Providers: Nicholas Gonzalas

DEPARTMENT OF PEDIATRICS/ST. PETERSBURG OFFICE OF THE CHAIRMAN PHONE (813) 892-4470



ALL CHILDREN'S HOSPITAL 801 SIXTH STREET SOUTH ST. PETERSBURG, FLORIDA 33701

August 20, 1991

John H. Renner, M.D. Consumer Health Information Research Institute 3521 Broadway Kansas City, MO 64111

Dear Dr. Renner:

Thank you very much for your letter of August 6.

I have been much distressed that Dr. Gonzales is treating patients with what I must conclude, at this point, is an unproven remedy for cancer. I had expected that if he pursued this line of treatment, he would do a carefully monitored study and ultimately a randomized, independently evaluated (blindfolded) analysis.

I did, indeed, agree, as a teacher of immunology and clinical oncology, to observe and advise Dr. Gonzales concerning pursuit of his desire to investigate Kelley's files to see if there was anything to Dr. Kelley's claims that a complex "nutritional" regimen he was using was producing impressive, sometimes complete remissions, of advanced cancers and even some complete remissions with long-term survival of patients with advanced cancer. Dr. Gonzales had settled on this inquiry because he said he had found that Kelley, who was promulgating what everyone considered cancer quackary, was very open with him and would permit him free access to his records. Kelley is said to have complained to Dr. Gonzales that no one in the medical profession would listen carefully to his claims and would not examine his records. It was easy for me to understand that situation, if true, because Kelley's theoretical formulation made no sense in the context of any form of modern scientific inquiry.

However, I never visited Kelley's offices, nor did I peruse any of Kelley's records. Dr. Gonzales said that he had been permitted to go through all of Kelley's records and files and that he had found a surprisingly large number of patients who apparently had been diagnosed as having advanced cancer. In these patients, Dr. Gonzales said, the diagnosis had apparently been made by impeccable means at major medical centers, and all had experienced dramatic responses of their concerns and sometimes long-term survivals. These diagnoses were said to have been confirmed or established by appropriate pathological analysis and objective clinical observations. However, since I was involved only to the extent of advising Dr. Gonzales about his independent student study and was not conducting a study of my own of the Kelley treatment, I did not seek on my own to match alleged responses of patients with the pathological findings or clinical records. All such data was simply presented to me as fact by Dr. Gonzales.

I advised Dr. Gonzales that if he was going to evaluate Kelley's treatment he should at first try to evaluate fifty patients suffering from otherwise highly

John H. Renner, M.D. Page Two August 20, 1991

lethal forms of advanced cancer who apparently had been healed or improved by treatment that employed only Kelley's methods.

These methods, I must stress, seemed to me to have no scientific rationale. Thus, of course, I could not and never have promulgated their use or investigated them independently. While doing this study, Dr. Gonzales completed his medical degree at Cornell Medical College. Quite surprisingly to me, he remained most enthusiastic about observations he had made delving into Kelley's records!

After serving a straight medical internship at Vanderbilt, Dr. Gonzales returned to study in my clinics and laboratory by taking a research fellowship in allergy, clinical immunology and bone marrow transplantation. He said he would carry on his studies of the Kelley regimen on his own spare time. Dr. Gonzales did satisfactory, although not outstanding, work on this fellowship with me. completed all assignments, and he learned to analyze and manage patients with primary and secondary immunodeficiency diseases and to apply bone marrow transplantation to treatment of children and adults with immunodeficiencies, leukemias and aplastic anemias. He did quite well on some aspects of this clinical work, and learned a considerable amount of clinical immunology . However, the more conventional approaches to treatment of cancer never seemed of real interest to Dr. Gonzales. He was thus not a research fellow whose accomplishments on his fellowship would have lead me to recommend him for further academic training or to pursue scientific work in the tradition of our laboratories. One reason for a less than top performance by Dr. Gonzales in my fellowship program, however, was that Dr. Gonzales was spending most of his spare time, including weekends and holidays, when he was not on call for our patients, apparently researching Kelley's records and studying Kelley's patients. Allegedly, he was trying to match findings by appropriate initial pathological and clinical analysis from established centers with the unexpected long-term well being and long-term survival of patients with advanced cancer whose improvement he associated with treatment by the Kelley regimen. I even helped in some of these analysis by reading independent pathological slides which Gonzales said came from the patients he was studying.

However, I did not attempt to test the Kelley regime in any way myself. I must stress that I never could understand Kelley's postulates; they made no sense to me in contemporary nutritional theory, modern biochemical theory or in pathophysiologic theory. Thus, I could not use any such observations being made by Dr. Gonzales in any of my research, even though I was investigating the influence of nutrition on development of cancer and other diseases associated with aging in experimental animals.

