# Withdrawal/Redaction Sheet
## Clinton Library

| DOCUMENT NO. AND TYPE | SUBJECT/TITLE | DATE | RESTRICTION |
|---|---|---|---|
| 001a. testimony | Judy Schneider (partial) (1 page) | 01/23/2001 | b(6) |
| 001b. testimony | Sandra Ehrenkranz (partial) (1 page) | 01/23/2001 | b(6) |
| 002a. testimony | Huaihai Shan (partial) (1 page) | nd | b(6) |
| 002b. resume | Huaihai Shan (partial) (1 page) | nd | b(6) |
| 003. letter | Ilyce Randell (partial) (2 pages) | nd | b(6) |

**COLLECTION:**
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43238

**FOLDER TITLE:**
WHCCAM Testimony Given, Lighthouse International Conference Center, January 23, 2001 [4]

2011-0568-S
kc890

**RESTRICTION CODES**

**Presidential Records Act - [44 U.S.C. 2204(a)]**

**P1 National Security Classified Information [(a)(1) of the PRA]**
**P2 Relating to the appointment to Federal office [(a)(2) of the PRA]**
**P3 Release would violate a Federal statute [(a)(3) of the PRA]**
**P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]**
**P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]**
**P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]**

**C. Closed in accordance with restrictions contained in donor's deed of gift.**
**PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).**
**RR. Document will be reviewed upon request.**

**Freedom of Information Act - [5 U.S.C. 552(b)]**

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**b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]**

STONY BROOK
STATE UNIVERSITY OF NEW YORK

*School of Social Welfare*
*Center for Health Promotion and Wellness*

Testimony Provided to the
White House Commission on Complementary and Alternative Medicine
New York City Town Hall Meeting
January 23, 2001
by

Charles L. Robbins, DSW
Associate Dean/School of Social Welfare
Chairperson/ Center for Health Promotion and Wellness
Director of Social Work/University Hospital
SUNY at Stony Brook

I would like to thank the honorable members of the White House Commission for the opportunity to address you this afternoon. I am Charles L. Robbins, DSW, the Associate Dean of the School of Social Welfare and Chair of our Center for Health Promotion and Wellness. You have just heard from several of my colleagues discussing the importance of considering culture in Complementary and Integrative Medicine. I am going to address issues of Public Health Education but must first comment that whether we are discussing Ancestral Medicine or Allopathic Medicine – if the health care provider and patient do not understand each other (and this is more than just language) – then one is not providing even adequate health care.

There are several areas in which the Federal Government has a responsibility to act as it impacts public health education:

1) The first of these is to ensure that the public has access to the information that is currently available about the products and services they are using. While it is not the Government's responsibility to decide what an individual can practice, it is the Government's responsibility to see to it that individuals have the necessary information to make an informed decision. This information can be provided in a nonjudgmental way in which specific recommendations are not made.
2) The government must ensure that allopathic physicians are aware of the practices that individuals from different parts of our country and from throughout the world are likely to be utilizing. They must be educated about the importance of engaging in nonjudgmental communication about these practices. Allopathic physicians and other health care providers must be educated to understand that their way is not the only way.
3) Likewise, the public must be educated that simply because something is said to be natural – does not mean that taking it is without consequence. Obviously individuals would not take substances that they believed to be inert, as they would produce no effect. Therefore the government must provide accurate information for the public on the risks and benefits of so-called natural substances.
4) There are two additional areas in which I urge the Commission to take action. The first has to do with the regulation of the supplement industry. I am not

suggesting that the Government dictate what supplements are available to the public or even evaluate the outcome claims made by the manufacturers. What I am suggesting is that the Government does have a responsibility to insure that what is on the contents label of a supplement package is in fact what is in the package. Today one does not know anything about the strength or purity or even if the substance they are ingesting is in fact the product on the label. It is time to tell this multi-million dollar industry that acceptance of this minimum level of regulation is simply part of the price of doing business.

5) Finally, an issue that is potentially a huge public health problem in this Country. This has been highlighted by Dr. David Eisenberg in his two national studies and can be seen in virtually all other professional work in this area. I am referring to the lack of communication between patient and allopathic health care provider about the Complementary and Alternative Medicine practices they are utilizing as well as the lack of communication between CAM providers and their patients about allopathic treatments they are using. As we see an exponential rise in the use of what we refer to as Complementary and Alternative Medicine practices, there is going to be an unfortunate explosion of negative drug/supplement interactions as well as the unforeseen consequences on specific health conditions by taking supplements. There are two areas in which the Government must act if is going to head off this crisis. The first is to require that all allopathic physicians are educated about the supplements and practices their patients utilize. The next step the Government must take is to launch a public health education campaign

utilizing public service announcements, television commercials and the print media to underscore the importance of patients and practitioners communicating. These must be targeted to both practitioners and the public. It is not adequate to simply undertake the public health education campaign, as, and I have experienced this myself, telling a physician who knows nothing about supplements and herbs what you are taking and having them seem uninterested is simply pointless and more importantly dangerous.

