

# Unconventional Medicine and Institutional Resistance: A Case History About the Uphill Battles Facing an Innovative Cancer Therapy

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## Abstract

This analysis revisits the controversial 1990 Office of Technology Assessment (OTA) report commissioned by the U.S. Congress to evaluate unconventional cancer treatments, comparing the political pressures on the medical establishments then to the present-day National Institutes of Health initiatives. The article argues that when political pressure forces the medical establishment to investigate therapies, the bias will be toward refuting them, applying burdensome standards, and overlooking potentially substantive data.

While the OTA report discussed multiple unconventional cancer treatments, this article refutes their critique of the methods of William Donald Kelley, D.D.S., and of the investigation of his work by Nicholas J. Gonzalez, M.D. Notably, the OTA initially omitted Gonzalez's most compelling data, later subjecting it to review by both unconventional and mainstream

physicians. The outcome revealed a polarization: physicians sympathetic to alternative medicine recognized unexpected remissions deserving scientific attention, while mainstream oncologists dismissed the results, mainly due to reliance on survival rather than tumor regression.

This narrative underscores the likelihood of methodological nitpicking when evaluating unconventional scientific evidence. It can serve as guidance and a warning for researchers in this area.

**Keywords:** National Institutes of Health (NIH); Office of Technology Assessment (OTA); Unconventional cancer treatments; Alternative medicine; Integrative oncology; Nutritional therapy; Pancreatic enzymes therapy; Kelley treatment; Nicholas J. Gonzalez, MD; William Donald Kelley, DDS

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The excitement over the current efforts of the National Institutes of Health to investigate nutritional and lifestyle approaches reminds me of the late 1980s, when the Office of Technology Assessment (OTA), an agency of the United States Congress, investigated unconventional cancer treatments. OTA received multiple requests to do this from both Democratic and Republican members of Congress. Advocates of such methods were quite exhilarated when OTA's work began in January 1987. However, as time passed, both proponents and foes felt the study was being run badly. An article in *Science* described it as "The most controversial project ever undertaken by Congress's think tank."<sup>1</sup>

I recently came across a draft copy of the OTA report, dated February 1990. The final version was published in September 1990 and is available online.<sup>2</sup> My entire professional career has been dedicated to one of the methods reviewed. My goal in this analysis of the OTA

report is to illustrate the reactions of the medical community when political forces pressure it to do something it does not want to do.

In 1981, between his second and third year of medical school, Nicholas J. Gonzalez, MD, met William Donald Kelley, DDS. Kelley had been treating cancer patients with a nutritional approach using diet, coffee enemas, and high-dose pancreatic enzymes for decades. Kelley invited Gonzalez to go through his records to assess whether his methods were of value.

So began a research project that was to conclude in 1987. Gonzalez compiled 50 case reports with a broad spectrum of cancer types. He also tracked every patient with pancreatic cancer who had visited Kelley between 1974 and 1982. The patients who did not follow through with any aspect of Kelley's program had a mean survival of 63 days; those who followed partially, survived 302 days; and those who followed completely, 8 years.<sup>3</sup>

I met Gonzalez in 1983, when I was a medical student, and he was an intern. I had a close view of the final years of his efforts. As time permitted, I was an editor and proofreader, reviewing the extensive quotations included in each case report from patients' medical records, relevant medical articles, and textbooks. Review of the cases convinced me that this method deserved a proper

investigation, with formal clinical trials. That was Gonzalez's goal.

As his time in academia ended, Gonzalez submitted individual case reports and the complete monograph to various publishers, but they were rejected. Editors either expressed disbelief, despite the included medical records, or felt the material was too controversial.

My medical internship and Gonzalez' immunology fellowship ended in June 1986. Subsequently, we stayed with Kelley at the Pennsylvania home of one of his patients, while Gonzalez continued to submit the manuscript to agents and publishers. During that time, in early 1987, OTA asked for a copy of the manuscript, titled "*One Man Alone*". Gonzalez sent one to them. But after more rejections from publishers, Kelley started to blame Gonzalez for the latest disappointment in a life that had already been filled with them.<sup>3</sup> In July 1987, we broke ties with him, and Gonzalez no longer strove for publication.

Instead, Gonzalez began a medical practice later that year in the hopes of continuing Kelley's work. Gonzalez describes that era in his 2010 foreword to *One Man Alone*.<sup>3</sup> It was a busy few years, even before I resumed my medical residency in 1989. I had forgotten that the manuscript had even been submitted to OTA until the draft copy of their report was released in February 1990.

