John Beard, D.Sc.

The Enzyme Treatment of Cancer and Its Scientific Basis

with a foreword by Nicholas J. Gonzalez, M.D.

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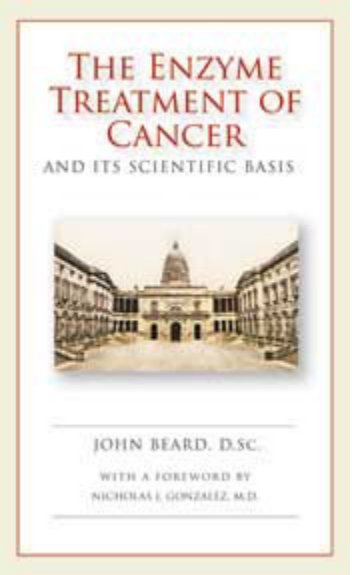
The Enzyme Treatment of Cancer and Its Scientific Basis:

being collected papers dealing with the origin, nature, and scientific treatment of the natural phenomenon known as malignant disease

John Beard, D.Sc.; with a foreword by Nicholas J. Gonzalez, M.D.

An Exact Reproduction of a Classic Work



Available through Amazon

ISBN: 978-0-9821965-2-6
Hardback: 320 pages including eight illustrations and references
Product dimensions: 5.5 x 8.5 inches

In a 1902 article written for the British medical journal Lancet, the English scientist John Beard, at the time Professor at the University of Edinburgh, first proposed that the pancreatic enzyme trypsin represents the body's primary defense against cancer and would be useful as a cancer treatment. Beard came to his conclusion as the result of some 20 years of hard laboratory research, that today holds up to rigorous scientific scrutiny. Despite his documentation and his impeccable reputation—he would be nominated for the Nobel Prize in 1905 for his work in embryology—the vast majority of cancer experts categorically rejected Beard's thesis outright.

But not everyone dismissed Dr. Beard. A number of physicians concluded that Beard might be right, and with his support began employing injectable pancreatic enzymes in the treatment of their own patients diagnosed with advanced cancer, often with remarkable results as reported in the conventional scientific literature. These successes seemed to provoke an even more intense backlash against the treatment, in a heated debate that lasted right through the first decade of the 20th century. In response to his critics, in 1911 Beard published The Enzyme Treatment of Cancer and Its Scientific Basis, outlining his hypothesis, his decades of research and the promising and compelling results. Though released by a major London publisher to some very positive reviews, the book was soon forgotten as the scientific community and the media enthusiastically latched on to Madame Curie's claim that radiation represented a simple, easy, non-toxic cure for cancer. It would be years before scientists realized radiation cured few cancers and was quite toxic—Madame Curie herself died as a

result of her exposure to uranium—but by that time, Beard was dead and forgotten.

In 2010, 152 years since Beard's birth, and nearly 100 years since publication of this book, it is time this pioneer's work be reread. With billions and billions of dollars spent in recent decades on cancer research with only slight success to show for all the effort, Beard's work warrants a thorough reconsideration.

This book is intended for general informational purposes, not as a medical manual or a how-to book for self-treatment. Please consult with your physician before starting or modifying any treatment program.

Read the Foreword, the Table of Contents, and a Review

About the Author:

John Beard, D.Sc.

Dr. John Beard was born in Lancashire, England in 1858, completed his secondary school education at Owens College in Manchester, and pursued undergraduate training in natural sciences at the University of London. He earned his doctoral degree at the University of Freiburg in Germany, concentrating on the development of sense organs in invertebrates and fish. Later, while affiliated with the University of Edinburgh, his study of the mammalian placenta led him to the conclusion that in its early incarnation, this tissue behaves much as a cancerous tumor. He then proposed that pancreatic enzymes regulate placental development, and in turn represent the body's main defense against cancer. Despite the controversy his enzyme thesis created, in 1906 he was nominated for the Nobel Prize for his work in embryology. In 1911, he published The Enzyme

Treatment of Cancer and Its Scientific Basis to favorable reviews. Though in his lifetime the scientific community never embraced his ideas about cancer—he died in relative obscurity in 1924—in recent years, evidence from molecular biology and stem cell research increasingly confirms many of Dr. Beard's fundamental precepts.

The enzyme treatment of cancer and its scientific basis:

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Excerpt from the Foreword

The year 2008 marked the 150th anniversary of the birth of Dr. John Beard, the pioneering University of Edinburgh embryologist who in 1902 first proposed an anti-cancer effect for the proteolytic enzyme trypsin and its related "ferments," as he called the pancreatic digestive secretions. Though his work generated considerable interest as well as controversy during his lifetime, by the time of his death in 1924, his ideas were virtually forgotten, relegated to a footnote of medical history. However, recent evidence from the world of molecular biology, as well as our own ongoing research efforts, continue to confirm the basic elements of Beard's hypothesis. So it is with great

satisfaction that at this time, I have the honor of introducing a reprinted version of his wonderful text, The Enzyme Treatment of Cancer, published in England in its first and only edition in 1911. In this remarkable book—which has never been previously reissued—Beard detailed his elaborate theory about enzymes and cancer, and the long route that led him from the most esoteric of embryological considerations, the development of the sense organs of fish, to thoughts about malignant disease, its origins, and its treatment.

The mid to latter half of the 19th century was a time of major advances in science in general, and the biomedical sciences in particular. In 1846, the American dentist/physician William Morton (1819-1868) first demonstrated the anesthetic effects of ether, in turn making complex surgeries possible and routine. In 1847, the Hungarian Ignaz Semmelweis (1818-1865), with little knowledge of microorganisms, proposed doctors simply wash their hands to avoid spreading the deadly puerperal fever of childbirth, which at the time was devastating the maternity wards of European hospitals. The German physician Rudolf Virchow (1821-1902), though he vehemently opposed Semmelweis' theories about hygiene, made enormous contributions to the field of pathology, defining the microscopic character of many diseases including leukemia and other cancers.

Louis Pasteur (1822-1895), one of the great pioneers in microbiology, codified the revolutionary germ theory of disease, claiming microorganisms such as bacteria were the source of many common deadly ailments. A variation of his famed vaccine for rabies is still used today. Joseph Lister (1827-1912), building on the suggestions of both Semmelweis and Pasteur, confirmed the value of sterile technique and in so doing, made surgery safer than anyone previously had thought possible. Paul Ehrlich (1854-1915) helped usher in the modern world of drug therapy for disease when he synthesized the first effective treatments for both sleeping sickness and syphilis. And though

neither a physician nor an academic scientist, the Austrian monk Gregor Mendel (1822-1884) unraveled the basics of inheritance by observing the humble pea plants growing in his monastery garden. His simple suggestions about the transmission of dominant and regressive traits from generation to generation ultimately served as the foundation for all 21st century molecular biology and molecular genetics, the driving force of contemporary medical research.

There were many other notables, many more achievements, and into this heady scientific world Beard came of age. He received undergraduate training in zoology at the Royal College of Science in London, before completing graduate training in zoology and embryology at the esteemed German universities of Wurzburg and Freiburg, where he obtained a Ph.D. degree in 1884. From 1890 until 1920, he taught at the University of Edinburgh, primarily as a Lecturer in Comparative Embryology and Vertebrate Zoology. In a memoir, a student of the time, Sir John S. Flett, described Beard in some detail:

He was an interesting man, somewhat of a crank, but an enthusiast who had studied under Huxley and spent several years at German universities. His methods were peculiar. He took a new textbook by Arnold Lang (subsequently translated) and read to us paragraphs selected from the book. I promptly purchased the German edition and hence found it easy to follow the course and fill up the gaps in prelection. Beard, however, was anything but a good teacher. He had two subjects which absorbed his interest: (a) the origin of sense organs, which he derived from the lateral line of fishes (b) the phylogeny of the vertebrata; and he was constantly diverging from his set subject and giving dissertations on these hobbies. It was very entertaining but had little reference to the schedule of subjects which we had to study for the examination. (1)

Beard, an embryologist by training, was not in his early career even vaguely interested in medical research, let alone cancer,

instead initially devoting his time to unraveling the development of sense organs such as the eye and ear in invertebrates and in fish. His Ph.D. studies, for example, dealt with the early formation of nerves in an obscure parasitic worm. (2) Many of his pioneering findings from this time, now proven correct, are standard fare in the embryology texts of our day.