The Government has the responsibility to protect the public health of its citizens. Adopting the steps toward appropriate public health education through the legislation and policies that I have suggested will significantly decrease the potential negative consequences of the monumental public interest in and utilization of Complementary and Alternative Medicine.

Thank you for your attention.

Testimony to the White House Commission on behalf of The American Association of Naturopathic Physicians
(AANP)
by

Andrew L. Rubman, ND - Liaison, AANP; Medical Director, Southbury Clinic for Traditional Medicines; Adjunct Assistant Professor of Clinical Medicine, College of Naturopathic Medicine, University of Bridgeport; naturdoc@bigfoot.com

I am again honored to address the Commission on matters related to my profession. I will briefly detail proposed steps to craft Federal Guidelines for curricula standards and education to apply to all medical training in The United States. Individuals functioning as physicians in our society need to be formally trained in the sciences and philosophies of what Dr. Gordon refer to as "The New Medicine". As curricula at Allopathic and Naturopathic medical schools become progressively similar our efforts need to focus on providing access to the philosophical differences in the disciplines that make these two branches of medicine inseparable, immiscible, and of equal value to the society. I submit for The Commission's information comparative curricula medical school data generated by the AANP in 1998.

As Allopathic philosophy emphasizes the identification and suppression of pathology, Naturopathic philosophy stresses the appreciation and enhancement of normal physiology. In order to understand the value of naturopathic medicine, allopathic basic and clinical medical science curricula need to be reworked to include these philosophical elements. In order to practice naturopathic medicine, these components need to be at the core of all formal medical education. I propose that "The New Medicine" include enough crossover within the two disciplines to allow both to appreciate the value of the other and to allow for seamless referral and patient co-management. This should not encourage one to practice the other's craft; to do so would be to act irresponsibly. This conjoint approach needs to be available to the public in all medical delivery facilities, including primary care and hospitals.

The AANP supports all efforts to educate the populace in becoming better healthcare consumers. A naturopathic physician serving in an advisory capacity can help the Federal Government design programs to decrease emergency facility utilization and improve the overall level of wellness far better than any extant effort. The current system provides only minimally effective guidance in this area. Furthermore, all facilities promoting wellness education, alternative healthcare, etc. need to have active oversight and participation of naturopathic physicians. I do not believe that allopathically trained physicians can responsibly function in this capacity.

Allopathic medical schools need to have naturopathic physicians on staff, providing curricula oversight and classroom instruction in this discipline. MD's and DO's should not be asked to provide this component. David Studdert, MPH, of Harvard School of Public Health, writes in the May 12, 1999 issue of JAMA that, " ... physicians (MD's) who choose to incorporate alternative treatments ... should ensure that they do not render (this therapy before) a patient gives express consent in light of full information about the

nature and risks of the therapy ...". How can a physician, untrained in these therapies and unaware of their proper application, inform their patients and thus, "do no harm"?

The obstacles that exist to this necessary deregulation of medicine are those of ignorance, greed, and misconception. Appointment of naturopathic physicians to all agencies and committees, dealing with medical school curricula, hospital practice, and public health information dissemination will move to correct this. A good step might be to consider this Commission's purview that of traditional medicines, not complementary and alternative. In closing I provide The Commissioners a copy of a picture of the 1902 graduating class of The American School of Naturopathy in New York City. These were truly traditional naturopathic physicians practicing traditional medicines.