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I insisted, expecting a truly negative result, that if Dr. Gonzales was seriously interested in the Kelley regime, he would need to collect and critically evaluate fifty advanced cancer patients and ascertain their outcome. After having done that, I pointed out to him that he might ascertain critically the outcome of every case on Kelley's series of one form of rapidly lethal cancer. I suggested adenocarcinoma of the pancreas because this disease is known to have an uniformly rapidly lethal outcome, regardless of what conventional therapies are used. I suggested that if the Kelley treatment were still promising after a critical analysis of these populations, Dr. Gonzales might progress to an independent test of this "miraculous" therapy. I insisted that what would be essential would be to design a randomized, preferably blindfold evaluated, controlled, clinical trial in which conventional therapy of far advanced, regularly fatal cancer would be compared with the results of treatment using the regimen in which Dr. Gonzales was interested.

I advised Dr. Gonzales not to apply in treatment such questionable dietary therapy without first carrying out an independent, scientific evaluation of the treatment. I particularly stressed that ultimately, and surely before I could take any interest in his work, he would have to use a randomized controlled, preferably, blindfolded evaluation in a clinical trial. Before, and since Dr. Gonzales left my laboratory, I repeatedly told Dr. Gonzales that he must not associate me in any way with any claims for the treatment. I felt that ultimately, evaluation of results of this line of treatment would have to be carried out entirely independently of Kelley and use a controlled design and independent evaluation. I was not interested, nor did I have time to reach an evaluation myself.

In other words, I would not myself be involved with this approach unless the entire testing of it could meet my usual high standard of analysis and evaluation.

I pointed out to Dr. Gonzales repeatedly that unless an independently monitored, prospective clinical trial was done, my name or reputation could not be used to support any claims.

What seems to be presented for Dr. Gonzales in the article written by the insurance representative, as far as it goes, reflects, although incompletely, the advice I gave Dr. Gonzales in this heuristic context. What is said is factually correct as far as it goes. What the insurance representative does not state is that I advised Dr. Gonzales repeatedly, and also the insurance representative who

John H. Renner, M.D. Page Four August 20, 1991

called me, that it would be wrong to promulgate any nutritional approach to the treatment of cancer, without establishing the validity of that treatment in an appropriately monitored, controlled clinical trial. When he left my laboratories and clinics six years ago, Dr. Gonzales said he was going to do such a study. He said his work in New York would be monitored by two disinterested but concerned practitioners of internal medicine with whom he would be sharing offices in New York.

Even though I have investigated extensively several nutritional approaches to prevention of experimental cancers and am thoroughly familiar with the literature in this field. I still know of no nutritional <u>treatment</u> which can cause remissions, to say nothing of curing advanced stages of human or animal cancers.

As you will see from the several enclosures, I have repeatedly implored Dr. Gonzales by word of mouth and in writing, even by a notarized letter, that he must not use my name to promulgate treatment which I do not advocate, have not advocated, do not condone and cannot support at the present state of knowledge.

Dr. Gonzales continues to imply that I have supported, do support or that my observations might be taken as support for this line of treatment. That conclusion is inappropriate and wholly unwarranted. I suspect at this juncture that Dr. Gonzales is trading on my name and reputation to promulgate a treatment which may very well be pure quackery. I have to wonder if his entire set of observations is a continuing scam. At any rate, I have not stood and will not stand behind it because I have not in any way evaluated this approach myself.

I will ask my lawyer to write perhaps an even more forceful, legally worded letter in an effort to make Dr. Gonzales cease and desist from implying that I approve of the treatment he is using for patients with advanced cancer. I do think that appropriate investigation of new ways to treat cancer is most justified, but Gonzales' study does not yet qualify as appropriate investigation.

I have no objection to your asking the American Cancer Society to look into Dr. Gonzales' claims. I hope they will be able to take action that can stop Dr. Gonzales from using my name to promulgate his treatment that uses a regimen which remains conjectural and completely unproven for the treatment of advanced cancers in my opinion.

I certainly do not condone Dr. Gonzales's current treatments until and unless he has shown them to be of value through definitive scientific analysis. If he is truly investigating this strange form of cancer therapy, his investigations

John H. Renner, M.D. Page Five August 20, 1991

should be done under Institutional Review Board approval and by predetermined protocol ideally with randomized blindfold- evaluation design.

Sincerely,

Robert A. Good, Ph.D., M.D., D.Sc.

