, virtually every one reported significant symptomatic relief from the enemas. In

my own practice patients repeatedly report the same improved well-being and relief of symptoms after a coffee enema. The enemas, in my experience, appear to be safe: I have yet to document a single serious side effect either in the thousands of Kelley patients I evaluated, or in my own practice. However, I do not encourage anyone to attempt coffee enemas except under the care of a knowledgeable physician.