



In Memoriam: Nicholas J. Gonzalez, MD

by Linda L. Isaacs, MD

I met Nick Gonzalez on October 31, 1983, on the first day of my internal medicine rotation as a third-year medical student at Vanderbilt University Medical School; he was the intern on the team. He was striking: a fast-walking, fast-talking New Yorker, brilliant and witty. He was incredibly efficient, one of the first interns to be able to leave the hospital at the end of the day, but his work was always done and his patients loved him.

On the last day of the rotation, he asked me for a date. Three months later, I contacted him and we met for lunch. That was when I began to learn more about him: a former journalist, he had developed an interest in nutrition from interviewing various luminaries in the field and had decided to go to medical school. While at Cornell Medical College, he met a dentist, William Donald Kelley, who had developed a nutritional approach to cancer that included dietary modifications, large quantities of pancreatic enzymes, and detoxification measures such as coffee enemas. Dr. Kelley invited Nick to investigate his work, and Nick found large numbers of patients with appropriately diagnosed cancer who had done extraordinarily well. However, Nick's research project found no favor with the faculty at Cornell, so he had not gotten the recommendations needed to get into the highly competitive residency programs in his beloved New York City. He wound up in Nashville, Tennessee, where he clearly felt out of place. And every day, he pushed himself to get home as quickly as possible so that he could make a few calls, write a few letters, to continue his Kelley project.

As we got to know each other in the following weeks, I heard more about the patients whom he had discovered in Dr. Kelley's practice. He told me of a patient with widely metastatic prostate cancer, admitted to the hospital for pain control, who after his discharge began the Kelley program; years later, he was completely well and playing in a ragtime

band. Another patient, who had uterine cancer metastatic to the lungs, had a repeat chest X-ray after several years on the Kelley program that showed no evidence of disease. And there were many more, all compelling, all making it very clear to me why this brilliant man had put his career on the line to follow up with this work.

In July 1984, Nick moved to Oklahoma City to pursue a fellowship in immunology under the direction of Dr. Robert A. Good, the former president of the Sloan Kettering Institute and Nick's mentor as he worked on his Kelley project. It was unusual to start a fellowship immediately after an internship, but Dr. Good promised Nick that he would be able to devote much of his time to his study of Dr. Kelley's work. Meanwhile, I was completing medical school in Nashville, and Nick and I stayed in touch by phone. Nick frequently visited Dr. Kelley in his office in Dallas, and Nick and Dr. Good even saw one of Dr. Kelley's patients in their clinic during that time.

Nick and I were married in May 1985, a week after I graduated from medical school. Dr. Good was the best man at our wedding; Dr. Kelley attended the ceremony. We moved to Florida, where Nick completed his fellowship with Dr. Good at All-Children's Hospital in St. Petersburg, while I did my internship in internal medicine at the University of South Florida. Nick continued his research on Dr. Kelley, assembling his findings into a lengthy monograph, then submitting some of the individual case reports to various medical journals for publication. The reception took both Nick and Dr. Good aback. A number of editors thought that the results had to be fraudulent despite the extensive documentation in the provided medical records. Some warned Dr. Good that his reputation would be tarnished by continued association with this project. It became obvious that Dr. Good could not help Nick get the results published

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or get funding for further research, so Nick made plans to leave at the end of his fellowship in June 1986.

Meanwhile, my own health was faltering. In medical school, I had begun to have fatigue and difficulty concentrating, and while I managed to complete my internship and pass my licensure examinations, by 1986 I had a full-blown case of what would later be called chronic fatigue syndrome. I resigned from my residency program, and Nick and I headed north to spend time with Dr. Kelley, who had moved to Pennsylvania to live with an ardent supporter of his work, Dr. Carol Morrison. The plan was that Nick would complete his Kelley monograph, get a literary agent, and get the work published, while I would begin the Kelley program myself to get well.

At this point, Dr. Kelley's work was in shambles. He had been involved in the treatment of the actor Steve McQueen and was pilloried in the press when McQueen died. He had trained a network of practitioners to administer his program, but their success in implementing it had been widely variable. He had lost faith in the company which manufactured the supplements that he recommended. Patients still contacted him looking for treatment, but he was increasingly fearful of proceeding.