His studies of neurons, how they initially form and grow, led him through a most convoluted route to consider the growth and development of the placenta. This tissue anchors the mammalian fetus to the uterus and serves as the point of connection between its blood supply, carrying the wastes of metabolism, and the blood vessels of the mother, supplying oxygen and nutrients. Beard did much to uncover the details of placental growth beginning after conception, first reporting that in many respects the tissue in its early stages appeared and behaved like a malignant tumor. (continued in the book)

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2. Beard J. The system of branchial sense organs and their associated ganglia in Ichthyopsida. Quart J Microsc Soc. 1885;11:52-90.

Return to The Enzyme Treatment of Cancer and Its Scientific Basis

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The Enzyme Treatment of Cancer by John Beard, D.Sc.

Posted on March 3, 2011 by Bob Livingston

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Listen up medical researchers! If you want the medical establishment to accept, or at least consider, your new health ideas that seem promising, you better have the right credentials, politics and media skills to put it across. And having the right friends doesn't hurt, either. Otherwise, no matter how wonderful your insight, the backlash against it is going to be devastating. Mainstream medical practitioners don't take kindly to outsiders impinging on their turf.

Consider John Beard, born in 1858, trained as an embryologist, nominated for the Nobel Prize in 1906 for his work in embryology and the author of *The Enzyme Treatment of Cancer*. A novel idea occurred to Beard as he was staring through his microscope at cells known as trophoblasts, the cells that form the outer layer of the placenta and attach it to the womb. As they

begin to develop and divide, Beard noted, trophoblasts resemble cancer cells. They multiply rapidly and accumulate like a tumor. They develop a new blood supply to feed themselves as tumors do. Plus, they invade the walls of the uterus the same way cancer cells invade the organs of the body.

However, Beard found that at a certain point during normal development of the placenta the trophoblasts give up their cancer-like proliferation and behave themselves. Through a mysterious process, the body signals the trophoblasts when it's time to settle down and call off the invasion. Remarkably, the trophoblasts listen and obey.

According to Beard, in humans, the key event that apparently halts trophoblastic cellular anarchy is the development, in the fetus, of the pancreas, the main gland that releases enzymes needed for digestion. Therefore, he thought, the enzymes released by the pancreas could be the body's way of telling the trophoblasts to cease and desist. And he was struck by an idea. Maybe the same enzymatic signals could halt cancer.

Subsequently, work with cancer patients seemed to show that Beard was on to something. Injection of pancreatic enzymes, which had already been isolated by other scientists, frequently produced an anti-cancer effect.

And what was Beard's thanks for his remarkable insight? A good deal of scorn and the relegation of his findings to the ash heap of medical history. His call for treating cancer with enzymes was laughed off. The more so since pre-World War I surgeons had just begun to use their scalpels for cutting out tumors and weren't about to drop their knives in favor of a more benign therapy.

A big part of Beard's dilemma was that he didn't know how to manage his public relations. A few years later, Madame Curie, a much more media-savvy scientist, sold the journalists of her day

on the idea that *radiation* (a new term she had coined with her husband) offered a high-tech, risk-free cancer cure. In her enthusiasm she never suspected that radiation itself was toxic — even though radiation eventually killed her when her bone marrow succumbed to years to exposure. Matter of fact, her lab was so filled with deadly beams that today her contaminated papers are still stored in lead-lined boxes.

The book *The Enzyme Treatment of Cancer and Its Scientific Basis* is a reissue of John Beard's seminal work from 1911. It explores his examinations of embryos and discusses how cancer's infiltration of body tissues mirrors the way a placenta implants itself on the walls of the womb.

The new edition of Beard's book features a foreword by Nicholas J. Gonzalez, M.D., a nationally known physician who has explored Beard's concepts and used them to devise enzyme based nutritional programs for cancer and other degenerative diseases.

The average reader may find much of Beard's book tedious. For example, a few of the chapters replay his conflicts with the medical establishment of his day, pointing out how he was misquoted and his work misinterpreted. While alternative medicine still copes with that type of treatment from mainstream doctors, the specifics of Beard's difficulties offer details mostly of interest to historians.

But for those who wish to understand the ins and outs of early cancer research, this book conveys a first-person narrative from a meticulous scientist who made some startlingly prescient observations about cancer. His, insights echo modern research: For example, scientists at Princeton are even now studying how metastasizing cancer uses enzymes and certain types of cellular signals to take root in bone. And researchers at Cold Spring Harbor Laboratory (CSHL) only recently discovered the stem

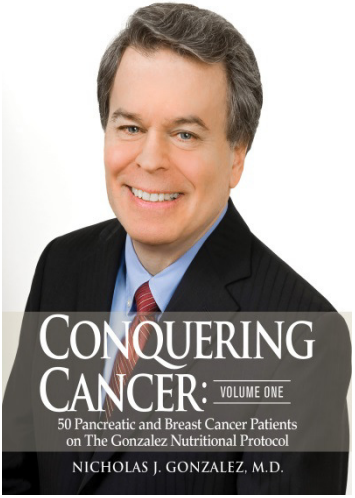
cells that give rise to carcinoma — cells that Beard would have called “vagrant germ cells.”

All of which makes you realize that another problem Beard had was that he was too far ahead of his time. And we’re still waiting for mainstream medicine to catch up.

Welcome to New Spring Press

New Spring Press publishes serious works in the fields of health, with an emphasis on nutrition, its impact on disease, and the theories of Nicholas J. Gonzalez MD and Dr. John Beard, the British scientist who pioneered the therapeutic uses of enzymes. We have the complete works of the late Nicholas J. Gonzalez, M.D. In addition to books, Dr. Gonzalez's lecture recordings on these topics are available.

NEW RELEASES

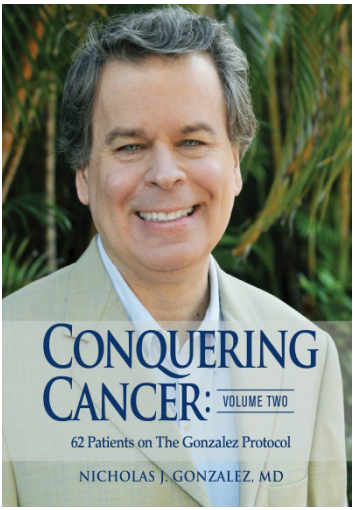


Dr. Gonzalez's two volume case report series, **Conquering Cancer**, published posthumously, is now available.

Conquering Cancer: Volume One - 50 Pancreatic and Breast Cancer Patients on the Gonzalez Nutritional Protocol.

Conquering Cancer: Volume Two - 62 Patients on the Gonzalez Protocol

You can order these books on Amazon in hardback and Kindle editions.

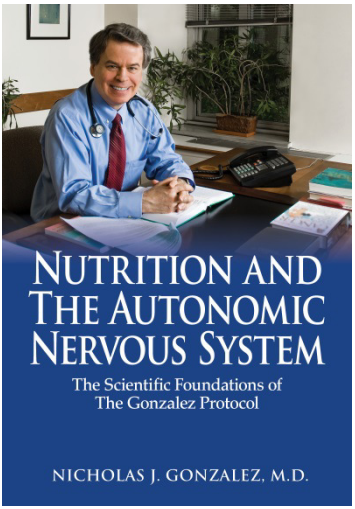


- This cancer case report series documents the effectiveness of The Gonzalez Protocol - the nutritional/enzyme cancer treatment designed by Nicholas J. Gonzalez, MD.

- The two volume book series provides an in-depth analysis of the Gonzalez Protocol in both theory and practice, with 112 representative patients diagnosed with a poor prognosis or terminal malignancies who did well under Dr. Gonzalez's care.

