

James Myers Budget
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Another Modern Prometheus?

Preface: The frame of this tale is fiction. The doctor depicted was real.

Matt sometimes wondered what it was like to be a famous statistician, *and* a sculptor. His idol Edward Tufte was both. Matt loved that Tufte laid into all sorts of beliefs, on the ground that you can take loose-fitting data wherever you want. Just tilt your head a bit, and of course your honored monument will line up with sunset at the solstice, or sunrise at the equinox. “[C]onforming alignments will lock into place if the desired answer is already known.”ⁱ And Tufte insisted that if you couldn’t answer the question, “Compared with what?” you couldn’t inform any decision worth making.

Matt thought of that after meeting with Sallie, a sales director at Noyco Pharma. He knew Sallie was seen as a hard-charger at Noyco. He knew he was seen as the hardass biostatistician. And he knew that since he’d come to the startup, he’d given Noyco more than one lesson that FDA didn’t think anything called “data” could be loose-fitting. FDA reviewers weren’t going to tilt their heads in any direction to pump up the Noyco CEO’s options. R&D guys were starting to get it: recocking numbers to make it *look* like the study came out was the road to rework hell.

Matt assumed his reputation was why Sallie asked to meet, after the announcement that he’d be working on new oncology drugs. She took him through them, bathing each in the best light; but all seemed far from testing in patients; it would be years before he’d see data.

As she packed to leave, Sallie asked, “Have you heard about the Gonzalez project?” He confessed he hadn’t.

“It’s one that Sam Grant is big on. You should check it out.”

“Why’s that?”

“Well, I sell drugs to docs. I’m not sure how I’d sell Gonzalez. And I don’t know if it’d help me sell anything else.”

Sam Grant, Matt knew, was a Drug-Development VP who relished a reputation as a maverick. His idol was Barry Marshall, the Australian doc who said that ulcers weren’t caused by stress and diet, but by bacteria. Marshall was at first ridiculed by the medical establishment; but he put his theory to proof, and he was proved right. He won a Nobel Prize. Sam Grant never stopped reminding the Noyco CEO of Barry Marshall.

Matt wasn’t used to getting warned off by sales people, so he poked around after Sallie’s visit. He couldn’t believe what he found. He liked things to add up, and Dr. Nicholas Gonzalez didn’t. It was like he was put together with mismatched parts. A *magna cum laude* English grad at Brown, Gonzalez got a job writing for Time, Inc. He covered medical topics, and became fascinated. He chucked journalism and went to Cornell medical school. He worked with Professor Robert A. Good, called “the father of immunology” -- even did a fellowship with him. For conventional medicine, Gonzalez checked the right boxes.

But while Gonzalez was still in medical school, a writer friend connected him with a William Kelley, an “alternative” cancer practitioner. Kelley was in the news for treating Steve McQueen’s cancer. Gonzalez, intrigued, investigated Kelley’s many claimed cancer cures. And Gonzalez was won over.

The very first thing that didn’t add for Matt was Kelley. Kelley was an orthodontist who’d lost his dental license for treating cancer without a medical license. His theories seemed crude. Kelley said that cancer was one disease, caused by diets that didn’t take into account distinct “metabolic types.” Wrong diet for your type, and you don’t make enough pancreatic enzymes to “digest” your cancer cells. Cancer was a placenta growing unchecked in the wrong spots. With the right nutrition – designed for your Kelley-determined metabolic type -- and “detoxification,” you could beat cancer. Key detoxifiers were coffee enemas. Matt knew those were old-school real medicine -- listed in the Merck Manual until 1972. That listing was held up by Kelley’s backers as proof coffee enemas were legit. “OK,” thought Matt, “I guess we need to accept bloodletting, too.”

