

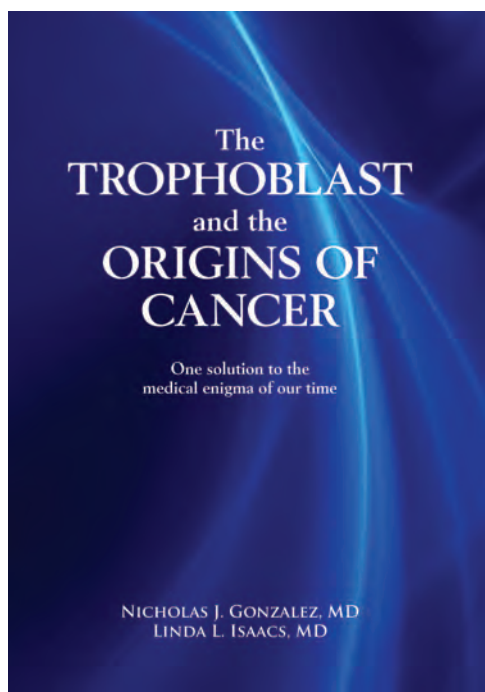


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Excerpt from *The Trophoblast and the Origins of Cancer: One Solution to the Medical Enigma of Our Time*

By Nicholas J. Gonzalez, M.D. and Linda L. Isaacs, M.D.



In the book *The Trophoblast and the Origins of Cancer*, the authors present the pioneering work of Dr. John Beard, the English scientist who 100 years ago may have solved the cancer riddle. It was Dr. Beard who first suggested that pancreatic enzymes, above and beyond their well-known digestive function, represent the body's main defense against cancer. In *Trophoblast*, Dr. Gonzalez shows how contemporary molecular biology proves much of what Dr. Beard said about cancer, its origins, and its effective treatment with enzymes.

For nearly three decades, Dr. Gonzalez has been studying and enlarging on the work of Dr. Beard, which was nearly lost to history. Today in his practice, Dr. Gonzalez and his colleague Dr. Linda Isaacs employ the enzyme therapy with considerable success in patients diagnosed with advanced cancer.

For the past several years, Dr. Gonzalez has been working on a series of books explaining the theory and practice of his therapy.

Trophoblast, the first in the series, is well-referenced from the scientific literature, but written for a general audience. As one reader commented, "You write so clearly that even the layperson can follow the medical side of the treatment and why it works."

"Thanks so much to Drs. Gonzalez and Isaacs for bringing us the complete, well-documented explanation!" Jonathan V. Wright, M.D.

The following is an excerpt from the book, previously published in the March 2010 issue of the journal *The Original Internist*. For further information, please visit www.newspringpress.com or Dr. Gonzalez's website, www.dr-gonzalez.com.

The Trophoblast and the Origins of Cancer: One solution to the medical enigma of our time by Nicholas J. Gonzalez, M.D. and Linda L. Isaacs, M.D. 7 x 10, 220 pages, full color illustrations and index. ISBN 978-0-9821965-0-2. \$49.95. Copyright © Nicholas J. Gonzalez and Linda L. Isaacs.

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The Evolution of Enzyme Treatment Adopted from the Trophoblast and the Origins of Cancer

by: Nicholas J. Gonzalez, M.D. and Linda L. Isaacs, M.D.

In our office, we offer an aggressive nutritional regimen for the treatment of cancer and other degenerative disease. Our therapy, in its most general sense, consists of three basic components; individualized diets, individualized supplement programs, and detoxification routines such as the coffee enemas. For cancer patients, we also specifically prescribe large doses of orally ingested pancreatic enzymes, taken around the clock, which we believe provide the main anti-cancer element in our therapy.