Andrew L. Rubman - 1/19/01

# Naturopathic and Major Medical Schools

## Comparative Curricula

| | National | Bastyr | Southwest | Johns Hopkins | Yale | Stanford |
|---|---|---|---|---|---|---|
| **Basic and Clinical Sciences** Anatomy, Cell Biology, Physiology, Pathology, Neurosciences, Clinical/ Physical Diagnosis, Histology, Genetics Biochemistry, Pharmacology, Lab Diagnosis, Pharmacognosy, Public Health, History, Philosophy, Ethics, Research and other coursework. | **1548** | **1639** | **1419** | **1771** | **1420** | **1383** |
| **Clerkships * and Allopathic Therapeutics** Lecture and Clinical Instruction in Dermatology, Family Medicine, Psychiatry, Internal Medicine, Radiology, Pediatrics, Obstetrics, Gynecology, Neurology, Surgery†, Ophthalmology, and Clinical Electives. | **2244** | **1925** | **1920** | **3391** | **2891** | **3897** |
| **Naturopathic Medicine** | | | | | | |
| **Naturopathic Philosophy** | **72** | **55** | **60** | -- | -- | -- |
| **Therapeutic Nutrition**** | **144** | **132** | **130** | -- | -- | -- |
| **Counseling‡** | **144** | **143** | **100** | -- | -- | -- |
| **Botanical Medicine** | **96** | **110** | **120** | -- | -- | -- |
| **Homeopathy** | **144** | **88** | **140** | -- | -- | -- |
| **Oriental Medicine** | **72** | **33** | **200** | -- | -- | -- |
| **Hydrotherapy** | **48** | **39** | **40** | -- | -- | -- |
| **Naturopathic Manipulative Therapy** | **156** | **176** | **180** | -- | -- | -- |
| **Ayurvedic Medicine** | -- | **22** | **20** | -- | -- | -- |
| **Naturopathic Case Analysis/ Management⁂** | -- | **66** | **120** | -- | -- | -- |
| **Advanced Naturopathic Therapeutics** | -- | **44** | **20** | -- | -- | -- |
| **Subtotal:** | **876** | **908** | **1130** | **0** | **0** | **0** |
| **Totals Reported Hours:** | **4668** | **4472** | **4469** | **5162** | **4311** (+ thesis) | **5280** |

* Clerkships are estimated to be 40 hours of mixed lecture and clinical training.

† Naturopathic physicians study minor surgery only.

** No dedicated coursework in therapeutic nutrition appears in the college catalogs of Hopkins, Yale or Stanford, although they indicate that the subject is addressed in other courses.

‡ Totals for John Hopkins, Yale and Stanford are included in psychiatry coursework.

⁂ Hours which could also be allocated to this category may be included elsewhere for some institutions because of terminology differences in the course catalog.

Sources: 1996-97 *Curriculum Directory* of the Association of American Medical Colleges
1995-97 catalog of National College of Naturopathic Medicine
1996-98 catalog of Bastyr University
1996-97 catalog of Southwest College of Naturopathic Medicine and Health Sciences

**For Information or Referrals:**
**American Association of Naturopathic Physicians**
**601 Valley Street, Suite 105**
**Seattle, WA 98109**
**(206) 298-0125**

# Naturopathic Medical Education

## Nutrition and Lifestyle Modification

Training in nutrition and lifestyle modification, in both classroom and clinical settings, has been part of the core curriculum of naturopathic physicians since the profession was organized in the United States in 1902. Naturopathic physicians are the only licensed primary health care providers with extensive training in therapeutic diets and preventive nutrition.

| **Coursework Recommended by U.S. Surgeon General** | **Naturopathic Physician** | **Registered Dietitian** | **Medical Doctor** |
|---|---|---|---|
| Biochemistry and Physiology | 321 | 120 | 369 |
| Basic nutrition, nutrition assessment and interpretation | 48 | 108 | Elective |
| Diet and disease; Therapeutic diets | 84 | 7 | 0[1] |
| Counseling | 130 | 36 | 0[2] |
| Internship | 1342[3] | 900[4] | 0[5] |
| National/State Exams | yes | yes | no[6] |
| **Total Hours:** | **1925** | **1171** | **369** |

**Notes:**

1. Not taught in most schools.
2. MDs receive about 170 hours of psychiatric clerkship, not likely to include behaviorally-oriented counseling.
3. This figure represents hours spent in outpatient clinics, where supervised training always includes dietary and lifestyle assessment.
4. May be performed in food management rather than clinical nutrition.
5. Medical internship does not normally include training in diet and disease.
6. Less than 4% of tests are in nutritional area, mostly in biochemistry, physiology, and pediatrics.

**Sources:**


The Surgeon General's Report on Nutrition and Health. 1988.

The 1996-98 curricula of Bastyr University, Seattle, Washington; 1995-97 curricula of National College of Naturopathic Medicine, Portland, Oregon; and 1996-97 curricula of Southwest College of Naturopathic Medicine. Naturopathic Physician hours are averages of these three colleges' programs.

The American Dietetic Association.

*Nutrition Education in U.S. Medical Schools.* National Academy Press. 1988.