Professor and Chairman

U.S.F. Department of Pediatrics

St. Petersburg

Distinguished Graduate Research Professor U.S.F./St. Petersburg

Physician-in-Chief All Children's Hospital

w/enclosures

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February 27, 1988

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UNIVERSITY OF SOUTH FLORIDA James A. Hallock, M.D. Associate Dean Nicholas Gonzalez, M.D. 737 Park Avenue New York, New York 10021

Dear Nick:

The enclosed article from the Binghamton, N.Y. newspaper was received today in my office. In this article, you are quoted as saying that you did a study on cancer patients with me.

As you know, I cannot and will not let my name be associated with your study until and unless randomized controlled trials comparing your approach to efforts at conventional treatment have been designed and carried out. I thought that was what you were now doing. This article, which contains much information that could be misinterpreted and which could be a function of a reporter's misinterpretation, implies that the studies were carried out at the Memorial Sloan-Kettering Cancer Center. It also implies that I in some way, parhaps by association, support your interpretations and that perhaps this treatment should be used as an approach to treatment of pre B cell leukemia. The latter I strongly object to, since pre B cell leukemia in a young child is quite curable by conventional chemotherapy, which includes prolonged consolidation therapy. Leaving such an erroneous impression does me a disservice and could be devastating to you.

You must write an appropriate correction of these impressions to the local newspaper.

I ask you once again not to associate my name or me with the Kelly treatment. Further, I urge that, as you continue these investigations, you do not associate me with them. I will be interested to hear of your studies after appropriate trials have been done in which you yourself have achieved results like those claimed by Dr. Kelly when you have had full control of all the variables possible and have followed your own patients see fally from beginning of treatment to





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March 14, 1988.

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Nicholas Gonzales, M.D. 737 Park Avenue New York, New York 10021

Dear Nick:

I continue to hear directly and indirectly that you use my name to fortify your promulgation of the "Kelley" regime. As you recall, I was permissive and permitted you to make observations concerning this approach to cancer therapy which I have never understood or condoned as an alternative to conventional cancer care. You must not continue to try to support your approach in testing this regimen by using my name.

As you well know, I could not accept authorship on the book you wrote because I could not fulfill my criteria for scientific authorship for this work. I did not and will not support the "Kelley" regimen until and unless a randomized, controlled trial has been carried out in a prospective fashion. You must not promulgate your enthusiasm for this approach by saying or inferring that I condone or support PEDIATRIC HEMATOLOGY/ONCOLOGY this approach as an acceptable alternative form of cancer therapy. I do not and will not support this alternative form of treatment, even for advanced cancer, until I have been convinced that an appropriate study and analysis, not just a set of observations over which I have not been in full control, have been carried out.

> Also, you must not imply in any of your communications that I am convinced about this approach or support it in any way.

Sincerely,

Robert A. Good, Ph.D., M.D.

Professor & Chairman, Department of Pediatrics University of South Florida/St. Petersburg

Physician-in-Chief All Children's Hospital

UNIVERSITY OF SOUTH FLORIDA James A. Hallock, M.D.

Associate Dean

the end of treatment. Such a study is appropriate only if the patients studied are patients suffering from advanced cancers for which no conventional therapy is known to exert an important influence on survival of the patient or regression of tumor. Pre B cell leukemia is not such a disease.

It is wrong to imply that nutritional therapy of any kind at this juncture could be used to cure B cell leukemia or substitute for consolidation chemotherapy. Such treatment should not be recommended as an effective treatment to be used to replace established regimens or chemotherapy or radiotherapy in leukemic children. It is best to say even for advanced untreatable cancer that a nutritional regimen deserves a careful phase I trial.

Sincerely,

Robert A. Good, Ph.D., M.D.

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encl.



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March 14, 1988

To Whom It May Concern:

I have read the transcript of Dr. Nicholas Gonzales' testimony in which, on a number of occassions, he mentions my name. Therefore, I thought it might resolve confusion if I state my own opinion concerning the use of dietary treatment as an approach to management of terminal cancer or an alternative to chemotherapy as treatment.

Dr. Gonzales was an Immunology Fellow in my laboratories and clinics for a two-year period from July 1984 to June 1986. In this context, he did have the opportunity to help my colleagues and me take care of a broad range of patients suffering from either primary or secondary immunodeficiency diseases and children and adults with leukemias, particularly, patients which we were evaluating for, or treating by, bone marrow transplantation. Dr. Gonzales did satisfactory work as a clinical fellow in this setting. Our approach to treatment of malignancies, including leukemias and particularly leukemias in children, in which Gonzales participitated has been most conventional, except in those patients with leukemias which have failed chemotherapies or in patients who are high-failure risk leukemias. For such patients, we have employed lethal total body irradiation and high-dose cyclophosphamide therapy plus bone marrow transplantation. Our approach to treatment of such malignancies by bone marrow transplantation

regularly follows the protocols set forth by the Stattle Bone Marrow Transplantation unit at the Fred Hutchison Cancer Center, under the leadership of Dr. E. Donnall Thomas.