The use of pancreatic enzymes against cancer has a long history, going back to Dr. John Beard (1858-1924), the English zoologist and embryologist who spent most of his research career at the University of Edinburgh in Scotland. By Beard's day, the main categories of pancreatic enzymes had been identified, the proteases that reduce proteins into simple amino acids, the amylases that cleave complex carbohydrates into simpler sugars, and the lipases that break down triglycerides into fatty acids. Physiologists of the time knew that the pancreas secreted these various enzymes along with bicarbonate into the duodenum during meals for digestion. But Beard proposed as early as 1902 that trypsin, the main pancreatic proteolytic enzyme, in addition to its known digestive responsibilities, represented our body's main defense against cancer – and would serve as an ideal cancer treatment. Subsequently, Beard tested his enzyme hypothesis in both animal models and in human patients, with great success, as reported in the scientific literature of his day. Unfortunately, more due to medical politics than anything else, Beard's useful treatment never became accepted medical practice, and when he died in 1924, he died in obscurity, his enzyme approach relegated to no more than a footnote to medical history.

During his lifetime, Dr. Beard recommended only injectable preparations of pancreatic enzymes as a cancer treatment assuming that for his specific purposes, orally ingested preparations would be of little value. The active components such as trypsin are proteins, and like any other protein ingested by mouth would face a series of formidable barriers, beginning with the hydrochloric acid present in the stomach. Any active enzymes that might survive this initial assault would then be subjected to auto-digestion within the alkaline duodenum. Should any trypsin remain, it could do little systemically; scientists at the time already knew the protease to be a fairly large molecule that, they believed, could not possibly pass through the intestinal mucosa.

By 1900, a number of pharmaceutical firms in Europe and in the US manufactured powdered enzyme products, designed as a treatment for diphtheria, a world-wide scourge until the advent of vaccines for the disease. The diphtheria bacillus killed its host by elaborating a tough fibrous membrane in the throat that could, if unchecked, lead to suffocation. In an animal model of the disease, a preparation of trypsin locally applied in the larynx appeared to dissolve this deadly tissue and when tested in humans, the enzyme worked quite well. An early reference to the successful treatment in humans dates from the October 23, 1886 issue of the *Journal of the American Medical Association*.¹

By 1900, two companies, Merck and the New York based Fairchild, affiliated with Burroughs Wellcome, marketed trypsin preparations derived from animal sources for treatment of the disease. An old catalogue of Fairchild we have uncovered from 1898 lists, as one of its products: "TRYPSIN. (FAIRCHILD.) ESPECIALLY PREPARED AS A SOLVENT FOR DIPHTHERITIC MEMBRANE."^{2(p57)} It seems around that time, companies such as Fairchild began marketing injectable preparations in addition to those intended for direct application.

By 1907, the initial successes reported in the literature generated considerable interest in Beard's enzyme treatment of cancer. In response to this enthusiasm, a growing number of firms began selling their own "trypsin" specifically as a cancer treatment in addition to those available from Merck and Fairchild. With trypsin formulations widely available, physicians both in the US and in Europe began applying the therapy, usually without consulting Beard, and with variable results. As both positive and negative reports began to filter into the literature, Beard began to suspect that many of the available preparations had little potency and hence, little efficacy. He himself, after testing various products, recommended only

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the enzymes available from Fairchild, which he thought most effective clinically.³

Manufacturers of pancreatic enzymes in those days faced numerous difficulties bringing a potent formulation to market. Then, as now, all commercial enzymes were extracted from the glands of animals, such as cattle and pigs, slaughtered for their meat. In the animal pancreas, the acinar cells synthesize and store the proteolytic components as inactive precursors such as trypsinogen and chymotrypsinogen, to protect the gland itself. During meals, in response to both hormonal and neural stimulus, the exocrine cells release their supply of inactive proteases directly into the pancreatic ducts. The ductal cells themselves secrete a bicarbonate-rich fluid, which along with the enzymes ultimately empties into the duodenum. Since the proteolytic component works best in a slightly alkaline pH, the accompanying bicarbonate neutralizes any acid arriving from the stomach during digestion, and in so doing creates the ideal environment for the enzymes to begin their work.