The *1996-97 Curriculum Directory of the Association of American Medical Colleges.* Medical school hours are averages for Johns Hopkins, Yale and Stanford medical schools.


Naturopathic Physicians, Registered Dietitians, and Medical Doctors may take nutrition electives above and beyond this core curriculum.


**For more information or referrals:**
**American Association of Naturopathic Physicians**
**601 Valley Street, Suite 105**
**Seattle, WA 98109**
**(206) 298-0125**

1902 Graduating Class of the American School of Naturopathy in New York City.

# Clinton Presidential Records
# Digital Records Marker

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**S**

Divider Title: _____

**Date:** January 23, 2001

**To:** White House Commission on CAM Policy
**From:** Faye Schenkman, Director of the Wholistic Health Center New York College for Wholistic Health Education and Research
**Regarding:** Policy Recommendations

Good morning. My name is Faye Schenkman and I am the Director of the Wholistic Health Center at the New York College For Wholistic Health Education and Research. I am a practitioner of Amma Therapeutic Massage, a diplomate in Oriental Herbalism and Bodywork and have personally been involved in the field of complementary and alternative medicine since 1976. The subject of breast cancer and alternative and complementary approaches to treatment of the disease is very complex. I am here today to speak very briefly on the need to incorporate wholistic modalities such as massage, acupuncture and herbalism into the fight against breast cancer.

The public is distressed by increased cancer incidence and the absence of real treatment gains for the major cancers despite the decades and billions of dollars spent since the initiation of the war on cancer. Breast cancer has reached epidemic proportions on Long Island where I reside and work, and is the leading cause of cancer death in women throughout the industrialized world and in many developing countries. There is a great deal of fear and no clear understanding of why the incidence of breast cancer has increased so substantially. Many women who have cancer are exploring alternative treatment especially if their recommended treatment is very difficult to endure or doesn't produce the desired effects. Most oncologists are not familiar with alternative and complementary therapies used by many of their patients. Chemotherapy's side effects have become increasingly difficult for women to tolerate as we all desire more gentle, as well as, effective treatments. The FDA is seen as ignoring research on natural, herbal products that have been standard treatment in Europe, for example, in favor of expensive technology and expensive drugs. Many women feel helpless and frightened. They do not understand why oncologic medicine does not incorporate non-toxic herbal remedies, nutrition and energy based modalities that are standard in other nations that help to alleviate stress and diminish symptoms. The United States is behind many European countries in integrating complementary modalities to enhance conventional oncologic care. We are also behind in the concept of preventative medicine.

The concept of prevention of breast cancer in the United States is limited to early detection, i.e., regular mammograms. From a wholistic standpoint, a great deal can be done to educate women and the public at large on ways to take responsibility for their health. There is a great deal of evidence showing many environmental toxins, especially pesticides, and dietary factors like high fat diets, processed foods, fast foods with trans fatty acids and low nutritional value all play a role in potentiating this rapid rise in breast cancer. Allopathic medicine has recently begun to acknowledge that the consumption of fruits, vegetables, legumes and whole grains and anti-oxidants can help reduce cancer risk. Oriental medical modalities, such as Amma massage, acupuncture and herbalism offer treatments designed to enhance the body's ability to defend itself against disease

and alleviate stress in addition to improving the quality of life and helping those who are sick to manage their symptoms and the effects of their treatments.

It is imperative that oncologists offer their patients a supportive environment in which patients can feel free to discuss what complementary therapies they are using. And it is even more imperative that physicians are educated in these therapies so that they can understand how these modalities can enhance their own treatments. Physicians need to be open about both the limitations and the achievements of western medicine. The benefits of complementary practices, their comforting, non-toxic approaches, can merge well with conventional oncology practices to enhance the patient's well-being and quality of life.

**Policy Recommendations:**
I offer the following recommendations to enhance the integration of CAM therapies into conventional medicine:

- Medical schools should be required to teach courses in Oriental medicine – not simply introductory courses but in-depth instruction in the fundamental principles of Oriental medicine so that they can understand the viewpoint and how diagnosis and treatment is made. Not necessarily so they can practice it themselves, but so that they can make appropriate referrals, collaborate, and integrate their treatments with the CAM treatments their patients are already having. Without an understanding of the concept of the energy system, it is impossible for Oriental modalities such as acupuncture, bodywork, herbalism to have any meaning to a Western trained physician.

- Physicians should have in-depth courses in herbal remedies, nutrition and supplementation taught by acknowledged experts in these fields.

- Physicians need to develop a reliable network of referrals in different CAM specialties.