- These two volumes of Conquering Cancer are the culmination of Dr. Gonzalez's twenty-eight-year medical career, as he died suddenly and unexpectedly in July 2015.

- Volume One and Two are now available to all those with an interest in cancer in general, the enzyme treatment of cancer in particular, alternative medicine, and The Gonzalez Protocol. **PLEASE NOTE: this is not a "how-to" book for self-treatment.**



In March 2017, we published Dr. Gonzalez's new book ***Nutrition and the Autonomic Nervous System - The Scientific Foundations of The Gonzalez Protocol***. You can order this book on Amazon in paperback and Kindle editions for just $19.95.

In this groundbreaking book, Dr. Nicholas Gonzalez (developer of The Gonzalez Protocol for the treatment of cancer and many other degenerative diseases) explains the importance of nutrition in maintaining and restoring the autonomic nervous system balance that is so crucial to good health.

- He describes how individual variation in nervous system function means that different individuals require different types of diets (ranging from largely raw food and vegetarian to diets high in fatty red meat, and every variation in between) in order to achieve good health.

- Drawing upon more than twenty-five years of private practice in New York, and prior research by Drs. Pottenger, Gellhorn,

and Kelley, he also explains why nutritional supplementation protocols similarly need to be individualized for optimal autonomic nervous system function.

- While this book is not a how-to manual, reading it will help you better understand how to maintain or improve your own health-or, if you are a health professional, to better assist your patients to remain healthy or recover from illness-without potentially harmful medications.

Other current book titles

The book What Went Wrong: The Truth Behind the Clinical Trial of the Enzyme Treatment of Cancer by Nicholas J. Gonzalez, M.D., won a Silver Award in the Independent Book Publishers Association 2013 Benjamin Franklin Awards (Science category)! For more information about the book, click here. An article adapted from the book, Some Thoughts about Scientific Bias, is available on Dr. Gonzalez's website.

The Trophoblast and the Origins of Cancer by Nicholas J. Gonzalez, M.D., and Linda L. Isaacs, M.D. This monograph comprehensively reviews Dr. Beard's theories regarding the origins of cancer and its treatment from the perspective of contemporary molecular biology. The authors include case histories of cancer patients successfully treated with an enzyme-based regimen This book is also now available on Amazon in Kindle editions.

The Enzyme Treatment of Cancer and Its Scientific Basis by Dr. John Beard. We have reprinted this volume, originally published in 1911, as a carefully reproduced hard cover edition with an added foreword by Dr. Gonzalez.

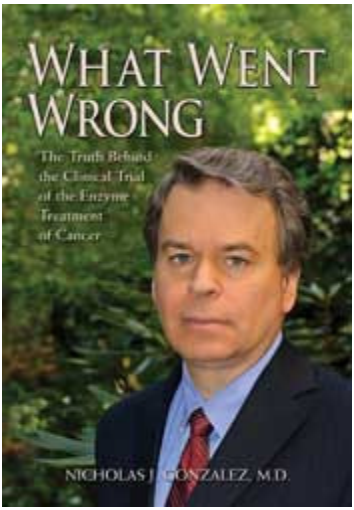
One Man Alone by Dr. Nicholas J. Gonzalez. In this monograph, completed as partial fulfillment of his immunology training, Dr. Gonzalez reviewed the treatment and successes of William Donald Kelley DDS, who refined Dr. Beard's original approach to cancer. Although originally completed in 1986, One Man Alone was not published until 2010, rewritten and with an updated introduction by Dr. Gonzalez. This research study has been generating interest in the alternative and conventional medical world for two decades. This book is now also available in Kindle editions on Amazon

What Went Wrong:

The Truth Behind the Clinical Trial of the Enzyme Treatment of Cancer

Nicholas J. Gonzalez, MD

The Battle for a Fair Evaluation of the Gonzalez Therapy



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In this book, Dr. Nicholas Gonzalez exposes what went wrong with the clinical trial "Pancreatic proteolytic enzyme therapy compared with gemcitabine-based chemotherapy for the treatment of pancreatic cancer," sponsored by the National Center for Complementary and Alternative Medicine and the National Cancer Institute, conducted under the auspices of Columbia University.

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- Examines how poor trial design and implementation condemned this project to failure.
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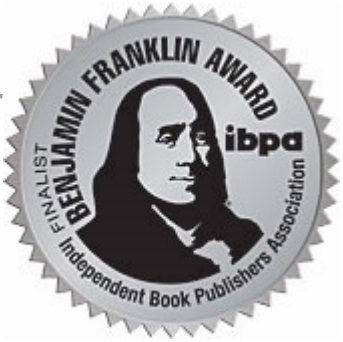

Read the Introduction, the Table of Contents, a Foreword by a patient (150 KB), Reviews, About the Author, and an article adapted from a portion of the book, Some Thoughts about Scientific Bias

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From the Back Cover:

Kilmer McCully, M.D., author of The Heart Revolution:

"For all who are interested in the pioneering studies of Gonzalez and Isaacs on the nutritional and metabolic control of cancer,

their new book What Went Wrong is highly recommended. This extraordinary story paints a detailed picture of mismanagement of a promising clinical trial of pancreatic cancer therapy by vested interests of the National Cancer Institute, the National Institutes of Health, and Academia. The story is one of conviction, persistence and dedication in the face of opposition by the cancer industry."

Paul J. Rosch, M.D., President, The American Institute of Stress:

"This book is about a $1.4 million grant awarded by the National Cancer Institute in 1998 to do a controlled clinical trial comparing the chemotherapeutic drug Gemzar to Dr. Gonzalez' enzyme approach in the treatment of patients with pancreatic cancer. Dr. Gonzalez documents how the study was mismanaged, how he had no control over the selection of patients, and how the protocol was violated in numerous ways that were subsequently confirmed by regulatory authorities. Yet, a misleading article was published without his knowledge and none of the responsible parties were ever admonished or held accountable. This tragic tale tends to support a growing suspicion that the cancer cartel of organizations, government agencies and vested interests is devoted more to preserving their enormous profits and reputations than to the prevention and cure of cancer."

Suzanne Somers, actress and author:

"This is a story that truly needed to be told. In this important book, Dr. Gonzalez carefully details his serious well-intentioned attempt to have his nutritional approach to cancer properly tested in a National Cancer Institute clinical trial, only to have the project mismanaged by the academic and government scientists in charge. It is a tale of indifference, indifference to scientific truth and indifference to patient well-being that reached right into the highest levels of the cancer research

world. It shows first hand the strong biases against natural therapies among the powers that be that keep useful treatments like his from seeing the light of day. For those with an interest in alternative medicine, and particularly for those who still have faith in the integrity of our conventional medical authorities, this book will be an eye-opener.

"Nick Gonzalez is a wonderfully knowledgeable, completely dedicated, idealistic physician. For my book Knockout I interviewed many of his patient successes who have conquered terrible cancer with his treatment, so I know the regimen works. Hopefully, this book will finally set the record straight about the NCI clinical trial and help get this researcher the credit he deserves."

Reviews:

"Reading What Went Wrong reminded me of the statement - the less the people know about how sausages and laws are made, the better they sleep in the night. One need only exchange the words 'laws' with 'CAM research' to understand my perspective. To date, few in the CAM community have been willing to wake up and enter into the fray of discussing an egregious miscarriage of justice for the pancreatic cancer community and for the future of honest dialogue about CAM research. …

"While What Went Wrong is a long read (more than 500 pages), it is organized in logical fashion and separated into 44 chapters. As one learns in this book, this is not the story of a single error in management of the study, but a series of violations of protocol, ethics, and law. …

“This is an essential read for everyone interested in CAM research.” Beth Clay, former NIH and US Congress staffer, in The Integrator Blog

“I highly recommend What Went Wrong. … Gonzalez's book shows us the deeply rooted institutional backlash that infuses the study of an effective, individualized, nonconventional therapy … . His experience is a shot across the bow of all nonconventional practitioners who strive to see their methods authentically evaluated and validated. It is a contemporary history that we would all be wise to study.” Greg Nigh, N.D., L.Ac., in Natural Medicine Journal, the official journal of the American Association of Naturopathic Physicians

“This book is alternately depressing, infuriating and inspiring.” Miriam Knight, editor, New Consciousness Review

“As Dr. Gonzalez reveals in his book What Went Wrong: The Truth Behind the Clinical Trial of the Enzyme Treatment of Cancer, poor trial design, poor implementation at the highest levels of the research, and improper supervision in the trial itself completely derailed the study.