In the duodenum the intestinal enzyme enterokinase secreted by the mucosal cells cleaves off a small six amino acid terminal from trypsinogen, converting the precursor into the active enzyme.^{4(p227)} Trypsin can then rapidly begin activating other trypsinogen and chymotrypsinogen molecules in a cascade effect.

At room temperature in the presence of even small amounts of moisture, the precursors can begin spontaneously converting into active enzymes, even in the absence of enterokinase. After only a few trypsin molecules so transform, these can then rapidly set off the activation process. Consequently, in an animal pancreas sitting in a slaughterhouse waiting to be collected for drug company use, all the enzymes can convert into the active configuration unless cooled on ice and processed very quickly. Since trypsin and chymotrypsin are themselves proteins, the potent enzymes can begin attacking one another, rendering the mixture into a collection of inert peptide fragments and amino acids.

From our readings in the literature, it seems that in Beard's era, the manufacturers used a very simple process to extract the enzymes, first mincing the glands in cold water, pressing the mixture, then removing the active component with alcohol. The alcohol would then be allowed to evaporate off, leaving the desired enzyme fraction.⁵

We suspect the procedure was neither exacting nor refined, the final preparation most likely containing little in the way of potential enzyme activity. To make matters worse,

those products intended for injectable use were provided in an aqueous solution in vial form, an ideal environment for the auto-digestion process to begin. Fairchild did market a dry powdered "trypsin" meant to be mixed with water immediately before injection, but even this proved so unstable that by 1907, as Beard reports, the company discontinued its sale.⁶

In the November 16, 1907 issue of *Lancet*, P. Tetens Hald, M.D., "Formerly Assistant in the Pharmacological Institute of the University of Copenhagen" and a Beard proponent, published the results of his evaluation of six popular enzyme products available at the time, including those marketed by Merck and Fairchild.⁷ In his research, he employed the same method used today to assess proteolytic activity, the casein digestion test. This simple assay measures the amount of the milk protein casein curdled over time by a known quantity of pancreas product. Today, laboratories measure enzymatic potency much the same way, rating activity with a 1-10X USP system, in which each unit signifies the product has digested 25 times its weight of casein. So, a gram of a "1X" product can digest 25 grams of casein, a gram of a "4X" product, 100 grams, and so on.

Dr. Hald contacted the manufacturers of the various products he analyzed in his laboratory, none of whom provided him with any information about the stability of the formulations they sold commercially. To his surprise, his assays revealed the potencies varied enormously, up to a factor of 400, and that the activity levels rarely correlated with the company's claims, as stated on the bottle or in its literature.

Dr. Hald writes:

The results are interesting in several respects. First, they show that preparations obtained from different makers vary exceedingly in strength. Thus the strongest of the preparations examined was 400 times more active than the weakest one. The feeble action of the preparations obtained from Zanoni and from Freund and Redlich was very striking.

Secondly, Table III shows that even the preparations of the same class may present considerable differences in strength. In one brand one of the supplies was even between 30 and 40 times stronger than the other one.⁷

In his 1911 book *The Enzyme Treatment of Cancer*, Dr. Beard himself bemoaned the dearth of standardized and potent enzyme preparations, a situation that led to inevitable treatment failures when physicians utilized products of

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poor quality. He actually quotes a Merck publication from the time, in which the writer discusses the confusion in the field:

The actual position of affairs in the past few years can best be described by quoting the impartial opinion of a competent author. On p. 340 of *E. Merck's Annual Report of Recent Advances in Pharmaceutical Chemistry and Therapeutics* (Darmstadt, vol. xxii., August, 1909) one may read regarding trypsin: "The mode of action and the value of pancreas preparations in cancer has not yet received a wholly reliable explanation. Great difficulties are encountered because the preparations used by the various investigators differ greatly in respect to their chemical properties, their purity, and in the amount of active substances they contain, and often these factors are not fully known to the student of the literature, or to the physician who has used them and describes their action. Further difficulties arise when pancreatin [whole pancreas product] and trypsin are described as substances of equal value, and how shall we gauge the action of pancreatin and trypsin ampullae whose mode of preparation and whose composition is not mentioned in the original paper, neither is there any mention made of their sterility or the method by which they have been sterilized? ...So long as the solutions of pancreatin and trypsin are treated as secret remedies no one will be able to form a clear picture of the value of trypsin treatment from the many publications which have appeared."^{6(p198)}