- Government should foster a climate of understanding and collaboration by allowing complementary and alternative therapies, such as acupuncture, massage, herbalism, chiropractic, biofeedback to practice in hospitals, in the armed forces.

- Government should help promote insurance reimbursement for CAM therapies. Currently many patients pay out of pocket for treatment and this limits their ability to receive these modalities.

- Research to better understand how to incorporate non-toxic herbal remedies, nutrition and energy based modalities such as acupuncture and massage therapy, that are standard in other nations and help to alleviate stress and diminish symptoms with conventional oncological treatment.

# Healing the Patient and Healing the System: Integrating Public Health with Complementary and Alternative Medicine

Robert "Red" Schiller, MD

Chairman, Department of Family Medicine
Beth Israel Medical Center

Assistant Professor, Department of Family Medicine
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The recent expansion of Complementary and Alternative Medicine (CAM) into various medical settings has brought profound benefits to all sectors of the Health Care System. Physicians have become more humanized, less judgmental, and often using these techniques on themselves and their families, before they feel comfortable recommending them to their patients. Patients are more knowledgeable about choices in treatment and they are more confident in challenging their physicians. Insurance companies having recognized the value of certain therapies now reimburse for them. Many medical research and educational institutions include CAM as part of their inquiry or curriculum.

However, these achievements have benefited only a fraction of the population. People with inadequate health coverage have little or no access to these therapies. Not only do these people often receive marginal conventional medical care; they can not share in the benefits of the innovative approaches of CAM. Ensuring equal access to CAM for all citizens should be a high priority for health care reform. I believe there is a tremendous opportunity to bring the reform of public health policy together with the expansion of the practice of CAM in an effort to not only correct this inequity, but to address many of the problems of the health care system. As Complementary Medicine has re-introduced healing and the mind-body connection into conventional medicine, so can these practices bring public health back into the sphere of the medical mainstream. The key to bringing public health and medicine together exists in strengthening the system of primary care and enhancing these services with integration of Complementary Medicine.

I am a family physician in practice for over 15 years, most of it in lower Manhattan. Although I received training in acupuncture, I currently practice mostly homeopathy with some general family practice patients. In 1984, a group of us from Montefiore Medical Center, including Richard Grossman, Dr. Sonja Lopez, and Dr. Ellen Tattelman, established an acupuncture program, and offered Western herbs and some basic homeopathy at a primary care practice that served a lower income population in Yonkers, New York. This was my first experience with an Integrative Medicine Practice, and it helped me understand the crucial elements to a successful use of complementary medicine in a conventional primary care setting.

We learned that it is essential to build complementary therapies upon an existing, successful primary care practice. Primary care is the most efficient

way that people access the health system. A primary care team is a model of collaboration and integration of services, and complementary therapies can become part of the routine referral network of the practice. The primary care base provides a steady source of patients and income to the practice. Many Integrative Health Centers have failed because they do not have this primary care economic base to sustain the inclusion of CAM.

However, of all the primary care practitioners, family physicians are ideally suited to achieve this integration. We are trained to practice collaboratively and already use the bio-psycho-social model in clinical practice. Expanding this model to include CAM therapies fits readily with this model. The fact that family physicians appear to the largest group of physicians who currently express interest in CAM comes as no surprise.

In 1994, the Beth Israel Medical Center and the Institute for Urban Family Health established a residency in Family Practice, the first in Manhattan. Training these residents in Complementary Medicine is part of the Residency's mission. We established a successful family practice site and introduced CAM as the practice developed. Many of the faculty are trained in these skills that are used in the residency clinical programs. However, we made a significant change two years ago with the introduction of a one-month *required* experience in Complementary Medicine. I believe we are the only residency program that has made this experience a requirement. The goal of this month is to teach the residents some basic skills that can be easily incorporated into their practice. The skills include one week in each of the following: 20 basic Western Herbs, Mind-Body Techniques for relaxation and stress management, Osteopathic Manipulation, and review of 10 nutritional supplements. There are some additional presentations in Homeopathy and Chinese Medicine for introductory purposes. We have learned over the years that physicians are ready for more than broad introductory exposure to Complementary Medicine; they want to leave conferences with basic skills and a good plan for continued education. Many of our graduates report that they are using some of these therapies, and we plan to collect data for a thorough analysis of the value of this training.

Beth Israel Medical Center has made a significant commitment to CAM with the creation of the Center for Health and Healing, which the Commission has already seen. There is close collaboration between our Department and the Center.