We have quite regularly also used very conventional vitamin, mineral, caloric and protein supplementation in our bone marrow transplant patients and in the patients I have been responsible for who have suffered from advanced cancer.

My position with respect to claims for treatment of advanced cancer by any nutritional regimen is that I do not know of any true scientific evidence that any nutritional regimen has been proved to be of benefit in treatment of cancer. This is of importance, especially in considering alternatives to treatment of children who suffer from acute leukemias, including B cell leukemia. The only established form of treatment of children with the latter disease to my knowledge is vigorous chemotherapy that involves induction of remission and administration of consolidation therapy, followed by prolonged maintenance therapy. It is wrong to infer that I would condone or support any nutritional regimen as an acceptable alternative to the chemotherapeutic approach to acute lymphoid leukemias of childhood which can provide very long-term cures in more than 50% of children with this disease. If the chemotherapy regimen were to fail and the leukemia to recur, I would then recommend turning to bone marrow transplantation after lethal total body irradiation plus cyclophosphamide chemotherapy in preparation for the marrow transplantation. I would not accept as an appropriate alternative any form of nutritional therapy as having been shown to be effective treatment for this disease.

As mentioned above, I have read the transcript of the hearing conducted in Oswego, New York, on February 23, 1988, in which Dr. Nicholas Gonzales has testified concerning an alternative form of treatment of cancer using a nutritional approach.

Although I might hope that someday we will know enough about both cancer and nutrition to be able to marshal an effective nutritional appraoch to treatment of cancer, this is not the case at the present time.

When Dr. Gonzales was a student of medicine at Cornell, he asked me if I would act as a faculty advisor for an elective project which he wished to pursue as a senior student at Cornell. He wanted to study a particular unproved remedy involving a very complex nutritional regimen that was based upon an unfounded theoretical framework. Although I would have much preferred to have this apparently highly intelligent, highly motivated student do an elective using conventional reasoning and established techniques of evaluation of anti-cancer activity, (e.g., in experimental systems), I considered that there might be heuristic value in the project Mr. Gonzales proposed, and that at the very least, Gonzales might learn important facts about the natural history of cancer.

Gonzales thus spent several months while a student and later, much of his spare time while he worked as an Immunology Fellow in my laboratory, evaluating cases which he selected from a large population of nutritionally treated patients allegedly suffering from advanced cancer. At no time did I personally investigate these patients directly as I would have were I carrying out such a study myself. I did observe under the microscope tissues allegedly derived from the diagnostic

biopsies of the cancer in the patients, and I carefully peruse the medical records, generally from leading cancer centers throughout the country, which ostensibly defined some of the patients Gonzales was showing me as very advanced or terminal cancers. Indeed, the collection of cases Gonzales showed me were generally representative of the kinds of cancer I recognize as being forms of cancer most refractory to any forms of cancer treatment. These patients were then identified to me as patients who had experienced extremely long survivals and were often described as being patients in vigorous good health. Gonzales said he had interviewed some of these patients and their family members in some detail.

Gonzales appeared to be convinced that the nutritional therapy being used to treat these patients was responsible for the apparent success of their treatment. I could not in any way vouch for the authenticity of the records and biopsies, or the relationship of either of these to the patients who allegedly showed the long-term survival, but if one accepted the apparent observations presented by Gonzales at face value, the experience with the 50 cases that Dr. Gonzales showed me were far outside general experience with any medical treatment of cancer I have experienced, read about or heard about in more than 40 years of medical practice, much of which has been focused on cancer in its many forms.

Dr. Gonzales generously asked me to author or coauthor a scientific article or a book about these patients, and I refused. As a scientist, I could not put my name on any description of such patients because I would not be able to fulfill two of the four criteria for scientific authoriship I insist on if my name is to be used in authorship of

scientific reports from my laboratories or clinics. All four of these criteria must be met if authorship on a scientific report is justified and can be accepted. These criteria are:

- 1. A person who authors or coauthors a scientific paper must be involved in the conception of the investigation and must participate in formulating the working hypothesis to be investigated;
- 2. A person who authors or coauthors a scientific paper must be involved in the execution or carrying out of the scientific effort in some significant way;
- 3. A person who authors or coauthors a scientific work must be able to defend all aspects of the research before an appropriate and most critical body of scientists. That is, the scientist must be able to accept full scientific responsibility for the research which is being described;
- 4. An author or coauthor must be able to accept the scientific platform he or she has constructed, which means he or she must be able to frame a derivative scientific postulate and design a subsequent experimental approach.

