Pseudoscience in Alternative Medicine

Many alternative treatments are said to work because they are based on science, and consumers who are not scientifically literate believe this. A critical review of the publications of alternative medical proponents in three selected areas—chelation therapy, antineoplastons, and coffee enemas—quickly exposes the fiction.

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I left the Sloan Kettering Institute in New York in 1981, after twenty-seven years of basic cancer research experience. I wanted to use that experience, so I decided to search around for an alternative treatment that made scientific sense and volunteer to help find evidence to justify its medical worth.

My education in alternative medicine began when I joined patient ombudsman Grace Powers Monaco's Candlelighters Childhood Cancer Foundation. This organization provides counsel to families on issues of informed consent for both established and alternative medical treatments. My job was to evaluate the science of the alternative treatments patients were asking about.

My studies led me to the following observations. Advertis-

ing, not science, is the lifeblood of these treatments. Alternative treatment practitioners attempt to impress potential patients by constructing bibliographies that cite everything they have ever written. Few are peer-reviewed research papers, and the journals are not in U.S. medical libraries. I learned that reporters have the naive notion that if they tell some of both sides of a story, their readers will know who was lying.

Alternative medicine practitioners must advertise to flourish. Thus, every request I made for published material resulted in a flood of mail from quacks all over the country. I received reprints of articles from pornography magazines, books, family magazines, supermarket tabloids, health-food-store handouts, clinic brochures, and pseudoscientific papers. Every mailing contained a request for money to aid in the fight against the Establishment or for a membership in a "club" that sells all-natural, totally safe lotions, motions, and potions to ensure youth, health, and irresistible sexual prowess.

It soon became obvious that getting our findings to medical consumers would be a problem. The National Cancer Institute (NCI) was aware of this, and in 1986 it requested grant applications to produce critical reviews of the claims of alternative treatments. As we had already collected a good deal of information about alternative medical treatments, we applied for and were awarded a grant in June 1988 (SBIR-R44, CA-4195302). Each review we did was peer-reviewed by experts in the field, and when the entire set was complete, we donated it to the NCI to be incorporated in their database (PDQ).

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The Chief of the Investigational Drug Branch, Cancer Therapy Evaluation Program, NCI, Dr. Michael Hawkins, responded. He thanked us for sending the database but said they could not accept it because they could not afford the expense of having it peer-reviewed, keeping it up to date, and appending it with "new" alternative treatments. This rejection of our gift came as a shock. After all, the NCI had paid us to do the work, we knew the existing PDQ had no information on alternative medicine, our monographs were already peer-reviewed, the alternative treatments we reviewed had not changed in decades, and no new ones were forthcoming. As a result of NCI's decision, our database now reposes, unused, in the archives of the American Cancer Society.

As scientific director of our group, I had all the files on each treatment. Since the database was not to be made available to the public, I decided to publish the results and conclusions I reached after reviewing each of some thirty treatments.

The following are abstracts of three of those reviews. They are on chelation therapy (Green 1993), antineoplastons (Green 1992a), and the Gerson diet and coffee enemas (Green 1992b).

Chelation Therapy

Chelation therapy is the intravenous infusion of ethylenediamine tetraacetic acid (EDTA), a synthetic amino acid. This water-soluble chemical can bind free metal ions in the blood circulation and carry them out of the body in the urine. Iron is bound most strongly and calcium most weakly. All the metal ions in the circulation that are bound more strongly than calcium are removed before calcium (Chenowith 1961).

Chelation therapy with EDTA is accepted by patients as an effective alternative to established medical interventions for atherosclerosis, coronary artery disease, and occlusive peripheral vascular disease. Essentially all of the claims made by chelation therapists are found in four how-to books (Walker and Gordon 1982; Trowbridge and Gordon 1985; Cranton 1989; Cranton and Brecher 1990). The jargon in these books creates the impression that chelation therapy is sound science.

Chelation therapists claim they have given millions of EDTA treatments and benefited hundreds of thousands of patients (Cranton 1989). They say the EDTA treatments work in one of two ways: 1) EDTA circulating in the blood chelates (binds) the calcium found in plaque (fatty deposits) on arterial walls. This destroys the structural integrity of the plaque, and it disintegrates (Walker and Gordon 1982). 2) Plaque is caused by injury to the arterial walls by free radicals generated by ionic iron. Chelating the iron with EDTA prevents free-radical formation and damage to artery walls (Cranton and Brecher 1990).

Rebuttal: Neither of these mechanisms is valid. Plaque results from the accumulation of new cells at the site of the repair of repeated arterial wall injuries. EDTA is water-soluble so it does not enter the lipid-rich arterial cell membranes to chelate the calcium. The calcium in plaque is not part of the plaque structure; it is a contaminant brought in late in the course of artery-wall healing. It has been experimentally proven that removing calcium from plaque does not cause the plaque to disintegrate (Wilder et al. 1962; Stemmerman 1978).