From my early years as a resident until now, I have believed that beyond broadening the therapeutic options for the patient, the real potential for CAM is its ability to potentially radically transform the Health Care System. Many of us were drawn to learn about these methods because we knew of fatal flaws in our training and in the practices where we cared for our patients. We hoped, even expected that the widespread use of these therapies would promote a more caring system, one that was devoted to healing, and that encouraged the curious, critical use of new or ancient, unconventional therapies. The excitement, enthusiasm, and positive results CAM practitioners experienced in the exam room need to be extended to the surrounding community in the form of health education, health promotion, and health care reform for the community.

Some issues are ready for the transforming potential of complementary Medicine.

Racial and economic disparities in providing even adequate care has been highlighted as among the more important issues in the Health Care Crisis. Now is the time to correct these disparities in access to Complementary Therapies.

Drawing on my clinical and administrative experience I make the following recommendations to the Commission:

1) People without health insurance or inadequate coverage or with Medicaid and Medicare are entitled to equal access to CAM Therapies. HCFA and State Legislatures should provide a basic package of coverage of CAM therapies that are available to all patients, and should mandate that commercial health plans provide similar coverage.

2) These Basic CAM Clinical Services need to be defined, based upon principles that permit some local or regional variation reflecting the diversity of communities, and the availability of qualified practitioners. These services should be developed as an extension of a primary care practice model in order to benefit from the comprehensiveness and cost-effectiveness of primary care.

3) Training of Health Care Providers, both Physician and Non-Physician providers in these basic therapies are needed to meet the overwhelming demand for these services. Priority should be given to enhancing the skills of current primary care providers.

4) Financial Support for this initiative is the most challenging problem. With a fixed health care budget, other services and training may have to be reduced or eliminated. This is the crucial role for Public Health Care Policy. Supporting programs that provide the greatest health benefit to given communities will assist in these decisions. Research in CAM has identified some effective therapies. However, even without adequate research, we may have to rely on clinical anecdotes or "clinical common sense" in an effort to get to evidence that we need in a timely fashion until more comprehensive studies are concluded.

Although I have stressed the primary care setting as the optimal place for the successful integration of CAM, I enthusiastically support the efforts many practitioners have made in a variety of settings that treat specific populations or conditions such as Women's Health, Cardiovascular Disease, and Cancer. The current health care system already emphasizes specialty care and the transforming potential of CAM will be less impact if limited to these practice sites.

The current success in the spread of Complementary Medicine is bittersweet. Many Americans have benefited from these achievements, but it appears the Integration of Complementary Medicine has not yet transformed our current system. In many ways this integration has duplicated the best and the worst of how we provide health care.

This Commission can begin to set the transformation potential of Complementary and Alternative Medicine in motion by identifying opportunities to make constructive changes and direct those of us with the energy, enthusiasm, and commitment to implement them.

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[001a]
130

January 23,2001
Judy Schneider
(b)(6)
Staten Island, N.Y. 10314
(b)(6)

I am here tonight wearing two hats. One is a member of The Executive Board of the Feingold Association of the United States, the oldest support group in the country for children with attention, behavior and learning problems. The second hat is that of an M.O.M.
When my daughter Kori was two and a half, she was on her way into autism. I kept saying , "There's a wall there. I can't get through the wall!" She was having psycho-motor seizures where she would wake up in the middle of the night with her legs and arm's flailing . She also showed signs of developmental delay. The Dr.'s recommended medicating her. It was at that time, 1978, my mom read an article about a new program, The Feingold Diet, that used dietary management to help these children. After 3 days on the program I had a new child. The seizures went away, she was sleeping through the night for the first time since she was born and she began to grow both physically and mentally. By the time she was in third grade she was in the gifted program and is currently a New York University graduate. By simply changing the brands of food in my daughter's diet she has become a productive member of society. In fact, she recently starred in an off-Broadway production where she played Miranda in The Tempest.

I request the Commission consider the following:
1. Parents need to be given, by their medical professionals, all the options for the treatment of attention, behavior and learning problems. One of these strategies needs to be dietary management which has been used successfully by the Feingold Association for 25 years.
2. The Feingold Program which costs $77 for the first year and $48 for renewal of materials, needs to become a reimbursable medical expense.
3. Additional research needs to be funded . One area which needs to be studied is the role enzymes play as part of this disorder. An interesting study was done in 1994 at Birmingham University, U.K. by Dr. Rosemary Waring . It showed an enzyme, phenol sulfotransferase (PST) which rids the body of phenolic compounds, was found in an extremely low level in her Autistic/ADHD population. Since most artificial flavors, colors and certain preservatives are phenolic based, without this enzyme present these foods may need to be removed from the diet. If this enzyme is the culprit a simple test needs to be standardized similar to the P.K.U. test to determine the level of this enzyme especially in children.
4. Dr.'s who select dietary management as the appropriate method of treatment for their patients, need to be protected from prosecution. I would like to bring to the Commission's attention the fact that Dr. Robert Sinaiko has been put on probation without the right to practice medicine by The Medical Board of California for prescribing

