

No Way to Run a Business

In considering his visit to the dark side, Augie decided,

“If that’s the worst, everything else is better. I was no longer fearful, fearful of the progress of the disease, fearful of the knowledge of whether I was loved and respected.” The Augie Nieto who returned home from Hoag Hospital was very different from the man who’d wandered into his bathroom in the small hours of Memorial Day morning to choke down a fistful of pills. Lynne noticed the change immediately. “Augie started looking forward,” she said.

He was back home by the first week in June and already anticipating the planned renewal of his and Lynne’s vows on the anniversary of their marriage. The service was scheduled for later that month, and family and friends who attended saw a renewed Augie, a determined and optimistic Augie, reaffirm his love for his wife of ten years. During this same period, he was also occupied with a constructive look back. He was only then beginning to digest all the details of his experience traveling the country visiting clinics and doctors devoted to ALS research and treatment. He had been in such an inky funk at the time, a state of psychological shock, that he’d barely been capable of putting one foot in front of the other. Upon reflection, Augie realized he’d come away with a distinct sense of how unsettled and outright contradictory much of the clinical perspective on ALS tended to be. In reviewing what he’d been told specifically and the literature that had been passed along to him, Augie became aware of how little was known about the disease he had. No one could say with any certainty whether sporadic ALS, Augie’s type, was genetically based or environmentally induced. Approaches to treatment varied from specialist to specialist, and Augie noticed the pronounced isolation of the neurologists from each other. “Everybody,” Augie remarked, “was working in a silo.” Historically, ALS research has been conducted by scientists and doctors attached to universities with grant funding supplied by the National Institutes of Health and various nonprofit organizations, led by the Muscular Dystrophy Association. Given the rareness of the disease, the competition for dollars, and the relatively low level of ALS funding (\$42 million projected for 2007 for ALS research, as compared to \$1 billion for Alzheimer’s and \$4.6 billion for cancer), these studies are prone to be modest in scope, and pharmaceutical companies can’t be bothered to invest their considerable research dollars in a disease that has only five thousand to seven thousand new cases annually.

By this time, Augie was fully awake to the complications of his disease and had shed denial in favor of an appetite for every scrap of ALS-related information he could come by. “I became a student of the research,” Augie said of that time, “and I found that institutional, academic researchers were under an incredible amount of pressure to generate a novel hypothesis and then prove its validity.” Unfortunately, Augie’s silo analogy was all too apt. Scientific findings rarely if ever traveled from one university institution to another in an efficient, informal way. Occasionally, peer-reviewed papers were presented at professional gatherings, but the process struck Augie as overly formalized and far too deliberate.

The trouble at bottom, as best as Augie could tell, was a strain of academic contamination. The researchers were highly protective of their studies and their data and cultivated a counterproductive isolation for what impressed Augie as petty reasons. The old joke goes that quarrels between academics are so fierce because the stakes are so small. In Augie’s view, here were researchers engaged in matters of life and death for Augie and his fellow ALS sufferers who were failing to treat the stakes with the urgency they deserved. They were behaving more like academics than healers. A frequent observation of Augie’s is that a “system is incapable of viewing itself,” so sometimes the most astute assessments are made by people coming from the outside. At the time, Augie may have been an ALS neophyte, but he was an old and highly successful hand in the corporate world. His observation of the leading ALS clinics and their maddening lack of interplay and organized oversight had led him to one concrete conclusion: “That’s no way to run a business.”

Part of Augie's education in the neurological intricacies of ALS and the general state of play in drug therapy and ALS treatment came in the form of a seminar he and Lynne attended at an Orange County hotel in the summer of 2005. The session was conducted by Jamie Heywood, whose younger brother, Stephen, had been diagnosed with ALS in December of 1998.

Jamie's response to his brother's illness had been to learn everything he could about ALS and the therapies available. His reaction to what he discovered had been much like Augie's. Jamie found research on the disease to be piecemeal and appallingly slow, fundamentally due to ALS's orphan status as a disease with a national prevalence of around thirty thousand cases annually. Moreover, the general approach to solving the considerable neurological puzzle presented by ALS impressed Jamie as far too conservative to produce the sorts of near-term results that might help his brother.

