

Butler, Jennie C

From: Williams, Carole A
Sent: Monday, April 10, 2000 11:32 AM
To: Butler, Jennie C; 'harristakoma@erols.com'
Subject: April 4 Public Meeting
Importance: High

Below are the statements from two panelists.



Holtgrewe
Testimony.doc

Alyce Ortuzar, Well Mind Association

I am attaching two files, one with my testimony, and another with an extensive book list. They are in Word Perfect. If there is a problem, I can cut and paste directly into the e-mail, if necessary



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TS 22

Testimony to the FDA on 4/6/00 from Alyce Ortuzar, President of the Well Mind Association of Greater Washington, 18606 New Hampshire, Ashton, MD 20861 (301)774-6617

What Do We Know, and When Did We Know It: Opposition to the FDA's efforts to regulate nutritional supplements

In 1949, Dr. Frederick Klenner documented his success at reversing polio, without any lingering paralysis or impairment, using high-dose intravenous Vitamin C. Throughout the 1970s, He published his successes with measles, chickenpox, third degree burns, and progressed cases of pneumonia, using over 200 grams in a 24-hour period when needed. I used it to reverse my Lymes Disease.

Klenner considered Vitamin C to be the safest, most effective antibiotic, because of its anti-bacterial, anti-microbial, and anti-viral properties, and recommended it as the treatment of choice in the emergency room if the doctor was not sure what was wrong with the patient. He was highly critical of the AMA and the FDA for ignoring his results, and for either recommending a dose too low to be effective, or for discrediting the treatment outright.

In the 1950s, psychiatrists Osmond and Hoffer published their double-blind studies, where they reversed acute schizophrenia using high doses of Vitamins C, B3, and B6. Also in the 1950s, the Chute brothers documented the ability of Vitamin E to prevent and treat heart disease. Data also indicate that intravenous magnesium can reduce deaths from heart attacks.

In 1962, Bill W., co-founder of Alcoholics Anonymous, attributed his success to a high-protein, low carbohydrate diet and niacin.

A 1966 National Medical Journal article (the association of black doctors) was published entitled, "Hypoglycemia As the Cause of Neuropsychiatric Disorders," implying that for most mental illnesses there is an underlying physical cause, and focusing on the brain, or on drugs, will not resolve the problem.

In 1968, Dr. John Tintera published his book Hypoadrenocorticism, documenting his ability to reverse alcoholism, hypoglycemia, arthritis, and certain schizophrenias, using a high-protein, low carbohydrate diet with adrenal cortical extract. He stated that his only failures were with patients who had been on prednisone first, which he found to be very toxic.

In the 1970s, Dr. Ben Feingold published The Feingold Diet, documenting that when he took kids experiencing behavior and learning problems off of foods with sugar, dyes, additives,

pesticides and other synthetic chemicals--all FDA, EPA, and USDA approved--he had about an 80 percent response rate.

In the 1980s, Parole Officer Barbara Reed, Ph.D., wrote Food, Teens, and Behavior, where she documented an 85 percent reduction in recidivism rates among 1000 parolees, including violent offenders, when she put them on a high protein, low carbohydrate diet, eliminating sugars, food dyes and additives, and focused on nutrition.

Studies claiming to refute these outcomes were paid for by the chemical and/or sugar industry, and were found to have serious design flaws. Dr. Linus Pauling, Nobel Prize recipient in chemistry, showed how claims by NIH and others of harm from high doses of Vitamin C, were not chemically possible.

In 1978, the FDA submitted false data, characterized by then Congressman Barry Goldwater, Jr. as "sloppy and suspect," to justify removing adrenal cortical extract (ACE) from the marketplace, in order to make the public a captive audience for prednisone, which the FDA said was safe. For forty years, Physicians Desk References had recorded no adverse effects from ACE, and mainstream medical journals now identify prednisone as very toxic even on a short-term basis.

In 1985, Dr. Ralph Moss publicly revealed that Sloan-Kettering had falsified the laetrile studies data, deliberately misleading the public by saying there was no evidence of efficacy, when in fact animal studies had demonstrated efficacy.

In 1988, an FDA Consumers publication falsely stated that intravenous vitamin treatments are useless. The 1989 FDA Health Fraud Kit further misled the public about the safety and efficacy of vitamins.

The FDA ignored evidence that folic acid could prevent certain serious birth defects until around 1994, and still refuses to recommend supplements. Instead, the FDA had it added to foods, which I believe will result in a false and dangerous sense of security among women who intend to get pregnant, and who will believe that they are consuming enough, when they really can't know the quantity of folic acid in what they are eating. Also, it is suspected that the iron added to foods, mandated by the FDA, is resulting in excesses that are causing heart attacks.

When the FDA took the natural L-Tryptophan off the market, the public was not informed that it was a genetically modified product that had caused the harm. Natural L-Tryptophan had been used for decades with no record of adverse events.