In both the draft and final versions, around 2400 words were devoted to an overview of Kelley's treatment methods, spiritual beliefs, and legal problems.<sup>2</sup> While the text does not say, in so many words, that Kelley's theoretical underpinnings are absurd, it is obvious that the quoted selections are designed to make him look unqualified. Furthermore, although Gonzalez's book describes decades of other scientists and physicians working with pancreatic enzymes and cancer, none of that was included, implying that Kelley came up with this theory himself.

Remarkably, the draft version did not include a discussion of the 50 case histories and the review of Kelley's pancreatic cancer patients that were in *One Man Alone*. It is as if someone decided that Kelley's theories were ridiculous, and so no one needed to read the cases.

At an advisory panel meeting on March 9, 1990, the omission of the case reports was brought up. Subsequently, as described in the introductory section of the final report:

OTA carried out a review of Gonzalez' material by six members of the advisory panel for this project, three physicians generally supportive of unconventional treatments (though none associated directly with the Kelley program) and three mainstream oncologists. Each case was assigned randomly to one unconventional and one mainstream physician.

What this review demonstrates most clearly is that some of Gonzalez' cases may be convincing to physicians already supportive of unconventional treatment but that they were not convincing to the mainstream physicians who participated in the OTA review ... Key issues appear to be lack of adequate documentation of the course of disease and reliance on unusually long survival rather than documented tumor regression in most cases.<sup>2</sup>

While six of the advisory panel members each looked at a third of the cases, no review was done of the section of *One Man Alone* discussing the follow-up of all patients with pancreatic cancer seen by Kelley over eight years.

In the section specifically about Kelley's work, the OTA report states:

"Specified criticisms of the case presentations included the lack of histologic diagnosis in several cases, the assumption that disease was metastatic without biopsy, discrepancies between the narrative and the medical records (e.g., in one case, the surgical pathology report states that the tumor arose 'in the colonic mucosa infiltrating into the wall,' Gonzalez describes the tumor as 'growing through the wall,' which would have a much poorer prognosis), discounting the effects of prior mainstream treatment (e.g., hormonal treatment, which, unlike cytotoxic chemotherapy, may take months to take full effect), and the general lack of reassessment of patients' conditions once begun on the Kelley treatment."<sup>2</sup>

I will provide a point-by-point response to these criticisms.

### 1. Lack of histologic diagnosis in several cases

To quote *One Man Alone*:

"For 48 cases, I provide biopsy confirmation of cancer, but the lack of such evidence for two patients, one with presumed bile duct carcinoma, the other with pancreatic... Both underwent exploratory surgery, at which time large, inoperable tumors were discovered with clear evidence of metastatic spread. In each case, the attending surgeon, believing the diagnosis obvious, chose not to risk biopsy, fearful of the risks involved with the procedure."<sup>3</sup>

The operative notes included with these two cases describe the surgeons' findings and decisions. Two cases are not "several cases," and a surgeon's assessment in the operating room of unresectable metastatic cancer carries some weight even without biopsy. Failing to do a biopsy by today's standards is unimaginable. However, in earlier eras, physicians may have been less likely to take risks to make academic points and to perform procedures only to generate billing.

### 2. Assumption that the disease was metastatic without biopsy

Gonzalez's review of Kelley's cases was retrospective. Most patients were seen in community practices, and not academic centers. Regardless of the setting, in the 1970s and early 1980s, CT (computed tomography) scans were not common, and needle biopsies were also rare. At that time, a history of biopsy-proven cancer plus a new lesion that appeared to be cancer was good enough for oncologists to proceed with chemotherapy and radiation. The advisory panel at OTA applied the standards of 1990 research centers to patients seen in a different era and setting.

As an example, Patient #50 had uterine cancer, treated with hysterectomy and radiation. Subsequently, after years

of abdominal pain, a 5.5 cm mass was removed from her pelvis and confirmed to be recurrent uterine cancer. Simultaneously, chest X-ray demonstrated multiple new pulmonary nodules. Without a biopsy of the lung nodules, her oncologist recommended chemotherapy, which she refused. She was then placed on 17-alpha-hydroxyprogesterone, which she took only for a few months. She then began with the Kelley program. A chest X-ray nine years later showed resolution of the lung masses.

To me, this is one of the strongest cases in *One Man Alone*. Since no biopsy was done, the OTA reviewers might have concluded that the pulmonary nodules were not cancerous. However, biopsy of such nodules was not the standard of the day. In the setting of documented recurrence in the pelvis, new pulmonary lesions were assumed to be cancer, and a risky biopsy was not thought necessary.