“The book also calls into question the validity of double-blind placebo studies as the gold standard of mainstream medicine. Dr. Gonzalez delves into biases of scientific health community that make the fair testing of unconventional treatments so difficult. …

“Dr. Gonzalez's experience is a testament to the failure of mainstream medicine.” Alliance for Natural Health USA

“What Went Wrong: The Truth Behind the Clinical Trial of the Enzyme Treatment of Cancer excoriates the horrendous mismanagement and subsequent cover-up of a National Cancer Institute/National Institutes of Health clinical trial to study author Nicholas J. Gonzalez, M.D.'s nutritional treatment

methods for patients diagnosed with inoperable pancreatic cancer. … The therapy was not properly evaluated or analyzed despite years of so-called research, depriving future cancer patients accurate information about all their treatment options. What Went Wrong is a striking case study of a scientific study gone terribly awry, and highly recommended for science and medical professionals as well as for concerned laypeople." The Midwest Book Review

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About the Author:

Nicholas J. Gonzalez, M.D.

Nicholas J. Gonzalez, M.D., died unexpectedly in July 2015. He graduated from Brown University, Phi Beta Kappa, magna cum laude with a degree in English Literature. He worked as a journalist, first at Time Inc., before pursuing premedical studies at Columbia University. He received his medical degree from Cornell University Medical College in 1983. During a postgraduate immunology fellowship under Dr. Robert A. Good, considered the father of modern immunology, Dr. Gonzalez investigated the nutritional cancer treatment developed by the dentist Dr. William Donald Kelley. Dr. Gonzalez's subsequent research has been funded by The Procter & Gamble Company, Nestle;, and the National Cancer Institute/National Institutes of Health. Since 1987, Dr. Gonzalez has been in private practice in New York City, treating cancer and other degenerative diseases with an enzyme-based nutritional regimen. Prior to his death, he published a series of books, of which What Went Wrong is the third. For more information on The Gonzalez Protocol and his books, see The Nicholas Gonzalez Foundation - a 501(c)3 nonprofit foundation website.

Introduction to What Went Wrong:

The Truth Behind the Clinical Trial of the Enzyme Treatment of Cancer

Nicholas J. Gonzalez, MD

From 1998 to 2005, my colleague Dr. Linda Isaacs and I worked closely with physicians and scientists from Columbia University, the National Cancer Institute (NCI), and the National Center for Complementary and Alternative Medicine (NCCAM), developing and pursuing a formal clinical trial comparing our nutritional treatment to chemotherapy in patients diagnosed with inoperable pancreatic cancer. When the project first began we were excited by, and grateful for, this opportunity to have our regimen tested under what we hoped would be rigorous academic supervision. In a personal sense, the study represented the culmination of nearly 15 long years of our own research efforts and our battles to have our therapy properly evaluated and eventually mainstreamed. We also hoped that in a more global sense, this effort would help usher in a new era of cooperation between mainstream institutions and serious alternative practitioners with promising new treatments. In those long ago days we truly believed that the endless and fruitless war between academic medicine and more unconventional approaches might be coming to an end, to everyoneâï¿½ï¿½s benefit.

From the outset, the project generated praise and enthusiasm in the alternative medicine press, as well as considerable interest in more traditional venues such as the New Yorker Magazine, but also some dismissive attacks. At times, we both felt we were in the middle of a firestorm. Nonetheless, whatever the obstacles we were determined to soldier on, prove to the scientific community the seriousness of our intent, and show once and for all that a treatment developed outside the academic world could come under scrutiny and be vindicated.

Now, some 14 years later, I am sorry to report that despite our early optimism the study collapsed in a morass of poor management and indifference by those assigned to supervise the project. Our enthusiasm long ago died, along with our faith in the academic research world, its concern for such noble ideals as scientific truth and compassion for the seriously ill. In a more practical sense, at this point we strongly believe that any serious-minded alternative cancer practitioner or researcher should avoid working with NCCAM, the NCI, and academic medical centers at all cost, and instead search for other avenues of support, either from industry or private foundations.

So what went wrong?

http://www.newspringpress.com/what-went-wrong-foreword.pdf

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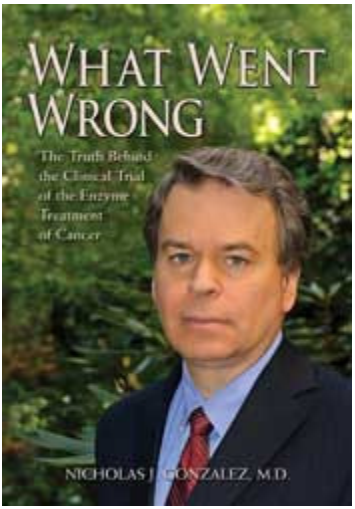

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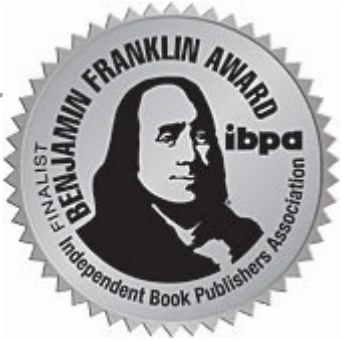

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"For all who are interested in the pioneering studies of Gonzalez and Isaacs on the nutritional and metabolic control of cancer, their new book What Went Wrong is highly recommended. This extraordinary story paints a detailed picture of mismanagement of a promising clinical trial of pancreatic cancer therapy by vested interests of the National Cancer Institute, the National Institutes of Health, and Academia. The story is one of conviction, persistence and dedication in the face of opposition by the cancer industry."

Paul J. Rosch, M.D., President, The American Institute of Stress:

"This book is about a $1.4 million grant awarded by the National Cancer Institute in 1998 to do a controlled clinical trial comparing the chemotherapeutic drug Gemzar to Dr. Gonzalez' enzyme approach in the treatment of patients with pancreatic cancer. Dr. Gonzalez documents how the study was mismanaged, how he had no control over the selection of patients, and how the protocol was violated in numerous ways that were subsequently confirmed by regulatory authorities. Yet, a misleading article was published without his knowledge and none of the responsible parties were ever admonished or held accountable. This tragic tale tends to support a growing suspicion that the cancer cartel of organizations, government agencies and vested interests is devoted more to preserving their enormous profits and reputations than to the prevention and cure of cancer."

Suzanne Somers, actress and author:

“This is a story that truly needed to be told. In this important book, Dr. Gonzalez carefully details his serious well-intentioned attempt to have his nutritional approach to cancer properly tested in a National Cancer Institute clinical trial, only to have the project mismanaged by the academic and government scientists in charge. It is a tale of indifference, indifference to scientific truth and indifference to patient well-being that reached right into the highest levels of the cancer research world. It shows first hand the strong biases against natural therapies among the powers that be that keep useful treatments like his from seeing the light of day. For those with an interest in alternative medicine, and particularly for those who still have faith in the integrity of our conventional medical authorities, this book will be an eye-opener.

“Nick Gonzalez is a wonderfully knowledgeable, completely dedicated, idealistic physician. For my book Knockout I interviewed many of his patient successes who have conquered terrible cancer with his treatment, so I know the regimen works. Hopefully, this book will finally set the record straight about the NCI clinical trial and help get this researcher the credit he deserves.”