And Kelley’s famous patient Steve McQueen died under Kelley’s care. Kelley’s explanation: McQueen was murdered. “During the night a government agent came into his room posing as a physician on duty and injected McQueen with a blood clotting medication, which was the cause of death.”ⁱⁱ Gonzalez didn’t go that far, but he did say Kelley’s treatment had worked, and McQueen died of a blood clot, not cancer.ⁱⁱⁱ

Gonzalez went all in on Kelley. He set up practice in Manhattan with his ex-wife, also a physician, offering Gonzalez's version of Kelley's regimen.

Matt knew he had to talk to Grant about Gonzalez. But before he did, he wanted to hear from someone closer to the project. He knew a group manager who was a straight shooter. He went to her.

She was eager to talk: "Sam brought Gonzalez in three months ago to lecture on his program. It was more Sam giving us an audience with the great man. The great man does love to talk. And talk. You know Sam's self-image: he's the guy who breaks the rules to win the game. Reinvents the game, he says. He's taken up base-jumping as a hobby – maybe to complete the picture. I think Dr. Gonzalez is Sam's fantasy self."

"What's Sam got you doing on this?"

"Garbage. I have Ph.D. pharmacologists working on whether regular coffee can substitute for organic. My chemists are trying to set specs for pancreatic enzymes from New Zealand swine. My guys are in despair. Sam, by the way, is on a Gonzalez-prescribed nutrition-plan. He's taking so much beta-carotene that he's orange. "

"How can I help?"

She started to speak, caught herself, then said "Well, ... convince the top guys there's no product here."

Matt almost laughed. “Damn,” he thought, “There’s a lot of fear here.”

Before meeting with Grant, Matt asked the lawyers what they could find on Gonzalez. They came up with this: Gonzalez had been put on probation for two years by New York State’s medical board for “departing from accepted practice.” And he had a malpractice case against him in Manhattan. It was brought by an art teacher who’d had uterine cancer, and was terrified of chemotherapy. She wound up blind after Gonzalez convinced her to skip that, and go with his therapy.

Matt’s meeting with Grant started as expected. They went through the portfolio: trials for new indications for the company’s products; early-phase studies for new compounds. Gonzalez came up last.

Grant led: “You heard about the Gonzalez project? You should know that our CEO thinks it’s the best thing this company has ever worked on.”

“The promise is exciting, Sam, but I don’t see how to reach it.”

“You’re a biostatistician. You need things to add up, and fall between those funny whiskers of significance. I do R&D. *By definition*, I’ve got to dream. Tear things apart, and put’em back together different. You know about Barry Marshall. Everybody crapped on him, and his theory.”

“I know about Marshall. He put a wild theory to proof. And he proved he was right – in the usual way. How does that happen with Gonzalez?”

“He’s working with Columbia Medical, Matt. Gonzalez has eleven pancreatic cancer patients with amazing survival -- some are still alive. That’ll get the National Cancer Institute to fund a study.”

Matt knew most pancreatic cancer was discovered late -- making it a death sentence. It was the perfect malady to draw patients to Gonzalez. The industry had a saying: ‘There’s no alternative medicine for curable diseases. The reverse is also true.’

“Well Sam, that’s the way to go. But some things might scare the Institute away. One, Gonzalez has history with his medical board. Two, he’s got a malpractice case.”

Grant was calm. “I know about those. The first was New York docs killing competition. The second is a patient screwed up by docs before she got to Nick. He’ll win his case.”

Matt was eased a bit by Gonzalez’s plan to test. Still, he asked the lawyers to send him transcripts after the malpractice trial started. They made dismal reading. Gonzalez pounded on two things: First, he’d told his patient his regimen wasn’t standard, so she took that risk. Second, she didn’t follow the prescribed regimen.

“Damn,” thought Matt, “It’s a closed system. ‘Use my regimen and get better, and it works. Use it and get worse, you’re not complying.’ All results confirm --- me.”

This was Matt's second problem in adding Gonzalez up. How could anybody good make the arguments he made? Matt took the time to read Gonzalez's book on Kelley. He read that Gonzalez started looking at 1,306 of Kelley's patients, then narrowed it to 1,000, then interviewed 455, then got records for 160, and by his own term, "arbitrarily" picked 50 to present.^{iv} Classic data-dredging.