In reference to the above, as an aside we find it interesting that by 1909 Beard's hypothesis had generated interest sufficient enough to warrant thoughtful discussion in the annual report of a major international pharmaceutical company. The above exposition also adds support to Beard's contention that the mixed results for enzyme treatment being reported in the literature most likely reflected no flaw in the theory, only variations in the quality of product.

A number of factors contributed to the decline of interest after 1911 in Dr. Beard's trophoblastic hypothesis and his enzyme approach to cancer. Certainly, the enthusiasm for the X-ray, discovered in 1895 by Röntgen, helped push Beard's treatment into the background.^{8,9} After all, two-time Nobel Laureate Madame Curie, widely admired and respected at all levels of society, had vigorously championed the mysterious invisible rays as a non-toxic cure for all cancer, a breakthrough the press promoted with great enthusiasm. Beard had no such media savvy science star to praise his ideas about the use of enzymes against malignant disease. And it would not be until after Beard's death in 1924 that researchers began to appreciate the severe limitations of radiation treatment, which in reality worked

well against only a few cancers. Even for those tumors that did respond initially, usually the disease recurred with a vengeance and the therapy once thought to be harmless actually could be quite toxic. An entire generation of radiation researchers died as a result of cavalier exposure to the rays, including Madame Curie herself who eventually succumbed to radiation-induced aplastic anemia.¹⁰ By then, Beard was long forgotten.

Above and beyond the influence of personality, the vagaries of the media, and the realities of scientific politics, we suspect that poor quality enzyme products did much to undermine Beard's treatment. In a sense, Beard was a victim of his own fame. The initial successes reported in the literature prompted many doctors to begin using any number of enzyme formulations without first consulting Beard about dosing and quality, with inevitable poor or mixed results. The disappointments fueled the backlash in the journals, to the point that after 1911, few doctors of Beard's generation even considered the treatment for their patients.¹¹

Subsequently, F.L. Morse, M.D. in St. Louis during the late 1920s and early 1930s,¹² and Frank Shively, M.D., a Dayton, Ohio surgeon active during the 1960s,¹³ rediscovered Beard's earlier papers and used injectable formulations of the pancreatic enzymes in their treatment protocols with reported success. Then in the 1960s, William Kelley, D.D.S. first appeared on the scene, with his complex cancer treatment involving a whole foods diet, large amounts of various nutritional supplements, detoxification routines, and prodigious doses of pancreatic enzymes ingested orally – but never injected.

Kelley claimed he discovered the anti-cancer properties of oral pancreatic enzymes serendipitously, without any apparent previous knowledge of Dr. Beard. Kelley had been a successful orthodontist with a serious interest in nutrition, practicing in Grapevine, Texas, when in the early 1960s while he was only in his mid-30s, he became devastatingly ill. His doctors eventually diagnosed advanced pancreatic cancer, though he never underwent tissue sampling – not uncommon in the days before CT scans and needle biopsies. In desperation, with four children dependent on him, Kelley devised his own nutritional program to slow the disease, including a largely organic, vegetarian raw foods type diet, a variety of supplements, and detoxification routines such as coffee enemas. He also added high doses of oral pancreatic enzymes to his regimen, not because of any familiarity with Beard's hypothesis of which he was at the time ignorant, but to help relieve his severe digestive distress – as occurs commonly in patients with pancreatic malignancy.

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Kelley's digestion was so poor, he began ingesting huge amounts of pancreatin around the clock hoping to keep his worsening symptoms – including excruciating pain whenever he ate - at bay. He discovered that with large doses, his tolerance for food improved and – to his surprise – his large tumors, palpable through the abdominal wall, seemed to regress. Perplexed, and ever the serious student, he scoured the medical literature looking for evidence that someone else might have observed an anti-cancer effect for the pancreatic enzymes. His search eventually led him to Dr. Beard's book and papers from 50 years earlier, but by that point, Kelley claimed, he had already worked out the rudiments of his treatment.