Reviews:

“Reading What Went Wrong reminded me of the statement - the less the people know about how sausages and laws are made, the better they sleep in the night. One need only exchange the words ‘laws’ with ‘CAM research’ to understand my perspective. To date, few in the CAM community have been willing to wake up and enter into the fray of discussing an egregious miscarriage of justice for the pancreatic cancer community and for the future of honest dialogue about CAM research. …

“While What Went Wrong is a long read (more than 500 pages), it is organized in logical fashion and separated into 44 chapters. As one learns in this book, this is not the story of a single error in management of the study, but a series of violations of protocol, ethics, and law. …

“This is an essential read for everyone interested in CAM research.” Beth Clay, former NIH and US Congress staffer, in The Integrator Blog

“I highly recommend What Went Wrong. … Gonzalez's book shows us the deeply rooted institutional backlash that infuses the study of an effective, individualized, nonconventional therapy … . His experience is a shot across the bow of all nonconventional practitioners who strive to see their methods authentically evaluated and validated. It is a contemporary history that we would all be wise to study.” Greg Nigh, N.D., L.Ac., in Natural Medicine Journal, the official journal of the American Association of Naturopathic Physicians

“This book is alternately depressing, infuriating and inspiring.” Miriam Knight, editor, New Consciousness Review

“As Dr. Gonzalez reveals in his book What Went Wrong: The Truth Behind the Clinical Trial of the Enzyme Treatment of Cancer, poor trial design, poor implementation at the highest levels of the research, and improper supervision in the trial itself completely derailed the study.

“The book also calls into question the validity of double-blind placebo studies as the gold standard of mainstream medicine. Dr. Gonzalez delves into biases of scientific health community that make the fair testing of unconventional treatments so difficult. …

“Dr. Gonzalez's experience is a testament to the failure of mainstream medicine.” Alliance for Natural Health USA

“What Went Wrong: The Truth Behind the Clinical Trial of the Enzyme Treatment of Cancer excoriates the horrendous mismanagement and subsequent cover-up of a National Cancer Institute/National Institutes of Health clinical trial to study author Nicholas J. Gonzalez, M.D.'s nutritional treatment methods for patients diagnosed with inoperable pancreatic cancer. … The therapy was not properly evaluated or analyzed despite years of so-called research, depriving future cancer patients accurate information about all their treatment options. What Went Wrong is a striking case study of a scientific study gone terribly awry, and highly recommended for science and medical professionals as well as for concerned laypeople.” The Midwest Book Review

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About the Author:

Nicholas J. Gonzalez, M.D.

Nicholas J. Gonzalez, M.D., died unexpectedly in July 2015. He graduated from Brown University, Phi Beta Kappa, magna cum laude with a degree in English Literature. He worked as a journalist, first at Time Inc., before pursuing premedical studies at Columbia University. He received his medical degree from Cornell University Medical College in 1983. During a postgraduate immunology fellowship under Dr. Robert A. Good, considered the father of modern immunology, Dr. Gonzalez investigated the nutritional cancer treatment developed by the dentist Dr. William Donald Kelley. Dr. Gonzalez's subsequent research has been funded by The Procter & Gamble Company, Nestle;, and the National Cancer Institute/National Institutes of Health. Since 1987, Dr. Gonzalez has been in private practice in New York City, treating cancer and other degenerative diseases with an enzyme-based nutritional regimen. Prior to his death, he published a series of books, of which What Went Wrong is the third. For more

information on The Gonzalez Protocol and his books, see The Nicholas Gonzalez Foundation - a 501(c)3 nonprofit foundation website.

Some Thoughts about Scientific Bias

By Nicholas J. Gonzalez, M.D.

From 1998 to 2005, my colleague Dr. Linda Isaacs and I worked closely with physicians and scientists from Columbia University, the National Cancer Institute (NCI), and the National Center for Complementary and Alternative Medicine (NCCAM), developing and pursuing a formal clinical trial comparing our nutritional approach to chemotherapy in patients diagnosed with inoperable pancreatic cancer. When the project first began we were excited by, and grateful for, this opportunity to have our therapy tested under what we hoped would be rigorous academic supervision. In a personal sense, the project represented the culmination of nearly 15 long years of our own research efforts, and our battles to have our therapy properly evaluated and eventually mainstreamed. We also hoped that in a more global sense, our particular clinical trial would help usher in a new era of cooperation between mainstream academic institutions, and serious alternative practitioners with promising new treatments. Indeed, in those long ago days as the project first began, we truly believed that the endless and fruitless war between mainstream medicine and more alternative approaches might finally be coming to an end, to everyone's benefit.

From the outset, the project generated praise and enthusiasm in the alternative press, as well as considerable interest in more mainstream venues such as the New Yorker Magazine (1), but

also some dismissive attacks. At times, we both felt we were in the middle of a firestorm. Nonetheless, whatever the obstacles we were determined to soldier on, prove to the scientific community the seriousness of our research efforts, and show once and for all that a treatment developed outside the academic world could come under scrutiny and be vindicated.

By 2005, the study had collapsed in a morass of indifference, mismanagement by the institutional administrators, and apparent cover-up of the mismanagement. As early as January 2005, a representative of the NIH who reviewed the data concluded that so many patients admitted for our nutritional therapy by the Columbia University Principal Investigator had been unable or unwilling to comply with the prescribed regimen that the data had no meaning. (2) When serious management problems continued unabated – such as the admission of patients by the Principal Investigator with no signed informed consent – in June 2006 I filed a formal complaint with the Office of Human Research Protections (OHRP), the NIH group charged with overseeing the conduct of Federally funded clinical trials. After a two-year evaluation, OHRP concluded that 42 of a total of 62 patients had been improperly admitted by the Principal Investigator at Columbia, including 40 not properly consented– a devastating finding. (3)

Furthermore, we were concerned at times that the Principal Investigator of the project seemed overly enthusiastic about the chemotherapy regimen employed in the trial – an enthusiasm that we thought might color the study's outcome. As it turns out, the Principal Investigator of the study at Columbia helped develop the very GTX protocol being used as the counter to our nutritional treatment. We had to discover this serious conflict of interest on our own, a conflict that should have precluded him from ever serving in any supervisory capacity over the management of our trial.

In August 2009, without my knowledge and despite the federal investigations completed or in progress, the Columbia team succeeded in publishing an article in the online version of the Journal of Clinical Oncology (JCO), claiming the study was properly run, patients were properly admitted, that all nutrition patients complied but simply failed to respond, in contradiction to the official NIH position on the data, and the devastating OHRP findings – which the authors fail to mention anywhere. When we learned of the article's existence the day it first appeared on the Internet, we filed a formal complaint with the Journal, whose editorial staff to my astonishment seemed totally ignorant of the study's problems and the government findings to date, or even that a federal investigation had been already conducted and concluded, with the findings on the internet for all to see. In response to my complaint, JCO pulled the print version only days before its scheduled appearance, and then claimed it was launching its own investigation of the article. However, Dr. Isaacs and I became suspicious of the alleged process when after six months no one from JCO had contacted us for documentation – which we would have been happy to provide. Eventually, the article did appear in the April 2010 issue, slightly edited, but still lacking any mention of the NIH critique of the data, or the OHRP findings of mismanagement. Ironically, about the time of the article's initial posting on the web in 2009, I had just finished a lengthy manuscript detailing the study's tainted history. Now, with an added chapter discussing in some detail the JCO article and with an enlarged "Conclusion," I am preparing the book for publication.

In this lengthy tome, I not only delve into the chaotic history of this clinical trial, but also explore the larger issue of scientific bias, which seemed so evident during the 10 years of our study's existence, and how bias can easily lead to scientific fraud. My research into the issue proved to be most enlightening, demonstrating to me without any doubt how pervasively bias infects the highest levels of the academic research world, and how pernicious and destructive is its influence. It was bias, I

believe, the inability of conventional scientists and physicians to entertain the possibility that my "odd" nutritional treatment could have any value in the treatment of advanced cancer that led in my opinion to the study's ultimate failure and what appeared to me a need to prove my therapy worthless. In retrospect, I believe that so great was the bias of those assigned to supervise the project, a legitimate scientific outcome seems to have been impossible.