That chelation of iron with EDTA will stop the generation of free radicals is untrue. In 1956, researchers discovered that when ionic iron was chelated with EDTA, its ability to generate powerful oxidizing radicals was *increased* tenfold (Green 1956). They also found that vitamin C causes a release of iron from tissues. Chelation therapists sometimes add vitamin C to the EDTA infusion mixture, and by doing so they are making more iron available to the body for free-radical formation.

These facts, along with the absence of objective evidence of clinical efficacy, prove that chelation with EDTA cannot be effective in treating coronary artery disease by the mechanisms described.

Antineoplastons

Unlike other alternative medical practitioners, Stanislaw R. Burzynski has published volumes of material. This impresses

patients, but unless they understand what they are reading, they cannot know what is implied. To a scientist, Burzynski's literature paints a clear picture of the quality of the evidence he offers in support of his theory.

Burzynski received an M.D. from a medical academy in Poland in 1967 and a D.Msc. in 1968. He did not finish a residency or train in oncology, and his bibliography does not mention clinical cancer research, urine, or antineoplastons during this period. Burzynski came to the United States in 1970 and worked in the department of anesthesiology at Baylor University, Houston, for three years, isolating peptides from rat brains. He got a license to practice medicine in 1973 and, with others, received a three-year grant to study the effect of urinary peptides on the growth of cancer cells in tissue culture. The grant was not renewed.

In 1976, with no preclinical or clinical cancer research experience, Burzynski announced a theory for the cure of cancer based on his assumption that spontaneous regression occurs because natural anticancer peptides, which he named *antineoplastons*, "normalize" cancer cells. Since urine contains lots of peptides, he concluded that there he would find antineoplastons. Less than one year later and based only on these assumptions, Burzynski used an extract from human urine (antineoplaston A) to treat twenty-one cancer patients at a clinic he opened. His shingle read, "Stanislaw R. Burzynski, M.D., *Ph.D.*"

By 1985, Burzynski had eight antineoplastons with which he was treating cancer patients. The first five were fractions from human urine. These he called A-1 through A-5. From A-2 he made A-10, which was *insoluble* 3-N-phenylacetlyamino piperidine 2,6-dione. He said A-10 was the anticancer peptide common to all his urine fractions. He then treated the insoluble A-10 with alkali, which yielded a soluble product he named AS-2.5. Further treatment of AS-2.5 with alkali yielded a product he called AS-2.1. Burzynski is currently treating patients with AS-2.1 and what he *calls* A-10.

Rebuttal: Burzynski's claim to a Ph.D. is questionable. Letters from the Ministry of Health, Warsaw, Poland, and from faculty at the Medical Academy at Lublin, Poland, say, respectively: 1) At the time Burzynski was in school, medical schools did not give a Ph.D. (Nizanskowski 1992); 2) Burzynski received the D.Msc. in 1968 after completing a one-year laboratory project and passing an exam (Kleinrok 1993). Burzynski did no independent research while in medical school (Bielinski 1987).

Phenylacetic acid (PA) is produced during normal metabolism. In humans, it is detoxified in the liver to phenylacetyl glutamine (PAG) and is excreted as such in the urine. When urine is heated with acid, the PAG loses water and becomes the insoluble 3-N-phenylacetylamino piperidine 2,6-dione. This is Burzynski's original A-10, the supposed anti-cancer peptide. Needing a way to make this "soluble," Burzynski treated A-10 with alkali. But treating insoluble A-10 with alkali does *not* make the A-10 soluble. It simply reinserts water into the molecule and regenerates the original PAG. This is his AS-2.5. From this, AS-2.1 is formed by the further treatment of AS-2.5 with alkali, which degrades it to a mixture of PA and PAG. Currently, Burzynski treats patients with AS-2.1 (PA and PAG) and what he calls A-10. But this "A-10" is really alkali-treated A-10. In other words, it is AS-2.5, or PAG. This is significant in view of the fact that Burzynski himself has reported that PAG is ineffective as a treatment for cancer (Burzynski 1985 and 1986).

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Burzynski's definition of antineoplastons has changed with each new product. The first preparations made from human urine (A-1 through A-5) were said to be information-carrying peptides. But the chromatograms of these show they are all the same. When he recovered insoluble A-10 from acid-treated A-2 and realized it came from urinary PAG, he added "amino acid derivatives" to his definition. Since neither AS-2.1 nor soluble "A-10" are peptides, he dropped that term from the definition.