This patient died in 2009 at the age of 95, a remarkable outcome, given that her initial surgery and radiation did not cure her disease, as documented by the pathology from the pelvic recurrence. A short course of hormonal therapy would not be curative.

### 3. Discrepancies between the narrative and the medical records

The specific example provided is as follows:

“in one case, the surgical pathology report states that the tumor arose ‘in the colonic mucosa infiltrating into the wall,’ Gonzalez describes the tumor as ‘growing through the wall,’ which would have a much poorer prognosis.”<sup>22</sup>

I reviewed Gonzalez’s narrative and the medical records for the three patients with colon cancer. Neither quoted passage is present.

In the first case, the pathology report describes “a moderately differentiated adenocarcinoma that infiltrates well into the perimuscular fat. ... Sections of the two grossly identified lymph nodes disclose that both of them are replaced by metastatic tumor ...”

In the second, “The cecal pouch is filled with bulky ulcerated neoplasm which is almost completely circumferential ... Tumor infiltrates directly into the contiguous mesentery.” The surgeon described hepatic lesions but did not biopsy them.

In the third, “infiltrating adenocarcinoma of the colon, intermediate differentiation with full thickness involvement of bowel wall.” In this case, Gonzalez described the tumor as “penetrating through the bowel wall,” but then, in his text, quoted the pathology report, which mentioned “full thickness involvement.”

In no case did a pathology report use the phrase “in the colonic mucosa infiltrating into the wall,” or describe such a finding. The only provided example of the OTA claim of “discrepancies between the narrative and the medical records” is simply wrong. I find this criticism especially insidious, since it is an accusation of dishonesty.

Gonzalez insisted on using extensive quotations from medical records, rather than summarizing them. I argued

at the time that these quotations were redundant, boring, and tedious to proofread. I now see that he was right.

### 4. Discounting the effects of prior mainstream treatment (e.g., hormonal treatment, which, unlike cytotoxic chemotherapy, may take months to take full effect)

To examine this issue, I reviewed the reports for patients with breast and prostate cancer, where hormonal treatment is commonly used. Earlier, I described a patient with uterine cancer who was treated briefly with a synthetic progesterone. Of the 5 patients with breast cancer, 3 never had hormonal therapy. One patient had bone recurrence 3 years after mastectomy, took diethylstilbestrol along with the Kelley program for 18 months, then stopped the diethylstilbestrol. It is hard to see that diethylstilbestrol can be credited for her excellent clinical status more than a decade later.

Another patient, premenopausal at diagnosis, had bilateral breast cancer. A year after her second mastectomy, she developed terrible back pain. In 1975, she was found to have osteolytic lesions on plain films and a positive bone scan. She underwent oophorectomy, but no other orthodox treatment, hormonal or otherwise. She had an excellent clinical status 10 years later and was still in good health when I spoke with her in 2016.

Of the five patients with prostate cancer, one never took hormonal therapy. One patient with widely metastatic disease to bone, admitted to the hospital for pain control, had an orchiectomy and a month or two of diethylstilbestrol. A short course of diethylstilbestrol does not explain his subsequent pain-free survival 10 years later. In two of the prostate cancer cases, there was sufficient overlap of diethylstilbestrol with the Kelley program to make it unclear whether success was due to diethylstilbestrol or not. Gonzalez provided references suggesting diethylstilbestrol would not typically be that effective.

### 5. General lack of reassessment of patients’ conditions once begun on the Kelley treatment

Gonzalez told me many times that it was difficult to obtain records even if the patients continued to seek care from their local doctors. In many cases, it had been years since diagnosis, and physicians’ offices claimed the records had been discarded. Kelley’s patients, for the most part, avoided doctors; many never returned to conventional care. This demand is another example of the standards of academia in 1990 being applied to a retrospective study of patients seen in the community in the 1970s.

The OTA report goes on to critique three of the cases in detail. They chose three of the weaker cases. As a side note, Gonzalez told me that he meant for all 50 cases to be read as a group. He believed that readers steeped in cancer orthodoxy would instinctively rationalize the patients’ good outcomes. However, after having done so 20 or 30 times, they might start to wonder if there was some value in Kelley’s methods. Unfortunately, the cases were divided

among reviewers, and each one would have reviewed only 16 or 17 cases.

After the critique of the cases, the report continues with a statement from a mainstream reviewer:

“Those of us who have worked over the years with cancer patients have come to respect the vagaries of human biology wherein there are cancer patients who for unclear reasons fare better than we would have expected.”<sup>2</sup>

I wonder, did the commenter ask these patients what they attributed their good outcome to? “Unclear reasons” could mean a reason that the mainstream physician could not or would not accept. I routinely hear from my patients that their oncologists refer to them as “miracle patients.” In no case has an oncologist asked these patients what they are doing.