From that very personal experience began Kelley's foray out of conventional orthodontics into the controversial world of nutritional cancer therapeutics. By the late 1960s, having long abandoned dentistry, he refocused his attention on treating, with his nutritional regimen, the very ill drawn from all over the country, most diagnosed with advanced malignancy. With the publication of his 1969 book *One Answer to Cancer*,¹⁴ Kelley for better or worse secured his position as a preeminent alternative cancer therapist, and inevitably as a target for the mainstream medical world which then, as now, had little use for proposed nutritional approaches to the disease.

Kelley intently studied the writings of Beard, who strongly insisted the treatment needed to be applied via injection. Nonetheless, for the duration of his career, Kelley only recommended oral formulations. Injectable preparations were still available in the US until 1966, when the FDA in its wisdom enacted a regulation removing them from the marketplace, perhaps in response to Dr. Shively's practice. In any event, as a dentist, Kelley lacked the legal right to prescribe injectable enzymes, so the question was moot. Most importantly, even if such products remained available and even if he had the authority to use them, his own experience treating himself, and his subsequent experience with hundreds of patients taught him that oral preparations worked very well despite Beard's claims to the contrary.

From the early 1900s, oral formulations of pancreatic enzymes were available with and without prescription in the US and Europe for a variety of uses, including treatment for diphtheria as well as digestive problems. A Dr. C.C. Rice, who published the first report we have been able to identify of a patient successfully treated with enzymes, recommended the Fairchild injectable preparation along with an oral supplement known as "Holadin."¹⁵ In the decades that followed, physicians prescribed these oral products for their patients diagnosed with pancreatic insufficiency such as occurs with pancreatitis or cystic

fibrosis, though no one until Kelley used them as a primary cancer treatment.

By 1950, the commercial demand for pancreatic enzymes such as trypsin had expanded greatly beyond their limited pharmaceutical application. For example, leather tanners used proteolytic enzymes to speed up curing, and candy manufacturers learned that trypsin, when added during the processing of chocolate, helped create a smoother product.

But the commercial suppliers still relied on the old mincing and alcohol method of extracting proteolytic enzymes from the animal gland, a very inefficient technique that gave a 10-15% yield.⁵ A potential bonanza awaited anyone who might develop a more efficient enzyme purification process.

The biochemist Ezra Levin of Champaign, Illinois, active during the 1940s and 1950s and at the time one of the leading experts in the manufacture of pancreatic enzymes, believed he had done just that. His lengthy 1950 US patent entitled *Production of Dried, Defatted Enzymatic Material* detailed his crowning achievement, an elaborate multi-step process for extracting active enzymes from the gland that he insisted was more efficient and more cost effective than the previous methodology.⁵ Instead of removing a portion of the enzymes from the pancreas tissue, leaving most behind in the discarded residue, Levin's new method involved first extracting the fat with appropriate solvents. Then any remaining water would be evaporated off via vacuum distillation, leaving all the enzymes in the remaining powder that yielded, at least theoretically, a very potent product.⁵ In a sense, Levin had reversed the traditional procedure in which the enzymes were extracted from the pancreatic tissue, with the water, fat, and most of the enzymes remaining behind as waste.

Levin saw as an added benefit that during the process, most if not all the precursors such as trypsinogen would also simultaneously activate, to yield a product of high potency with purported minimal processing losses; a product which Levin and his customers thought most ideal for pharmaceutical as well as industrial use.

Levin had made two assumptions, as he perfected his method. First, he believed that the fat in the gland – and the pancreas is a fatty gland – had no useful purpose beyond its role as a storage depot for excess calories, and needed to be removed. To him, fat seemed little more than inert filler. Second, he always assumed the more activated the product, the better.