In response, Jamie and a couple of friends—none of them with medical training—started the ALS Therapy Development Foundation in his basement. The object was to engage in what Jamie called “guerilla research” and thereby revolutionize the stodgy traditional approach to ALS therapy. The plan initially was to raise enough money to fund cutting-edge research, but given the general paucity of it, the ALS Therapy Development Foundation eventually opened a laboratory of its own. The foundation took space in a Cambridge, Massachusetts, warehouse district and started its own mouse lab with the intention of testing every approved pharmaceutical agent available that might have even an accidental effect on the degenerative progress of ALS. The foundation was canvassing for a drug without bothering to develop a theory of ALS and its causes first, an approach bluntly antithetical to the academic method.

The creatures employed in such tests, called SOD1 mice, are genetically engineered with a human gene that gives them a form of ALS. Their symptoms are much more compacted than those exhibited in people. The mice generally lose their ability to walk after ninety days and die in four or five months. The mice are also fairly pricey at upwards of seventy-five dollars an animal, before housing and testing are factored into the equation, which raises the price per mouse to nearly two thousand dollars. So the ALS Therapy Development Foundation, in funding its own laboratory, needed to bring in cash at a healthy clip to keep ahead of the cost of operations.

To that end, Jamie traveled the country delivering his ALS 101 seminars and soliciting donations. The session Augie attended lasted the better part of an afternoon and had drawn the friends and families of ALS sufferers, along with several ALS patients. Jamie gave a layman's account of the medical history of ALS and described the slow, degenerative progress of the disease in language the audience could readily understand.

Augie responded instinctively to Jamie's passion for his mission. Jamie was after nothing less than an outright cure for ALS and some therapeutic means of reversing the ravages of the disease. The prevailing view among physicians, as voiced by Lynne's oncologist brother Kent, tends to be less ambitious. “With ALS, the hope is to revert it to a chronic disease,” Kent said. “I think of it as a parallel with cancer, where we can treat some cancers and get people back to normal.” He went on to add, however, that “to reverse the effects of ALS, you're almost faced with having to reconstitute the nervous system.”

In pursuing a cure, Jamie had done everything within reason to bring the plight of his brother to the attention of the nation. With the exception of Mitch Albom's sociology professor, Morrie Schwartz, no ALS sufferer was more widely known than Jamie's brother, Stephen Heywood.

Stephen and Jamie were featured in a *New Yorker* profile, and their circumstances were presented at exhaustive length in a book by Jonathan Weiner, *His Brother's Keeper*. Additionally, at the time of Jamie's L.A. seminar, the family had been living under the scrutiny of a pair of filmmakers for a

couple of years. The result would be *So Much So Fast*, a documentary devoted to the travails of Stephen's disease and to the heroic efforts of the volunteers and employees at Jamie's ALS Therapy Development Foundation to find a cure.

What Augie detected in Jamie was the power of singleminded devotion, not all of it harnessed to best effect. As a businessman—and more pertinently, as the CEO of a successful manufacturing concern—Augie had developed a nose for efficiency. So while he admired Jamie's tireless commitment to his stricken brother and applauded his ambitions, Augie couldn't altogether endorse the foundation's scattershot approach to fund-raising, which appeared to leave Jamie scrambling for cash to keep the operation afloat.

"I saw how great the science was," Augie said of the foundation, "but I found the fund-raising more a matter of happenstance and not well disciplined."

Like Jamie, Augie wanted to find a cure for ALS, and he was growing increasingly aware that the effort would require a monumental amount of money and an entirely new way of thinking about medical research. Augie, ever the entrepreneur, found himself entertaining the notion of replacing the traditional academic research model with an industrial one. Work would be efficient and speedy; data would be openly shared; potential drug targets would be licensed for profit to pharmaceutical companies.

The man widely known as the Henry Ford of the fitness industry was, by grim necessity, considering a new career.

Augie:

I saw my first ALS patient at Jamie's seminar. He was in a wheelchair in the back of the room. All I could see was his chair. All I could hear was his respirator.

Lynne:

I remember that. It was like . . . holy shit! That's ALS.