dietary management for an ADHD patient after medication had been unsuccessful. According to the California Board "ADHD is a psychiatric disorder whose only treatment is pharmacological." I heartily request that this situation and that of other Dr.'s in the same category needs to be reviewed.
5. We need to understand the role of the pharmaceutical lobby in decisions being made by both medical professionals and medical boards in excluding dietary management as a treatment option. Dr. Sinaiko was about to standardize a test to predict which children would benefit from dietary management just prior to his enditement.

I would to end my comments by sharing a true anecdote. When my daughter was about to enter high school we had a discussion about drug use. She simply said, "Ma. I don't do artificial flavors and colors why would I do drugs!"

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[0016]

I am a person with ADHD, the mother of a highly successful son with ADHD and grandmother to his child with ADHD. My family has successfully implemented the Feingold Elimination Diet and find that it results in a significant improvement in ADHD and its co-morbidity's.

The Feingold Program, as Dr. Feingold's elimination diet came to be known, eliminates all artificial colors, artificial flavors, and the preservatives BHA, BHT, & TBHQ. For some people it, eliminates aspirin and a group of fruits and vegetables related chemically to the salycilate in the aspirin.

The Feingold Association was founded by parents, in order to give support and make it easier for people who wish to implement the program. The Feingold Program addresses the symptoms and co-morbidity's of ADHD. The Feingold Program should be the first choice a physician offers parents of young patients. It seems reasonable that for the pre-school age child it should be the optimum choice.

We are here to help every person who wishes to try the Feingold Program. Over the past 25 years the Feingold Association, has developed a system to research ingredients in food and non-food products. A booklet is available that lists products, by brand name, that meet the standard of the Feingold Program. We are the only organization providing this service. Because the current legislation regarding labeling is not sufficiently stringent for children who respond to the Feingold Program the likelihood of success by just reading labels is low. The failure is often blamed on the Program rather than the method they used to implement it. The Feingold Association is run by volunteers whose families have benefitted from the program, many of us with 20 or more years of experience. We have come to understand that for some children the program needs to be individualized, with the elimination of other allergenic foods. Symptomatic improvement is often striking.

In addition to the brand name food list we also supply a fast food list, medication guide, mail order list, resource list, telephone help line, and internet support group. The Feingold Association's news letter updates the food and non-food product list, it also contains relevant, informative articles.

As members of the White House Commission you should know that the Feingold Association would be pleased if the government insisted on full disclosure of all ingredients used in processing and packaging a product. All these ingredients should be listed on the product. It would make it easier to follow the program and obviate the need for our product research center.

Respectfully submitted to the White House Commission
January 23, 2001
by Sandra Ehrenkranz
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# A simple, conservative medical approach to ADHD

## The risk-free program that has helped America's children for twenty-five years is the first place to begin.

Hyperactivity is not new; neither are learning difficulties. But by the 1970s pediatricians in the United States were alarmed by the growing numbers of children they saw who had difficulty behaving, focusing and functioning normally. When one of their respected colleagues reported that he had successfully treated many of these youngsters with a simple diet, his work was enthusiastically received. After 8 years of clinical research and the publication of papers on this work, Ben Feingold, M.D., presented the information at the 1973 conference of the American Medical Association. Feingold was chief of allergy at the Kaiser Permanente Medical Center in San Francisco, had taught pediatrics, and was considered a pioneer in the fields of allergy and immunology.

The diet eliminates these synthetic additives:

Artificial colors (these are derived from petroleum)
Artificial flavors (these can be manufactured from countless natural and synthetic substances)

Initially, aspirin and foods that are believed to contain a chemical related to aspirin, are removed; once a favorable response is seen they may be reintroduced one at a time.

Feingold found that about 1/3 of the children improved significantly; 1/3 improved to some degree, and the other 1/3 did not show improvement.

Later, he would also remove the anti-oxidant preservatives BHA, BHT, & TBHQ. After this, the success rate increased, and by the time of his death in 1982 the diet had been further refined, and the success rate was over 70%.