On the first page of his patent, an introductory summary of his method reflects his two basic assumptions:

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By the present invention, trypsinogen is converted to trypsin and chymotrypsinogen to chymotrypsin by pre-activation to a maximum and is then dried and defatted simultaneously as hereinafter described, while this high enzymatic activity is held substantially without change, to produce highly active raw powders equal in activity to the fresh gland.⁵

Levin actually created a company, Viobin, for years a subsidiary of A.H. Robbins, to manufacture and market his enzyme products. The Levin method proved so successful that by the 1960s, Viobin provided most of the enzymes used in the US, both for pharmaceutical and other industrial purposes. Even other manufacturers that ventured into the enzyme business themselves relied on variations of the Levin patent.

Throughout the 1970s, Kelley designed his own extensive line of supplements, produced by a number of different companies. At one point, he told me he had gone through 14 such firms in 20 years, changing when he felt quality control failed to meet his standards, which in the supplement industry in those days tended to be lax. However, whatever company name might appear on the label, Kelley insisted the pancreatic raw material be purchased from Viobin, which he always claimed to be the best available enzyme. The various distributors he used would purchase the pancreatin in bulk powdered form and encapsulate the material, with the final product bottled and distributed under Kelley's personal label. Even though other suppliers approached him, for all of Dr. Kelley's 20 years in practice as a nutritional therapist, he stuck by Viobin through the years of his great success and his growing reputation.

The Levin method could be adjusted, by shortening or lengthening the processing time, to provide pancreatin of various potencies as measured on the 1-10X scale, with 1X representing the least, and 10X, the maximum possible activity. During the 1970s, Viobin actually sold pancreatin of various activity levels, a number of which Kelley tried out over the years. Eventually, after vacillating back and forth from weaker to stronger then back to weaker formulations, he settled for a time on the 4X which provided more than half of the total potential enzyme content as inactive precursors.

By the time I (Dr. Gonzalez) met Kelley during the summer of 1981, he had become convinced that the more active the oral product, the better the effect against cancer. He wanted 8-10X, nothing less, for all his patients. He seemed at times almost fanatical about the issue of enzyme strength, insisting he wanted no precursors in his formulation. I even traveled with Kelley to Wisconsin to

meet with the manufacturer he used at the time, to discuss with them his new plans for the strongest supplement possible, containing only 10X pancreatin. I also met several times with representatives of Viobin, to discuss their enzymes and the feasibility of providing large amounts of the 10X material.

As I pursued my investigation of Dr. Kelley's therapy and practice over the next five years under my mentor, the late Robert A. Good, M.D., Ph.D., I concentrated my efforts primarily on Kelley's results with advanced cancer. As a side project, I also tried to evaluate the relative efficacy of the different pancreatic formulations he had recommended during his time in practice. From Kelley's records and our conversations about the issue, I had a fairly good idea of which strength of enzyme he used during which period.

From my review of Kelley's patient charts on a year by year basis, it seemed to me that his greatest success as a practitioner occurred during the decade 1970-1980, when he relied primarily on the 4X pancreatin, containing a high percentage of inactive precursors. After 1981, he opted for increasingly more activated product, eventually settling on the 10X potency. However, it appeared that his success declined markedly as he prescribed a "stronger" preparation. Admittedly, other factors might have come into play: beginning in 1981, Kelley himself withdrew from direct patient care, turning his therapy over to a constellation of "Kelley Counselors" whom he had trained via a series of weekend seminars. Though he had over the years certified over 1000 such practitioners, only several dozen were active at the time I met Kelley, and these consisted of a very mixed group of people, in both educational background and ability. Some were practicing physicians, dentists, and chiropractors, others had no professional education in health care whatsoever. While a number I found to be very competent and dedicated, including several who lacked formal medical training, many were far less so. It would be hard to sort out the influence of this dramatic shift in the administration of his program on its successful application.