In contrast to the negativity of the mainstream reviewers, the physicians described as sympathetic to alternative medicine were more positive. As an example:

“in the cases I have marked legitimate, based upon the facts presented and beyond any reasonable medical doubt, it appears that totally unexpected remissions occurred. If there is such a thing as ‘best cases,’ these appear to fulfill that definition. It would be unscientific to ignore such data.”<sup>2</sup>

Who would be more reliable in their assessment: the experts in oncology, or the generally supportive physicians on the advisory panel? The superficial answer would be the experts, but that may not be correct. In his book *Blind Spots*, Marty Makary, MD, provided several examples of top-flight experts dismissing new ideas and evidence that challenge their beliefs.<sup>4</sup> He wrote:

“If a shoddy study supports what people already believe, it’s hailed as definitive science, but if a strong study conflicts with a foregone conclusion, it’s ignored or nitpicked. ... When I was a student at the Harvard School of Public Health, we had a standard homework assignment. We would take six studies that had recently been published by *JAMA* and the *New England Journal* and nitpick them to death. ... What I learned was to design research studies optimally, but what was frightening was that I also learned how to destroy any study I didn’t like.”<sup>4</sup>

He goes on to provide examples of how nitpicking permeates grant funding and article acceptance, before concluding:

“To resurrect the scientific method, we need to be objective in how we evaluate research, including research we don’t like by people we don’t like.”<sup>4</sup>

What harm did the OTA report cause? While the OTA report generated tremendous heat while it was underway, both friends and foes of alternative cancer treatments were dissatisfied with the final report. Upon looking at articles critical of Gonzalez’s and my subsequent research efforts, I did not find this report among the references.

A prominent nutritional textbook, *Modern Nutrition in Health and Disease*, published in 2006, mentioned it.<sup>5</sup> In the chapter titled “Alternative nutrition therapies,” Barrett states:

“Treatment said to be similar is still provided today by Nicholas Gonzalez, MD, of New York City, who claims to have analyzed Kelley’s records and drafted a book about his findings. The manuscript was never published, but experts who evaluated its chapter on 50 cases found no evidence of benefit.”<sup>5</sup>

No nuance here, no mention that none of the experts read all 50 cases, and that some physicians read the cases and felt there was a possibility of benefit.

Since the OTA report was rarely mentioned in other scholarly works, it is difficult to assess its impact. However, the advisory panel for the OTA effort included well-known figures in the integrative medicine world, such as Andrew Weil, MD, and Michael Lerner, PhD, of Commonweal. Had I been in their shoes, that erroneous claim of misquoting medical records would have made me wary of being supportive.

Another advisory panel member, Barrie R. Cassileth, PhD, later started an integrative medicine unit at Memorial Sloan-Kettering and became the founding president of the Society for Integrative Oncology. As we pursued our clinical research efforts during the 1990s and early 2000s, Cassileth frequently made disparaging comments to the press.<sup>6</sup>

Why then did Gonzalez not contest the OTA report after its release in 1990? Gonzalez and I had severed ties with Kelley in 1987 due to his erratic behavior, so different from that of the man Gonzalez worked with while reviewing the cases.<sup>3</sup> The changes in Kelley were perhaps understandable because of the years of stress, attacks, and disappointments he had endured, but he had become impossible to work with. Publishing *One Man Alone* at that time would have led both potential patients and the media to seek Kelley out, giving him a larger audience when his emotional and professional capacities were already challenged.<sup>3</sup> The tragic story of Kelley’s final years does not diminish his tenacity or his brilliance when he was in his prime.

The manuscript remained unpublished until well after Kelley died in 2005. Now, you can read the 50 cases and decide for yourself if Gonzalez and I were right to forgo careers in orthodox medicine and embark on our long and ultimately futile effort to get this method fairly investigated.<sup>3,7,8</sup> For myself, I have no regrets. Case reports from Gonzalez’s and my practice keep me motivated to persevere.<sup>9-12</sup>

What then can current researchers expect, as political winds push scientists at the National Institutes of Health to investigate things they do not want to?

- Expect to have theories picked apart while data are ignored.
- Expect to have impossibly high standards applied.
- Expect to have diagnoses questioned.
- Expect to have errors made and never retracted.
- Forewarned is forearmed.

### Author Disclosure Statement

No financial support or conflict of interest to declare.

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