Nick's efforts to get the monograph published did not go well. Even though he had a reputable agent, some editors at publishing houses still questioned the truthfulness of the patient histories, despite the inclusion of the patients' medical records. Other editors said that the medical divisions of their publishing companies would have serious concerns if the book was accepted. As Dr. Kelley's hopes of the book's publication died, his behavior became increasingly strange. He dispatched letter after letter to his mailing list, his paranoia becoming increasingly evident, and he became suspicious of Nick and me. Finally, Nick decided that we should leave and try to recreate the work independently, as Dr. Kelley was clearly not functional.

We left for New York City in the spring of 1987, to live in Nick's mother's house. We had no money, no office, and no place to refer prospective patients to purchase the supplements that they would need. With characteristic doggedness, Nick set to work. He investigated the manufacturing processes and potencies of various pancreas products and decided which one was most likely to work. He found supplements with which we could recreate, as closely as possible, the customized programs that Dr. Kelley had devised for different types of patients. The family of a former Kelley patient was willing to serve as the distributor of supplements to the patients. A contact from Nick's journalism days offered office space, first at night and on the weekends, then during regular office hours. And a number of alternative cancer referral sources, such as the Cancer Control Society, helped get the word out that Dr. Nick Gonzalez was offering his version of Dr. Kelley's work from his office in New York City. Dr. Robert Atkins had Nick on his radio show multiple times, and this too helped recruit patients.

Meanwhile, I continued my efforts to improve my own health, and with the better-quality products that we were using, I finally felt well enough to resume my interrupted medical residency in June 1989. I completed it without difficulty and passed my internal medicine boards in 1991. During my residency, our marriage disintegrated, in retrospect I believe due partly to communication issues stemming from our very different cultural backgrounds. We also had a few too many 2 a.m. conversations about enzyme chemistry; we both eventually remarried to people outside the medical profession, limiting how much we could talk shop during "off" hours. But just as many divorced parents forge a new working relationship for the good of their children, so our joint commitment to our work helped us weather the divorce and build a new friendship. After I completed my residency, I joined him in his practice, and in 1993 we moved to a new office space where we could both see patients.

By this time, Nick had started to accumulate his own long-term success stories among his patients. I remember particularly a patient with breast cancer metastatic to the liver and brain, with documented resolution of disease on the therapy; and another patient with renal cancer who had a metastatic lesion the size of an egg protruding from his skull, whose disease regressed after he began his protocol. In articles and at conferences, Nick discussed his and Dr. Kelley's successes, and this drew attention from both supporters and critics. In 1993, he was invited to present cases at the National Cancer Institute by the associate director of the Cancer Therapy Evaluation Program, as part of its early effort to consider nontraditional therapies. Nick and I compiled the records for 25 cases, with a variety of cancer types. After the session, the associate director suggested a pilot study with pancreatic cancer, though no funding for such a study was volunteered.

Shortly thereafter, the Nestec Corporation (Nestlé) provided the funding and the trial began. But around the same time, someone filed a complaint with the state medical board, and this gave it the opening to begin a lengthy investigation of Nick's competence. Hundreds of thousands of dollars in legal bills later, the state board placed Nick on probation pending evaluation and "retraining." The evaluation process revealed only that Nick's handwriting was terrible, and to the office staff's relief, he began to use a dictation service. And the oncologist who subsequently sat in on Nick's patient visits as part of the "retraining" became a lifelong friend and supporter. Nick completed the requirements of the state board and the probation ended, but the damage to his reputation remained.

Meanwhile, the pilot study for patients with pancreatic cancer was under way. One of the patients on the trial was an employee of Procter & Gamble. Intrigued by how well this patient did, the vice president for health care contacted the office, and eventually Procter & Gamble entered into a research agreement with Nick, providing welcome scientific input. During that time, we were able to improve the process by which the enzymes for our program were made.

The pilot study ended in 1998, and the results were published in the June 1999 issue of *Nutrition and Cancer*.¹ Of 11 patients followed in the trial, 8 suffered stage IV disease.

Nine (81%) lived 1 year, 5 lived 2 years (45%), 4 lived 3 years (36%), and 2 lived longer than 4 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.²

Our happiness at the acceptance and publication of this article was muted by other concurrent events. In the 1990s, Nick lost two malpractice lawsuits. The more serious of the two involved a woman with uterine cancer who had called the office twice to ask for an appointment and had been turned away with instructions to get surgery. Months after her initial contact, she finally did, and was found on hysterectomy to have an adenocarcinoma with papillary and clear cell features, a particularly aggressive type of cancer. She was offered entry into a clinical trial for high-risk and recurrent endometrial cancer, but instead contacted the office and became Nick's patient. Around 9 months later, she developed back pain and was found to have a metastatic tumor in the spine which was surgically removed. She discontinued her nutritional program and began chemotherapy, and subsequently went blind. Her lawyers claimed that had she entered the clinical trial that she was offered and received treatment immediately, instead of waiting until a recurrence was found, she would never have had the recurrence and would not have gone blind.