Regardless of the cause, I could track a significant fall off in responders beginning about 1982 – in fact, during the years 1984-1985, as I actively brought my research to a close, I knew of only one impressive result, a patient with stage IV Hodgkin's disease whose cancer regressed completely on the enzyme therapy. This single success during that time represented a far different situation than Kelley's glory days of the 1970s when, by my investigation of his charts, many hundreds of patients with properly diagnosed cancer had done well. But this patient was to my knowledge the last great success, and by 1986, Kel-

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ley in great frustration had closed his organization, essentially cutting off his treatment after 20 years. He believed that “disloyal” counselors and greedy supplement manufacturers had effectively sabotaged his life’s work.

I finished my project under Dr. Good in 1986, but sadly Kelley turned increasingly paranoid, at one point thinking I had been sent by the CIA to steal his therapy for the government. After 1987, I had no further direct contact with Kelley, who for a long time essentially disappeared from view.

When my colleague Dr. Linda Isaacs and I subsequently arrived in New York in the fall of 1987 determined to salvage Kelley’s treatment, we knew if we were to succeed in practice, we needed a reliable source of enzymes. As I thought about the situation, I realized we must determine the optimal composition for the enzyme product in terms of relative fat and protein content, as well as the ideal level of proteolytic activity – and hopefully find a source that met our specifications.

I had already begun to move away from the Levin methodology as the best for manufacturing pancreatic enzymes. In terms of composition, I knew that he had designed his extraction method to remove as much fat as possible, which he perceived as useless filler. I thought in this regard Levin, as well as Kelley, who accepted without question Levin’s dictates, had been wrong, that fat might allow for a more stable product and provide physiological benefit. By 1987, researchers had already begun to suspect that fat was not just a simple warehouse for storing excess energy, but a metabolically active tissue secreting a variety of enzymes and hormones that regulate the processing of sugars and fatty acids. Perhaps, I thought, the lipid component of the pancreas might itself provide some additional effect, a complement to the proteolytic activity. So as a first order of business, I decided to search for an enzyme preparation containing significant fat.

Ezra Levin also assumed that the more active the product the better, the mantra Kelley again professed to me with total conviction. But I knew from my exhaustive evaluation of Kelley’s files that as he opted for a more potent enzyme formulation, his response rate fell significantly. In frustration, he assumed he only needed to prescribe an even stronger enzyme, or change encapsulators, etc., instead of retracing his steps and going backward to the less active 4X enzymes he had earlier used with great success.

I became convinced that as brilliant as Kelley had been in his prime, he had erred in his later years by assuming that

“purer and stronger” is always unquestionably better. I suspected that the fat depleted, highly activated supplements may have been prone to deteriorate once encapsulated, susceptible to rapid auto-digestion on the shelf. That may have been part of Kelley’s problem during the mid-1980s. I also became convinced that the fat in the gland might not only help stabilize the mix, but provide synergistic factors to assist the proteolytic enzymes in their fight against malignant cells. Finally, I came to believe that an enzyme with less activity, with more of the total potential as precursor, might not only be more stable in the bottle, but more effective against cancer.

As a first order of business, I obtained samples of pancreatin from a number of suppliers who manufactured their own products. I also visited several health food stores and nutritional pharmacies in Manhattan, such as Willner’s, purchasing a variety of pancreatic enzyme supplements. In the kitchen of my mother’s home in Queens where we were staying at the time, I set up my own enzyme assay, using Knox gelatin as my protein substrate instead of casein, and the Viobin preparation Viokase as my standard by which to measure the activity of other products. I dissolved each capsule or tablet in a slightly alkaline solution to help promote the enzymatic reactions, and then observed the amount of gelatin digested over time. The assay, which I repeated many times over a number of weeks, worked quite well. Unfortunately, nearly all of the enzymes I tested seemed highly activated and highly processed, with all the fat removed.

Finally, I learned of the pancreas enzyme product derived from New Zealand pigs available from Allergy Research Group, a nutritional supplement company of some renown based in Northern California. As a start, I was happy about the source, since I had learned that New Zealand had perhaps the cleanest environment of any country on earth, as well as the strictest laws for raising animals for commercial use. Diseases such as hoof and mouth disease and trichinosis, I was told, had never been reported there.