I came to realize, as I thought about the subject, bias has two sides, or two faces. I observed, during the eight years of the clinical trial in question, that bias can be a fundamental, often fanatical disdain for someone or something not conforming to the accepted, perhaps a better word is imprinted, model, regardless of fact or reason. But as its corollary, bias is a fundamental irrational belief, even a fanatical belief, in the goodness of someone or something, despite all evidence to the contrary. In either case, working unconsciously or very consciously, bias too often as I have sadly learned prompts researchers to manipulate the conduct of a trial and its data to insure the outcome conforms to their worldview.

In my book I discuss two cases to illustrate scientific fraud resulting from this latter form of bias, the fanatical belief in the goodness of something despite all evidence of the contrary. The first instance, the promotion of bone marrow transplantation as a treatment for women diagnosed with breast cancer, continued throughout the entire decade of the 1990s, and the second, the infamous NIH HIV-Nevirapine study, came to a head of sorts in the late 1990s. We will address each of these two examples in order.

Bone marrow transplantation (BMT) or, as it is known today, stem cell transplantation, has proven most effective against diseases of the marrow cell lines, such as inherited

immunodeficiency diseases, leukemia, and lymphoma. (4) For these conditions, during the treatment patients first undergo high dose chemotherapy, often coupled with total body radiation, to obliterate the diseased bone marrow. Subsequently, hematopoietic (marrow) stem cells from a genetically compatible donor are infused intravenously into the patient. These "foreign" stem cells, by a very precise homing mechanism, eventually make their way to the marrow where they restore the depleted cell lines. Theoretically, the process offers great promise, but the obstacles have been many. As a start, most studies report that at least 10% of patients undergoing the procedure die as a consequence of the treatment, with mortality rates described as high as 30-50% in cases of an unrelated but matched donor. (4-6) Then, the transplant can fail for any number of reasons, or the newly formed immune cells with the donor's genetic identity can start attacking the tissues of the host patient in the potentially deadly graft-versus-host disease. Even if the transplant does take hold without significant damage to the host, in cases of leukemia and lymphoma nests of cancerous cells can survive the induction therapy, allowing the disease to recur. (4)

During the 1980s, many oncologists and researchers – including my former boss, Robert Good, who performed the first bone marrow transplant in history in 1969 – began to suggest that in addition to such immune or blood malignancies, BMT might prove useful against a host of difficult-to-treat recurrent or metastatic cancers, such as metastatic breast and ovarian cancer, that don't involve abnormalities in the bone marrow cell lines. For these diseases, significant toxicity, particularly life-threatening suppression of the bone marrow, limited the chemotherapy doses oncologists traditionally prescribed. However, with the tool of BMT at their disposal, oncologists theoretically could administer very high doses of chemotherapy to these patients, far higher than would previously be possible, then heroically infuse hematopoietic stem cells to salvage the destroyed marrow. As an underlying principle, oncologists

assumed that if chemotherapy provided some value at standard, tolerable doses against a particular cancer, extremely high doses would offer greater benefit. Some researchers enthusiastically claimed BMT might even allow for a chance of cure in many previously incurable cancers– a hypothesis that was, at the time, largely unchallenged.

However, the expensive procedure cost anywhere from $75,000 to $450,000 or even higher, a major obstacle to patients since initially insurance companies refused to pay for what they perceived as an unproven, strictly experimental treatment. But by 1994, the oncology profession, working with aggressive attorneys and patient advocacy groups, had forced insurance companies through a series of lawsuits to cover the therapy in women diagnosed with metastatic or poor-prognosis breast cancer, though no real evidence yet existed to support its use in this circumstance. The media got on the bandwagon, nearly universally portraying insurance companies as heartless, money-hungry, cold-blooded tyrants, denying an obviously useful therapy to the most desperate of patients, these women with poor-prognosis and metastatic breast cancer. In 1993, Congress got into the fray, with 54 of its members demanding insurance companies, in the case of women with breast cancer, be forced to cover this presumed life-saving but expensive procedure. Other than the insurance companies, virtually no one in the medical profession, no one in the media, and no one in Congress seemed to care too much that little if any evidence existed to indicate this potentially deadly treatment actually benefited women with the disease.

Eventually, the National Cancer Institute decided in its wisdom that it might make sense to test the procedure in controlled clinical trials, to determine if this therapy – by the early 1990s already in routine use – worked. By the mid to late 1990s, five such studies had been completed and the results published in the peer-reviewed literature. Four of the trials showed no improvement compared to standard chemotherapy, but in stark

contrast to the negative findings, the data from the fifth, as described in the October 13, 1995 issue of none other than the Journal of Clinical Oncology, the "premier" voice of the American Society of Clinical Oncology, confirmed, or so it seemed, great value for the treatment. In an article entitled "High-dose chemotherapy with hematopoietic rescue as primary treatment for metastatic breast cancer: a randomized trial," WR Bezwoda of the University of the Witwatersrand, South Africa and colleagues described a significant treatment benefit for autologous bone marrow or peripheral blood stem cell transplantation after high-dose chemotherapy compared to standard chemotherapy. (7) In their paper the authors report a complete response rate of 51% for BMT versus 4% for traditional chemotherapy – truly a remarkable difference. Although the results seemed far too good to be true, I remember so well the media, as well as the scientific establishment, lauding the one positive study.

Fortunately, a few honest researchers began to question the South African trial and its methodology, since the data so strongly contrasted with that of the other four studies. However, though approached by several concerned oncologists, the NCI refused to support an independent evaluation of the South African data, and JCO did not retract the article. When the author declined to open up his books to appropriate scrutiny by a team of skeptical oncologists, the data's legitimacy came into question. Eventually, a formal investigation into this miraculous Bezwoda trial concluded the whole affair was a fraud, the data essentially created out of thin air.

Unfortunately, the oncology profession at large ignored early warning signs, so desperate were doctors to believe this therapy – which conformed to their belief in the value of chemotherapy – must show benefit. In 1999, even after serious doubts had been raised, the American Society of Clinical Oncology, the publisher of JCO, invited Bezwoda to present the honored plenary session lecture at one of their international conferences.

It wasn't until 2001, six years after the initial publication, when faced with indisputable evidence proving the article a fraud did JCO finally retract the document. (8) At that point, oncologists stopped promoting the procedure for patients with non-blood line tumors, before seamlessly moving on to the next new therapeutic miracle – anti-angiogenesis as I remember – with no apology to the families of those women who had been victimized.

The May 4, 2002 issue of the British Medical Journal published a lengthy summary of the entire disaster, entitled "Presumed benefit: lessons from the American experience with marrow transplantation for breast cancer." (9) I suggest anyone naive enough to believe that conventional physicians in general, and oncologists in particular, are objective, unbiased scientific practitioners employing only proven methods of treatment should read this article. The authors place the concept of unproven medicine where it rightly belongs, smack in the middle of the conventional medical world.

More recently, the insightful book False Hope (available at Amazon), published in 2007, describes the whole breast cancer-bone marrow transplantation affair from the beginning. (10) The authors, two physicians along with a Ph.D. political scientist and a lawyer who specializes in public health issues, tell the incredible story of over-enthusiastic oncologists – among those named, Dr. Karen Antman, former ASCO President, early supervisor of my trial, and co-author on the current JCO article about my study – pushing bone marrow transplantation as if it were some grand solution, despite minimal positive evidence to support its use, and despite good data showing it did nothing for the disease.

The whole bone marrow transplantation-breast cancer travesty wasn't just a question of over-zealous scientists promoting some new harmless theoretical idea in the laboratory that subsequently proves to be nonsense. The story is much darker

than that, it's a story of fanatical oncologists manipulating the legal profession and the media to promote without any real documentation to support its use an expensive and potentially deadly procedure that killed anywhere from 10-30% of the women undergoing the treatment. At the time, even under the best of circumstances, bone marrow transplantation often required long hospital stays, frequently involving battles with infection and bone marrow failure. Unfortunately, the false JCO article kept this worthless treatment alive, encouraged women with incurable and poor-prognosis breast cancer to line up, positive and optimistic, anxious to receive a therapy that at best did nothing and at worst killed many prematurely. It's estimated – though no one knows for sure the exact number – that upwards of 40,000 women underwent the procedure for treatment of breast cancer.