Gonzalez's presentations followed a set format: pages of purported medical records with names blacked out. But a letter or two wouldn't be obscured. Why not – for an air of mystery? And most survivals and cures weren't documented, just asserted. To Matt, it reeked of BS.

So Matt wondered: did Gonzalez believe his own hype -- that Kelley, and by association, Nicholas Gonzalez, was such a titan? And if he did believe it, why build defenses with disclaimers and releases? Just lawyers at work?

Matt found he had a lot of "help" trying to add up Gonzalez. People from finance, medical affairs, and R&D stopped by to share the latest. A sales rep described how she'd been ordered to visit Gonzalez's practice, and was treated to a tour of the back room where Gonzalez and his staff took their coffee enemas -- from the personally-labelled bags hanging ready there.

None of Matt's helpers were sharing concerns with Grant.

A jury broke that silence. Gonzalez lost his malpractice case, and became the first physician in New York State history to have *punitive* malpractice damages against him.^v In a nod to the defense, the jury found the patient 49% responsible for her problems – in essence, for going to Gonzalez.

The New York Daily News headline “Cancer Doc Hit for \$2.5M-Plus”^{vi} meant far more at Noyco than debates on the worth and scope of alternative medicine. Sam Grant moved on, and Noyco’s Gonzalez project died.

But Matt continued to see news of Gonzalez. One Sunday in the Times’ wedding announcements, there was Nick Gonzalez, smiling with his new bride.

And Matt saw the Gonzalez therapy got its government trial in pancreatic cancer. The data: the control on standard drugs lived three times longer, and better, than the metabolic-therapy group.

It seemed like a slam dunk. But no one was satisfied. Purists were pissed that the study was run at all. Patients couldn’t be randomized -- too few accepted random assignment to the Gonzalez leg. So patients were recruited who self-selected to it. They suffered. The purists said sick volunteers were tortured to placate alternative-medicine fans in Congress.

For his part, Gonzalez was defiant. He said nobody in the study got his therapy. Subjects in the metabolic leg were too sick, he said, to comply with a regimen requiring

such *devotion*. They weren't screened, or treated, by him or other adepts. He scribed a book laying the results on "a morass of poor management and indifference by those assigned to supervise the project." He urged alternative cancer practitioners to shun government, and medical schools, and try for money from industry and foundations.^{vii}

"Good old Nick," thought Matt: "He tills his field. If he doesn't like what grows, someone's poisoned it. He's unverifiable, and unfalsifiable. Created a world where he can live as a shaman. Maybe he is that – but he's no titan. He's an exile."

Long after leaving Noyco, Matt saw that Nicholas Gonzalez, the life-sustainer, died of an "apparent" heart attack at 67. Believers said he was assassinated by "big pharma."^{viii}

Matt wondered, "Who'd bother? The guy didn't add up."

ⁱ Tufte, Edward R., *Beautiful Evidence*, Graphic Press, 2006, at 29.

ⁱⁱ W.D. Kelley, *One Answer to Cancer: Reviewed after 32 Years, 1967 – 1999. With Cancer Cure Suppressed*. <http://www.drkelley.com/CANLIVER55.html>

ⁱⁱⁱ <https://thetruthaboutcancer.com/steve-mcqueen-death/>

^{iv} Gonzalez, Nicholas J, *One Man Alone: An Investigation of Nutrition, Cancer, and William Donald Kelley*. New Spring Press, 1987, 2010 at 52-53.

^v The award of punitive damages was reversed on appeal. *Charell v. Gonzalez*, 251 A.D.2d 72, 673 N.Y.S.2d 685, 687 (1998).

^{vi} *New York Daily News*, March 31, 1997.

^{vii} http://www.dr-gonzalez.com/jco_rebuttal.htm

^{viii} See, e.g., <https://www.globalresearch.ca/cancer-and-autism-mysterious-deaths-of-alternative-health-doctors-who-have-real-cures-not-approved-by-the-fda/5465809>