I also wanted enzymes derived from the pig pancreas, thought to be most similar to the human organ. For decades, before the advent of genetically engineered preparations, physicians treated their diabetic patients with pig insulin, which proved to be quite similar in terms of amino acid structure to the human variety. In a similar manner, pig enzymes, I had learned from my conversations with Viobin scientists, most closely resembled ours, of all commercially available sources.

Most importantly, the Allergy Research Group (ARG) specifications described their pancreas supplement as a
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freeze dried product, minimally processed, *with the fat intact*, yet it still tested active at moderate levels by my own assay - exactly what we wanted. Though the material had not been intentionally activated as per Levin, I suspected during the handling of the glands, some of the precursors spontaneously converted, fortuitously to the precise level we thought ideal. Then, with freeze drying complete, all activation would come to a halt, leaving a stable product with most of the proteolytic enzymes in the precursor form.

I contacted the founder of ARG, Dr. Stephen Levine, and introduced myself, explaining my plan to open up a practice and my need for good quality enzymes. Though I was virtually unknown at the time, he agreed to provide me with as much of the product as we required. With a supply of enzymes guaranteed, in late 1987 we opened our practice with great optimism in an office in Manhattan. To our relief, this enzyme worked quite well, confirming my belief that a minimally processed lightly activated preparation, with the fat intact, was ideal for our purposes. One of my first successes dated from December 1987, a woman diagnosed with inflammatory breast cancer who had developed metastases into the bone while receiving chemotherapy. Told she had terminal disease, she somehow learned about us and began our program. She is alive today, over 21 years later, in excellent health with all scans long ago showing complete regression of her disease.

We treated all our early successes, right up until 1995, with pancreatic enzymes available from ARG. Between 1995 and 1998, we entered into a research and development arrangement with Procter & Gamble, who generously provided extensive financial support as well as a team of scientists to help us determine definitively the best enzyme formulation for our purposes. The company spent considerable time, effort, and money evaluating our enzymes, even sending researchers to New Zealand to observe first hand the entire processing of the pancreas glands from slaughterhouse to finished material. With such assistance, we eventually refined the methodology still further, to help guarantee consistent manufacture of a stable, modestly active, minimally processed product with most of the enzymes – but not all - in the precursor form, and with a certain percentage of fat remaining. Working with our New Zealand supplier, we developed a method to help assure the desired potency with each batch, without the need for Levin's complicated system of fat extraction and vacuum distillation. Today, we still rely on that same enzyme preparation, which we find works even more effectively than our earlier supplement.

About the Authors:

Dr. Nicholas Gonzalez: Dr. Gonzalez graduated from Brown University, Phi Beta Kappa, magna cum laude. He worked as a journalist, first at Time Inc., before pursuing premedical studies at Columbia University and receiving his medical degree from Cornell University Medical College in 1983. During a postgraduate immunology fellowship under Dr. Robert A. Good, considered the father of modern immunology, Dr. Gonzalez's investigated the nutritional regimen developed by the dentist Dr. William Kelley and used in the treatment of advanced cancer. Dr. Gonzalez's research has been funded by The Procter & Gamble Company, Nestle, and the National Cancer Institute/National Institutes of Health. For more information, see his website at www.dr-gonzalez.com.

Dr. Linda Isaacs: Dr. Isaacs has been working with Dr. Gonzalez in his private practice and research efforts since 1985. She graduated from the University of Kentucky, Phi Beta Kappa with High Distinction, and subsequently received her medical degree from Vanderbilt University School of Medicine. She completed a residency in Internal Medicine at the Department of Veteran's Affairs Medical Center at New York University Medical School and is Board Certified in Internal Medicine.

Excerpted from: *The Trophoblast and the Origins of Cancer: One solution to the medical enigma of our time* by Nicholas J. Gonzalez, M.D. and Linda L. Isaacs, M.D.

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