

A Cautionary Tale for Alternative Medicine

review by Howard Straus, President, Cancer Research Wellness Institute

What Went Wrong: The Truth Behind the Clinical Trial of the Enzyme Treatment of Cancer, by Nicholas J. Gonzalez, MD
 New Spring Press, New York City
 ©2012; 583 pp.

Dr. Nicholas Gonzalez, a regular contributor to the *Townsend Letter*, has written a book chronicling the ins and outs of the much-awaited NCI/NCCAM clinical trial of his holistic, enzyme- and nutrition-based treatment for pancreatic cancer. Many of us in the alternative medicine world had waited for years with bated breath for the results, which ended up disappointing at best. Now we can find out *What Went Wrong*.

Though the trial began with the major parties in general agreement that significant preliminary results warranted a full-scale, federally funded, controlled trial, the implementation left much to be desired from the very beginning. The difficult start was exacerbated over the first couple of years of the study when the administrators who were originally positive or enthusiastic about the trial moved on to other positions in government or private foundations, and were replaced by officials who were either neutral or openly hostile to the protocol being tested.

Gonzalez and his partner, Dr. Linda Isaacs, found themselves constantly battling their "colleagues" on the trial's steering committee on points of enrollment, a key parameter when the nutritional/dietary treatment to be tested depends on the cooperation and support of family and local physicians. The powers that be, for example, insisted the protocol for the study include an "intent-to-treat" provision, which means that as soon as a patient was formally approved for entry into the nutrition, he was considered as entered – even if he never followed the regimen for a day. Though used in drug studies, such a requirement is ill-suited for a lifestyle-type therapy. Unfortunately, as Gonzalez carefully documents, patient after patient was considered a "Gonzalez treatment failure," even though many never followed the therapy, followed it incompletely, or only briefly.

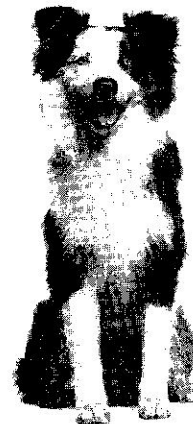


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➤ And it is interesting, reading through the book that the administrators of the study enforced this rule rigorously, as opposed to other rules that might have benefited the nutrition arm of the trial. Time and again, patients were enrolled into the study inappropriately and at times excessively late after diagnosis (a virtual death sentence for an advanced pancreatic cancer patient), making it impossible for them to ever take a single treatment, yet all these were considered "Gonzalez failures." The ultimate result of all this seems to have far more to do with medical politics than with a dispassionate and honest test of a medical procedure. (Imagine a breaking strength test on a steel beam, except that the beam was not properly delivered to the testing facility. The result would never be recorded as "beam failed.")

Lest the reader think that was the only, or even the worst, roadblock, there were many additional and more serious breaches of scientific protocol by the chief investigator, Dr. John Chabot of Columbia University. Gonzalez has documented these breaches in his book in painful detail, dispassionately and exhaustively, quoting directly from official correspondence with government regulatory agencies, investigators, even congress members and other government officials, asking them repeatedly to enforce, even obey, their own rules and laws. None of these pleas for fairness, or even enforcement of the regulations concerning research integrity or trial participant safety, were heeded.

There is no doubt about the validity of Gonzalez's allegations and complaints. In many cases, the violations were admitted to in writing by the very agencies responsible for enforcing the rules and regulations. Still, there were no enforcement actions, sanctions against the violators, nor adverse consequences; and the infractions continued unabated, unpunished. The Office of Research Integrity (ORI), charged with guaranteeing the integrity of scientific research funded by the federal government, failed to take any substantive action despite the thoroughly documented failings on the part of the principal investigator. The Office for Human Research Protections (OHRP), whose task it is to ensure that the subjects of human trials funded by the federal government are treated with maximum safety consistent with the experiment, failed repeatedly to take what should have been appropriate and firm action against the Columbia team. When the violations of the patients' safety and survival were documented, the OHRP left it to the university to investigate itself! Though OHRP did ultimately determine that 42 out of the 62 patients entered into the trial had been inappropriately admitted by the Columbia team, no significant punitive action was taken against those responsible for the confirmed mismanagement.

Probably the most egregious failure of the entire trial, and the one that explains much of the blatant bias in the way the trial was conducted, was appointing Chabot as principal investigator of this trial. Despite his lack of familiarity with the nutrition treatment being tested, Chabot was charged with supervising the study comparing this complex nutritional and enzyme therapy for advanced pancreatic cancer against a novel chemotherapeutic regime as a control. But as we learn, Chabot was one of the main developers of the very protocol against which the nutritional therapy was being tested, a fact that was never brought to the attention of Gonzalez and Isaacs, and only came to light some years into the trial. None of the federal or university organizations seemed to have any problem with this most blatant conflict of interest, a fact that alone should have disqualified Chabot as the

principal investigator. None of the agencies that were supposed to protect patients seemed to care that advanced pancreatic cancer patients were left untreated for weeks as they waited for a decision about their eligibility from Columbia, a period of time that anyone familiar with the rapid progression of the disease knows, as Chabot does, would lose the "window of opportunity" for treatment, and condemn the patient to a painful and hopeless death. In many cases those patients ultimately assigned to the nutrition arm by Chabot were kept waiting for weeks for his decision, during which time they were untreated by any means. No explanation was offered for the sometimes extraordinary delays.

This book offers copious extracts from years of correspondence and patient records, and should be a warning to any alternative practitioners, or any physicians who go against the immensely profitable pharmaceutical paradigm, that they will not be treated well, they will not even be treated fairly by government or by their colleagues. But even more chilling is the callous and cynical disregard with which the desperate pancreatic cancer patients were tossed under the bus for the agendas and egos of the investigators. These patients, who had faith that the medical profession was trying to cure their cancer, or at least do ethical research, were abandoned to their disease so that the allopathic physicians could prove a point, and destroy a reputation. These patients were left hanging by their government, by the medical establishment, by the research organizations set up to protect them. It should give pause to any patient hoping for legitimate results from a clinical trial, as the documentation shows that they were simply being used as expendable ammunition, rather than being treated with the honesty, human dignity, and care expected from physicians. I would never advise anyone to submit to such organizational and official abuse.

Oh, and incidentally, despite the systematic, long-term, and thorough undermining of the nutritional treatment, deeply buried in the final report is the noteworthy result that the two longest-surviving patients at the time the study came to a close in 2006 were enrolled in the nutritional arm, treated by Gonzalez and Isaacs. Unfortunately, neither Gonzalez nor Isaacs was given the "guaranteed" opportunity to contribute to the final report, which was eventually published without their knowledge, and which claimed inappropriately their therapy hadn't essentially shown any benefit.

If I have any criticism of this book, it is that the complaints eventually became somewhat repetitive. I can understand why, since they were submitted to a whole alphabet soup of government regulatory agencies over the course of nearly 10 years, and had to be repeated and documented in detail each time. My criticism does not have to do with a lack of careful and thorough documentation, but with a surfeit. Still, skipping repetitive areas is preferable to lacking the proof that one might need. It is my hope that some federal agency could use this very thoroughly documented book to investigate whether physicians and administrators actually might have violated the law, if only to ensure that they don't continue to do it, and that others conducting such highly manipulated "trials" might have a second thought about the consequences.

What Went Wrong is a cautionary tale for alternative practitioners, for desperate patients and their families. It is painfully obvious that many agencies in and out of our government do not want a cure, much less a prevention, for the immensely profitable disease of cancer, and they are willing to sacrifice anyone whom they need to make sure that no cure is discovered. ♦