Imagine the situation a little differently. Let's think what would happen if some alternative practitioner promoted a nutritional or herbal regimen that cost up to $450,000 for a year's worth of therapy, that was extremely toxic and in fact so toxic it killed 10-30% of those foolish to put down the money and undergo the treatment, that when introduced had no legitimate data to support its efficacy, and when tested in clinical trials under the supervision of its proponents, the extraordinarily positive data reported ultimately proved to be fabricated. That alternative practitioner not only would be the subject of intensive legal, regulatory, and media attack, he or she would be in prison for fraud. But I know of no oncologist sent to jail for encouraging women, in the complete absence of legitimate data, to undergo bone marrow transplantation for breast cancer.

Moving on to the second great recent example of scientific fraud at the highest levels, I first learned of the HIV-Nevirapine study in mid-2007 from my friend Robert Scott Bell, host of a national radio show devoted to alternative medicine issues, particularly

the politics of the field. In recent years, I had appeared on his show several times to discuss my therapy, my approach to cancer, and particularly the NCI clinical trial which had generated considerable interest within the alternative health care world. In the spring of 2007, Robert, who normally hosted his show from a studio in Florida where he lives, happened to be in New York, attending a several-day conference on alternative medicine held at the Hilton Hotel in midtown Manhattan. He had set up a booth outside the lecture hall, complete with microphones so he could conduct interviews and broadcast his Sunday show live from the conference. He asked me to come by in the afternoon to talk about my therapy in general, but particularly, about the status of the clinical trial – at that point under investigation by the OHRP. I arrived early, before his show had gone on air, and he and I talked for some time about the trial's disastrous turn. He seemed very disappointed though not surprised that the study had essentially fallen apart due to apparent mismanagement on the part of the conventional investigators assigned to supervise the project.

As I regaled him with the evidence I had collected, he asked me if I had been following the scandalous revelations about the HIV-Nevirapine study conducted in Africa, a highly funded, highly lauded NIH project testing the use of the anti-HIV drug nevirapine to prevent the transmission of HIV from infected pregnant women to their babies. I had heard of the study, and allegations of mismanagement as reported in the press, but I hadn't followed the issue closely. He explained that the project had apparently been so poorly supervised from its beginning that patients, both the women and their babies, had been put at risk and that the evidence of wrongdoing on the part of NIH scientists had been deftly covered up and suppressed, right up into the highest levels of the NIH. When an NIH whistleblower, Dr. Jonathan Fishbein, tried to expose the mismanagement, he had been viciously attacked, then fired in retribution for his complaining. Fortunately, Robert informed me, Congress had taken up the cause, listened to Fishbein, and in its own

investigations vindicated his allegations. As a result, Fishbein had been reinstated at the NIH.

Robert thought my situation sounded, in some ways, similar to that faced by Fishbein, who found the regulatory agencies completely indifferent to evidence of serious mismanagement, scientific fraud, and corruption. After learning about the HIV-Nevirapine fiasco, Robert had contacted Dr. Fishbein, who had then appeared on his radio several times to tell his story.

Spurred on by Robert's revelations about the HIV-Nevirapine trial, over the next few months I began my own investigation into its history. What I found would leave me seriously questioning whether any of the oversight offices within the DHHS or NIH hierarchy have the competence, the motivation, or the simple integrity to investigate aggressively instances of scientific misconduct and fraud committed by their own.

As I learned, the National Institute of Allergy and Infectious Disease, a division of the NIH, conducted the HIV-Nevirapine trial in Uganda from 1997-1999, under the direction of a group of esteemed international researchers. In this effort, the investigators hoped to determine if the anti-retroviral drug nevirapine, manufactured by Boehringer, administered to HIV-positive mothers and their babies after birth could prevent transmission of the virus.

During and after the project, U.S. Government spokespeople aggressively touted the trial as an exemplary example of U.S. efforts to help stem the tide of AIDS in Africa. The NIH, excited about the very encouraging preliminary results, even released the data before its publication in the peer-reviewed literature, reporting an astonishing 48% decrease in HIV transmission with nevirapine compared to the group receiving a short course of the control, AZT, the previous standard approach to the problem of mother-infant transmission. Not only did the new regimen prove effective, the treatment, the

early documents claimed, was easily administered, inexpensive, with few reported side effects.

On September 4, 1999, in the prominent international journal Lancet, the HIV-Nevirapine team formally published the data to great acclaim, ushering in, they reported, a new era in HIV prevention, a major step to halting the massive epidemic of the disease in Africa. (11) As a result of the study, in January 2001 Ugandan authorities approved the drug for use as a preventive against HIV transmission to the babies of HIV-positive women. Subsequently, in July of 2001, Boehringer, the manufacturer, submitted an application to the FDA seeking approval for use of the drug as a preventive for mother-baby transmission in the U.S.

However, by early 2002, scientists outside the NIH began to question the initial enthusiastic reports of a great new advance against the HIV epidemic. In preparation for the required FDA review, an internal audit of the data at Boehringer uncovered evidence of numerous and significant protocol irregularities which, as the official reports stated, violated the integrity of the data from the trial that had already been published in Lancet. (12) In response to Boehringer's concerns, the Office of Human Research Protections then launched its own investigation.

An article appearing in USA Today in 2005 discussed in detail the questions that began surfacing in early 2002:

Boehringer Ingelheim, the Connecticut-based company that makes nevirapine, told NIH it identified at least one "critical compliance issue" that compromised the integrity of the study and more than four dozen issues it described as "serious" and "major."

Boehringer and NIH auditors cited concerns such as failing to get patients' consent about changes in the experiment,

administering wrong doses and delays and underreporting of "fatal and life threatening" problems. (13)

The USA Today article then quoted an official report written by a private firm, Westat, contracted to investigate the study:

It appeared likely, in fact, that many adverse events and perhaps a significant number of serious adverse events for both mother and infant may not have been collected or reported in a timely manner…

Westat reported there were 14 deaths not reported in the study database as of early 2002 and that the top two researchers in Uganda acknowledged "thousands" of bad reactions that weren't disclosed. (13)

In March of 2002, NIH officials began meeting for apparent damage control, as USA Today reports:

NIH officials reviewed the bad news in early March 2002.

Meeting minutes, written in shorthand, raised broad concerns: Half the babies in the study were also enrolled in a vitamin A study that could have affected the outcome, and medical staff running the trials didn't follow procedures for divulging serious adverse events (SAEs).

"No mtg minutes, no training doc(umentation), site used their own criteria for grading SAEs. No lab normal values & serious underreporting of SAEs," the minutes stated.

The minutes quote an NIH official who visited Uganda as saying, "The site staff doesn't know what they don't know..."

In January 2002, Boehringer sent NIH an early copy of its report. But the drug maker, fearing publicity about the report might destroy its chance to get the FDA approval of the drug for

domestic use, asked NIH to destroy it before FDA regulators could learn about it.