Burzynski claims that A-10 acts by intercalating DNA. This conclusion was reached in molecular modeling experiments using the piperidine. But the soluble "A-10" is not the piperidine. It is PAG, and PAG does not intercalate DNA.

These facts, along with Burzynski's failure to demonstrate that antineoplastons can "normalize" cancers in patients, force one to conclude that his claims for an effective treatment of cancer are not believable.

The Gerson Diet and Detoxification with Coffee Enemas

The use of diets and coffee enemas to treat cancer is based on the teachings of Max Gerson, a German M.D. who practiced about seventy-five years ago when the biology of cancer was virtually unknown. He believed that cancer was a degenerative disease that developed when aerobic energy metabolism in the liver and intestine was converted to anaerobic metabolism by "poisons" from processed foods.

The idea that purges could rid the body of its "corrupt humors" has been practiced by "healers" since the fifth century. Proponents promoting coffee enemas still believe that "an unpoisoned body" possesses reserves that can recognize and destroy cancer. Gerson's treatment requires patients to have a prolonged period of detoxification with coffee enemas and to adhere, for life if possible, to a diet of juices from raw fruits, vegetables, and calf liver, all produced without pesticides or fertilizers and prepared without sugar, starch, salt, or artificial coloring.

Proponents of the Gerson treatment allege that normal cells depend on oxygen and oxidizing enzymes to maintain aerobic metabolism. When this system is poisoned by "toxins" in

processed foods, it falls back into anaerobic metabolism, produces inferior energy, and becomes cancer. Detoxification is accomplished with enemas containing coffee because coffee stimulates liver bile production and activates an enzyme, glutathione-s-transferase, which neutralizes the free radicals in the blood. The coffee enema causes the toxin-laden bile to be flushed out of the gallbladder into the intestines and through the colon to be excreted. Gerson has stated that for a patient to be "healed," the patient's body must be detoxified. After detoxification, he says, the essential organs will destroy the cancer by an inflammatory allergic reaction. Healing is activated by the special diet of natural nontoxic foods that include "ionized minerals of the potassium group, juices of green leaves and raw calves liver, thyroid extract, and iodine" (Green 1992b).

Rebuttal: Over the last thirty years the scientific literature has shown that: carcinogens are not respiratory poisons; most respiratory poisons are not carcinogens; oxygen does not inhibit the growth of cancer cells either in vitro or in vivo; the absence of oxygen does not induce or accelerate cancer growth; effective anticancer drugs are the ones that affect DNA synthesis not fermentation; energy from fermentation is not inferior by any measure; tumors increase oxidative metabolism of fats and carbohydrates to gain energy; and there is no evidence of the "poisoning" of aerobic metabolism in tumor cells (Aisenberg 1961).

The hepatology literature does not show that bile is a vehicle for toxin removal. A primary function of bile is to move metabolites from the liver to body tissues. To conserve bile and to ensure that the metabolites it carries are not lost during transit through the intestine, more than 95 percent of the bile entering the intestines is reabsorbed and returned to the liver before it reaches the colon. If Gerson's postulate were true, toxins carried in the bile would not be excreted but would recirculate through the body endlessly (Arius 1982).

Coffee does not stimulate bile production; it causes release of bile from the gall bladder. Bile does not contain glutathione, and glutathione is not a precursor for bile formation (Chasseaud 1979).

In the short term, the action of an enema causes an insignificant loss of bile from the intestine. But the amount of bile lost from frequent enemas over a period of months is appreciable. Under such circumstances, severe nutritional consequences associated with malabsorption can and do result (Eisele and Reay 1980).

The pathogenesis of inflammation and its role in the immune system have been defined in studies showing that inflammation suppresses fat metabolism and cellular oxidations, and increases the rate of glycolysis, tissue wasting, septic shock, and hemorrhagic necrosis in all cells, normal and malignant. Proponents of the Gerson treatment have never shown that there is a "healing" inflammatory process that focuses specifically on tumor cells.

Finally, Gerson proponents have never identified the "poisons" in processed foods and have never shown them to be present in voided enema fluids or that an all-natural diet of the juices of raw fruits, vegetables, and calf liver can stimulate any kind of "healing." All the evidence in the scientific literature today indicates that mutagenesis, and not the interference with oxidative metabolism, is the cause of cancer (Joklik et al. 1984).

Summation

In 1905 *Collier's* magazine carried a series called "The Great American Fraud—The Evils of Quackery." That series detailed dozens of nostrums in hundreds of pages of text. Here, space limitations made it necessary to demonstrate the results of our critical scientific evaluations on three selected treatments. But, the results speak for themselves. I hope that, as in the cases presented here, the interested reader will see how, with the proper methods, one can identify the frauds and dangers inseparable in today's alternative medicine.

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