If such criteria are insisted upon and are actually met, the issue of scientific authorship does not prove to be a difficult problem.

With regard to Gonzales' investigations, since I could not qualify for either criteria #2 or criteria #3 and also had difficulty identifying with criteria #4, I refused any scientific identification with Gonzales' study.

It is incorrect to infer that I advocate the approach Gonzales discussed in his testimony for treatment of any form of cancer at this juncture. To my knowledge, I have never used this approach in treating any of my cancer patients. I have never referred any of my patients to anyone for such therapy. I do not accept this approach or any nutritional approach as being an alternative to full chemotherapy with induction, consolidation and maintenance phases for treatment of any of the forms of acute leukemia of childhood.

This having been stated, I wish to add that I respect Dr. Gonzales as a person. He is a well-informed, reasonably trained clinical scientist who should be able to carry out investigations of his working hypothesis and try to do appropriate testing of that approach in a properly randomized, controlled clinical trial in patients who suffer from currently incurable forms of advanced cancer. He is not, however, a fully trained, Board-eligible or Board-certifified oncologist or pediatric hematologist/oncologist.

B cell or pre-B cell leukemia in childhood is not a disease for which there is no effective scientifically based therapy. I would conclude that the proper approach to this disease is chemotherapy, including proper induction, consolidation and prolonged maintenance chemotherapy. I do not accept any other approach as viable or correct. Nutritional supports in a conventional context might be designed which could contribute to a child's well-being while being given such scientifically-established treatment.

I have felt constrained to write these words because the legal implication of Dr. Gonzales' testimony and cross-examination might be misinterpreted to leave the incorrect impression that I had actively

contributed to gathering and analyzing the information from which Dr. Gonzales is reasoning, or that I agree with Dr. Gonzales' interpretation of the observations he has made on the nutritional treatment of cancer and the viability of nutritional therapy as an alternative to full chemotherapy in the treatment of any form of cancer, particularly acute lymphoid leukemia of childhood.

Sincerely,

Robert A. Good, Ph.D., M.D.

Professor & Chairman, Department of Pediatrics
University of South Florida/St. Petersburg

Physician-in-Chief

All Children's Hospital

STATE OF FLORIDA COUNTY OF PINELLAS Signed and subscribed to before me this 14th day of March, A.D., 1988.

Notary Fublic State of Florida

My commission expires

KOTARY FUBLIC STATE OF FLORIDA RY COMMISSION EXP JUNE 21,1991 BONDED THRU GENERAL INS. UND.





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John C. Barnes, M.D.

UNIVERSITY OF SOUTH FLORIDA James A. Hallock, M.D. Associate Dean December 8, 1988

Nicholas Gonzalez, M.D. 737 Park Avenue New York, New York 10021

Dear Dr. Gonzalez:

It keeps coming to my attention that my name continues to be associated with your nutritional approach to the treatment of cancer.

As I have told you repeatedly, I cannot support or condone your treatment unless evidence is presented that randomized trials have been performed which reveal significant benefit.

The latest source of my concern has been claims that I have said your treatment works. These claims were made by "Can Help", an organization centered in the state of Oregon or Washington and apparently associated with or headed by Pat O'Grady Jr. These people claim that they have interviewed me and that I have said your treatment works.

Of course, as you and they know, I have never said that and, indeed, have repeatedly stated to you and to anyone who has asked me that since I have not been in direct control of any of the observations you have made except by reviewing information you have provided to me that I do not know of benefit nor can I recommend or vouch for your treatments. No data from randomized trials have come to my attention and I continue to insist that such observations are essential to a scientific evaluation.



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Nicholas Gonzalez, M.D. 737 Park Avenue New York, N.Y. 10021

Dear Nick:

I have told you several times and I have written you more than once to indicate that until your approach to nutritional treatment of cancer has been subjected to a randomized controlled analysis, I will not be identified with it.

You <u>must not</u> use my name or your association with my laboratory as support of or means of promulgating your nutritional treatment of cancer. I must insist that your association of me and my name with these efforts is inappropriate. Please stop.

Sincerely yours,

Robert A. Good, Ph.D., M.D., D.Sc.

Professor & Chairman

U.S.F. Department of Pediatrics/

St. Petersburg

Graduate Research Professor University of South Florida

Physician-in-Chief All Children's Hospital

RAG/lkc