"Sensitive information. Asked for it to be destroyed when audit is upon us," NIH official Mary Anne Luzar wrote on the cover page of Boehringer's report…

Lane [an NIH scientist] said the request to destroy the report was inappropriate and NIH never complied. But he conceded his agency inappropriately kept the audit from FDA for weeks... (13)

In March 2002, as the evidence of mismanagement mounted, Boehringer withdrew its application to the FDA. Despite the growing storm over the data, on June 19, 2002 President Bush unveiled his 500 million dollar "New Mother and Child HIV Prevention Initiative," with none other than the drug nevirapine lauded as the showcase intervention and stating the US "will support programs that administer a single dose of nevirapine to the mother at the time of delivery, and at least one dose to the infant shortly after." As described by USA Today:

"This major commitment of my government to prevent mother-to-child HIV transmission is the first of this scale by any government, anywhere," Bush said in a Rose Garden announcement. (13)

No one at the NIH had bothered to tell the President that the study had been in shambles, its data questionable at best. NIH officials, fully aware of Boehringer's and its own audits, deliberately kept the bad news from the White House:

But the National Institutes of Health, the government's premier health research agency, chose not to inform the White House as it scrambled to keep its experts' concerns from scuttling the use of nevirapine in Africa as a cheap solution, according to documents obtained by the Associated Press. (13)

In July 2002, less than a month after the Bush announcement, the Department of Health and Human Services notified the Ugandan government that the once lauded study had repeatedly violated NIH requirements for protection of research subjects:

NIH's nevirapine research in Uganda was so riddled with sloppy record keeping that NIH investigators couldn't be sure from patient records which mothers got the drug…

The NIH research "may have represented a failure to minimize risk to the subjects," the Office of Human Research Protections told Ugandan authorities in summer 2002. (13)

During this time, the NIH higher-ups not only failed to inform the President about the serious protocol violations, the unreported serious side effects including deaths, and the poor management of the trial, they chose not to inform the press. The growing scandal remained a big NIH secret.

In March 2003, the Division of AIDS (DAIDS) released its own report about the study's management, strangely excluding any critical statements made by NIH experts. The press, along with the White House, seemed at the time blissfully unaware of the ongoing scandal, so successful were the attempts to keep the bad news out of public – or White House – view.

In July of 2003, the Institute of Allergy and Infectious Diseases contracted Dr. Jonathan Fishbein, a clinical trials expert, to serve as the first Director of Office Policy in Clinical Research Operations in the Division of AIDS. In this capacity, Dr. Fishbein "was to assure that DAIDS sponsored clinical research was in compliance with applicable regulations, guidance and policies and meets established standards of quality, integrity and ethics to protect the volunteers." (12) His superiors at DAIDS, according to published reports, advised Fishbein that they wanted the office to operate "like a virtual drug company."

Two weeks later, despite the feverish attempts of NIH officials to hide the problems, South African regulators, now aware of the troubling reports, announced they would discount the flawed HIV-Nevirapine data when assessing the drug's value as a preventive. (12)

Despite the growing storm, on September 11, 2003, Lancet published a follow-up article on the HIV-Nevirapine study that ignored all allegations of mismanagement and fraud, instead once again enthusiastically proclaiming the value of the drug in preventing mother-baby HIV transmission. (14) So much for the integrity of peer-reviewed publications! At that point Dr. Fishbein, assuredly not much of a team player and oddly determined to take his oversight responsibilities seriously, filed a formal complaint against the Deputy Director of DAIDS, Dr. Jonathan Kagan, with the new DAIDS director, Dr. Edmund Tramont. In true bureaucratic fashion, Dr. Tramont responded by allowing Dr. Kagan himself to inform Dr. Fishbein that Fishbein's employment with the Division had been abruptly terminated. Dr. Fishbein in turn, on March 3, 2004, notified the Department of Health and Human Services Counsel that "on information and belief, Edmund C. Tramont, M.D., Director, DAIDS, knowingly and willfully altered conclusions in the HIVNET 012 remonitoring report to conceal serious deficiencies in the study." (12)

Four days later, Dr. Fishbein repeated his allegations of scientific misconduct in the HIVNET 012 remonitoring effort to officials of the U.S. House of Representatives, Energy and Commerce Committee, Subcommittee on Oversight and Investigations.18 Finally, in May, the Subcommittee, in conjunction with NIH officials, arranged for a formal review of the whole study by the Institute of Medicine (IOM), a non-governmental organization in Washington charged with assessing and mediating scientific controversies. In addition, the Office of NIH Director Zerhouni began its own investigation, the results of which were released in July of 2004.

An Associated Press article written a year after Dr. Fishbein's firing discussed the NIH report and provided a very unflattering portrait of the Division of AIDS:

The government's AIDS research agency "is a troubled organization," and its managers have feuded, used sexually explicit language, and engaged in other inappropriate conduct that hampers its global fight against the disease, an internal review has found.

The review for the director's office of the National Institutes of Health substantiates many of the concerns that a whistle-blower, Dr. Jonathan Fishbein, raised about the agency's AIDS research division and its senior managers.

The division suffers from "turf battles and rivalries between physicians and PhD scientists," and the situation had been "rife for too long," the report concluded.

Nonetheless, the NIH formally fired Fishbein on Friday, over the objections of several members of Congress. The top Republican and Democrat on the Senate Finance Committee are protesting, saying the firing was an example of whistle-blower punishment…

Fishbein, a private sector safety specialist, was hired by the NIH in 2003 to improve the safety of its AIDS research. He alleges that he was fired because he raised concerns about several studies and filed a complaint against one of the division's managers alleging sexual harassment and a hostile workplace.

In a series of developments relevant to the internal review, the news media have reported that:

An NIH AIDS study in Africa violated federal safety regulations.

Senior NIH managers engaged in sexually explicit pranks and sent expletive-laced e-mail messages to subordinates…

An internal report, written on Aug. 9, 2004, by a special adviser to NIH chief Elias A. Zerhouni but never made public, raised concerns that the NIH's efforts to fire Fishbein at the very least gave the "appearance of reprisal." (15)

Surprisingly, at times truth does come out on top. As the DAIDS scandal exploded in the press and as government investigations continued, finally, in 2006, the NIH hierarchy forced DAIDS to reinstate Dr. Fishbein. An AP story reported:

A medical safety expert whose firing drew national attention to the lack of whistleblower protections in some areas of federal research is back on the government payroll.

The National Institutes of Health's reinstatement of Dr. Jonathan Fishbein settles a two-year battle that prompted investigations into allegations of scientific misconduct and sexual harassment in federal AIDS research. (16)

After I had studied in some depth the HIV-Nevirapine fiasco, I spoke to Robert Bell several times about Dr. Fishbein and the harassment he had endured. Robert described Dr. Fishbein as a man of great idealism and obvious honor, qualities apparently quite rare among government scientists. Tragically, the vicious attacks he suffered at the hands of his colleagues and superiors at the NIH had left him disillusioned and discouraged. The NIH not only ignored his honest and well-motivated concerns, but had sought to punish him for being so relentless in the pursuit of the truth. After his firing, he doubted he would work again in medicine, so determined was the NIH to destroy his credibility as a scientist. Despite Fishbein's reinstatement, Robert thought he would be viewed as a pariah to be avoided at all costs. His future career at the NIH could hardly be a happy one.

In the HIV-Nevirapine affair, Dr. Isaacs and I saw a warning of NIH incompetence and blatant corruption, a morality play of sorts about the perversion of scientific truth for personal and political gain at the highest levels of the Federal research community. But as we were to learn, the HIV-Nevirapine trial was far more, in terms of our own clinical study, than just a cautionary tale. As it turns out, some time before the scandal broke in the press, the supervisor of the study, Dr. Jack Killen, had very quietly been moved to the National Center for Complementary and Alternative Medicine – where he had been placed in charge of my project, without a word to me about his previous experiences within the NIH. And now, having helped manage not one but two highly-watched Federal studies that collapsed into chaos, he has been rewarded with a promotion at NCCAM.

In the conclusion to my book, I call, with some seriousness, for the closing of all government scientific institutions, since they seem unable to rid themselves of the pernicious biases that are forever the enemy of legitimate scientific enterprise, and ultimately, the truth. Our experiences have taught Dr. Isaacs and myself that in these alleged bastions of scientific progress, new ideas that do not conform to the prevailing model will be fought to the death with little concern for the true purpose of research, the objective, unbiased search for the truth, for the benefit of us all. Trust me, we've been there, in the belly of the beast, and it is not a pleasant place to be.

Adapted from the upcoming book What Went Wrong by Nicholas J. Gonzalez, M.D.

For information regarding this book, and for other works by Dr. Gonzalez, please subscribe to our announcement list or contact New Spring Press.

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