The FDA recall rate over a ten-year period is 52 percent. The book The Great White Lies by Wall Street Journal Reporter Walter Bogdanovich, documents between 10,000 and 50,000 deaths a

year from a certain family of heart drugs the FDA had refused to take off the market.

A November, 1994 issue of *Newsweek* concluded that because something is FDA approved, does not mean it is either safe or effective. A June, 1988 *JAMA* article acknowledged that over 100,000 people die a year from FDA approved drugs taken as directed, and many more are maimed by the drugs. Vitamin proponent Dr. Earl Mandell, M.D., poured over CDC data in the 1980s and could not find even one death attributed to vitamins.

So much for the FDA's "gold standard" and "sound science."

Existing safety and truth-in-advertising laws already cover supplements. Many lives would be saved if the FDA enforced these laws against the drug industry; toxic treatments with unacceptably low outcome data, such as chemotherapy and radiation, would and should be banned.

These adverse safety data for drugs reveal that the wrong questions are being asked, and flawed parameters are being imposed. People are dying as a result of the FDA's betrayal of its mandate for safety, which has been subsumed by the more ambiguous standards for efficacy, in the FDA's power grab on behalf of the chemical, food, and drug industries, documented in the 1993 expose Racketeering in Medicine by Tulane Medical School Professor James Carter, M.D.

The most infamous example is that of Michael Taylor, a lawyer for Monsanto, who was hired by the FDA to write the rules for genetically modified foods which Monsanto manufactures. The rules prohibited any labeling, and Monsanto threatened stores with lawsuits who displayed products labeled "BgH free," until Ben and Jerry's challenged those FDA rules in court.

The FDA has also abused its authority and misused limited resources by spending millions to try to destroy Dr. Burzynski, whose only "crime" is curing serious organ cancers with a nontoxic chemotherapy treatment the drug companies, NIH, NCI, and ACS can't profit from. (NCI randomly looked at seven of Dr. B's cases and said in all seven, his treatments appeared to have been effective.) And the so-called "peer reviews" the FDA insists on are shams, and have been involved in shameful scandals for failing to disclose the financial interests of the authors in the companies whose products they were reviewing. The publications themselves depend on the drug industry for funding.

Many holistic practitioners view double blind studies as unethical, because they entail withholding treatments from participants that practitioners have found to be effective. There is so much good research and outcome data on these natural treatments, practitioners have developed protocols and safety and efficacy dose ranges, knowing that individual needs and

variations are critical to their successful outcomes. The highly imperfect FDA paradigm treats everyone the same, and therefore should not be the benchmark for standard of care in this country.

The FDA should leave holistic medicine to the holistic practitioners, and acknowledge the wealth of research and outcome data supporting claims for vitamin and herbal treatment options. Testifying before Congressman Burton's FDA oversight committee in 1998, Dr. Peter Matthiessen, Chief of Witten University Medical Service in Germany, presented the pluralistic German medical system as a model for the United States to replicate. Using scientifically reproducible data for quality, efficacy, and cost effectiveness, modalities such as phytotherapy, homeopathy, and anthroposophical medicine are respected and reimbursed.

In 1995, the State of Maryland released a legislative study comparing allopathic with holistic treatments for six disorders, looking at outcomes, side effects, and cost, based on documentation found in medical publications. Holistic medicine dramatically outperformed the allopathic treatments.

In summary, the FDA should be a clearinghouse for verifiable research and outcome data from practitioners, researchers, and consumers, and labels should reflect this information. What works for one, may not work for another, and people will not continue to use what does not work. But for the FDA to suppress and deny this information is unethical.

Neither DISHEA nor the Pearson case would have been necessary, if a non-corrupt FDA had been serving the public, adhering to the "First Do No Harm" paradigm. I believe that research shows that for every drug (which all have mild to serious side effects), there is a natural, nontoxic alternative.

books

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Date: 3/3/100, 5:20 PM
Re: Special C-SPAN Alert to DC/VA/MD Subscribers

Come to the National Press Club at 14th and F Streets in Washington on Tuesday, March 21 at 6:30 PM for a Book Rap about C-SPAN's "Who's Buried In Grant's Tomb?" This new book explores a different way to learn presidential historyby touring presidents' graves and libraries.

C-SPAN's Brian Lamb and presidential historian Richard Norton Smith will tell tales of how the presidents died and where and how they were buried. They'll show photos of presidential gravesites, from the grand and glorious to the solemn and serene. The event will be in The First Amendment Room and is FREE and OPEN TO THE PUBLIC. Reservations are requested due to limited seating. Please e-mail lauraf@npcpress.org or call 202-662-7564 today.

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ATTN: Carole Williams
FROM: Alyce Ortuzar
RE: FDA testimony presented on 4/6/00

Sorry for the delay. I e-mailed my testimony to you this morning. However, I noticed two errors that I did correct, but somehow were still in the file.

At the top of page 1 talking about the 1950s, the author "chute" should be spelled "Shute."

At the bottom of page 2, talking about the book "Great White Lies," the author's name is Walt Bogdanich. Thank you.

Alyce Ortuzar (301)774-6617