Some facts about the case are not included in this scenario. The pathologist who reviewed the slides from the surgically removed tumor in the spine stated that what was present was necrotic debris, and that no viable cancer was seen. And most remarkable was the patient's survival. Metastatic uterine cancer of any variety is a rapidly terminal disease, regardless of treatment. Yet the patient was still alive at the time of the malpractice trial, years after the spinal tumor was found; she eventually passed away nearly 20 years after her original diagnosis.

The records are compatible with the patient's having had undiagnosed metastatic disease to the spine at the time the uterus was removed, with the enzyme treatment having rendered the disease necrotic, the necrotic tissue becoming inflamed and symptomatic, and the subsequent chemotherapy unnecessary. But the jury found in favor of the plaintiff, with an award in excess of Nick's malpractice policy.

Nick eventually won a legal malpractice case against the attorney who had ineptly defended him. But again, the damage to his reputation and to his finances had been done. He was forced to declare bankruptcy and to sell the apartment that he loved. The medical practice survived, but it was a horribly stressful time, with financial struggles, with endless paperwork demands from attorneys, with reporters call to request interviews, and with articles in the press both positive and negative.

In the midst of all this, in 1998, 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, it was ineptly managed by the academicians involved, who published an article about

it without our consent in 2009.³ Nick's book *What Went Wrong: The Truth Behind the Clinical Trial of the Enzyme Treatment of Cancer* details the problems with the trial quite thoroughly, and spells out why we did not think the published paper's results were valid.⁴

I recently wrote an article about the problems in the study's design that doomed it from the outset.⁵ Even as I wrote it, I wondered why we had ever agreed to proceed. But in the wake of Nick's sudden death, I have found myself thinking back to the 1990s and to all the terrible things that we endured back then. Had Nick not been subjected to the injustices of the state board investigation and a malpractice suit by a woman whose life he may well have saved, had we not been coping with an onslaught of unnecessary work brought on by these issues, we might have had the clarity of mind and the willpower to fight for a better trial design.

However, even after the bitter disappointment of the clinical trial, we continued to treat patients, with continued success. Nick's book about Dr. Kelley's patients was finally published, and Nick had been working on a book of case reports at the time of his death.⁶ In the days afterwards, I heard from patients of mine with condolences; a patient with melanoma with biopsy-proven lung metastases, now 4 years out from that diagnosis, another patient with pancreatic cancer now 14 years from diagnosis. I have seen many more patients, his and mine, whose lives have been transformed by the methods he fought so hard to preserve and study. These patients and their stories help give me the determination to do what I can to keep Nick's memory alive, and to continue the work so that perhaps a future generation of researchers can pick up where we left off.

Nick rarely spoke publicly about the obstacles and injustices that he had to deal with as he pursued his work. But I think it is important, as a witness to many of them and as a part of his legacy, to chronicle them. He had many opportunities to turn aside and pursue a more conventional and comfortable path as an academic researcher. He never did; he fought on for what he believed was right, and for that I will always honor him.

Notes

1. Gonzalez NJ, Isaacs LL. Evaluation of pancreatic proteolytic enzyme treatment of adenocarcinoma of the pancreas, with nutrition and detoxification support. *Nutr Cancer*. 1999;33(2):117-124.
2. Burris HA, Moore MJ, Andersen J, et al. Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: a randomized trial. *J Clin Oncol*. 1997;15(6):2403-2413.
3. Chabot JA, Tsai WY, Fine RL, et al. Pancreatic proteolytic enzyme therapy compared with gemcitabine-based chemotherapy for the treatment of pancreatic cancer. *J Clin Oncol*. 2010;28(12):2058-2063.
4. Gonzalez NJ. *What Went Wrong: The Truth Behind the Clinical Trial of the Enzyme Treatment of Cancer*. New York: New Spring Press; 2012.
5. Isaacs LL. Research battles: survival tips from a veteran. *Integr Med Clin J*. In press.
6. Gonzalez NJ. *One Man Alone: An Investigation of Nutrition, Cancer, and William Donald Kelley*. New York: New Spring Press; 2010. ♦