What Feingold named the "Kaiser-Permanente Diet" gained wide publicity after the American Medical Association arranged for press conferences to be held around the country, and sent Dr. Feingold out to tell of this new information. Feingold called for research to identify the scientific basis for the successes he was seeing in his patients; he knew this would be a formidable task and that it could take many years to understand how certain compounds affect our behavior, ability to learn, and our general health. He suggested that the research begin with food dyes since there were only a few of them still permitted to be used. It would be several years before the first studies were completed, but after only a few months, the AMA abruptly, inexplicably, dropped their support.

Even before the 1973 AMA conference, the lobby representing the interests of the food, chemical and pharmaceutical industries was busily engaged in damage control. The lobby, called the "Nutrition Foundation" used many tactics to address what they appear to have perceived as a threat.

After the medical association had their change of heart, Random House asked Feingold to write a book directed to parents, and in 1974 *Why Your Child Is Hyperactive* was published. Grateful parents who had benefited from this book began to form support groups, and in 1976 they established a national non-profit organization and named it the Feingold Association of the United States.

The role of the Association was, and remains, that of:
1. helping parents use the program, and
2. generating public awareness of the potential role of foods and food additives in behavior, learning and health.

The Association:
- Identifies brand name foods that are free of the unwanted additives.
- Prints this information, and literature to guide families through using the program. (This includes a Handbook, recipes, menu suggestions, information on finding undyed medicines and non-food products, information on other non-profit organizations that offer various types of assistance on related problems.)
- Offers on-line and telephone help in finding suitable brand name foods and resolving non-medical problems.
- Provides information to interested persons and organizations.

For the past 25 years the Feingold Association has provided information and assistance to families in the United States and abroad. The Association is composed primarily of parents and professionals who donate their time, and do what they can to help other families. We rely on membership dues and fundraising from member families to meet the bulk of our expenses. Like all groups of this type, people donate their time and energy because they receive the reward of seeing the program work effectively for the great majority of families. We have not conducted academic research and do not have the resources to track the outcomes on an ongoing basis. We are hopeful that an unbiased resource will someday fully evaluate the success rate of this program. Our own informal tracking suggests a success rate of between 75% and 86%.

**There have been many criticisms of the Feingold Program.**

Most are based on information that is not supported by fact such as:

Criticism: "The diet is restrictive."
In fact, the Feingold Program allows foods of all type, including: meat, dairy products, grains, most vegetables, some fruits initially (with the remainder added later). All types of foods are permitted, including candy, ice cream, cookies, junk food, pizza, soda, Big Macs, etc. Families select from among the many acceptable brand name products included in the Feingold *Foodlists*.

Criticism: "Children hate being on the Feingold diet."
Since they can still have their favorite types of food (in the versions that are free of the unwanted additives) they generally do not have to give up anything.

Criticism: "The Feingold diet cuts out sugar, chocolate, refined grains, etc."
This is not true and has never been the case.

Criticism: "It's expensive to follow this program."
Initially, families replace the unallowed products with new ones, but after that there need not be an increase in cost.

Criticism: "Everything in the supermarket contains additives."
The Feingold program only cuts out three groups of additives (plus synthetic sweeteners). Most food additives are not eliminated.

Criticism: "One bite of the wrong food can sabotage the diet."
If a child is sensitive to a particular substance, and eats it, he will probably experience a reaction; but this does not destroy the diet. The family simply deals with the reaction and when it is over, avoids the food/additive in the future. Children soon learn what they can and cannot tolerate, and follow the regimen that works best for them. Typically, once a person has followed the diet for a year or more, reactions diminish.

Criticism: "The improvement is due to a placebo effect. The improvement is due to increased parental attention."
The newer studies were designed to eliminate this. One of the earliest studies (Harley study at the University of Wisconsin) showed that neither placebo effect nor increased parental attention were factors. If the positive effects were the result of psychological factors, a person would be able to eat the prohibited additives and not experience a reaction.

Criticism: "The studies have shown that only a very small percentage (1% to 10%) of the children improve."
There are no such studies.

Criticism: "There are no studies that prove the Feingold diet works."
There have not been any studies of the Feingold diet as it is actually used. Portions of the diet (especially dyes) have been studied, and have yielded supportive results.
In 1998 the National Institutes of Health Consensus Development panel reviewed the scientific literature on diet for ADHD and called the research "intriguing," and "suggesting further research." The nonprofit Center for Science in the Public Interest published the report *Diet, ADHD & Behavior, a Quarter Century Review*, recommending diet as the first treatment to be tried.

Criticism: "Busy mothers cannot take the time to cook from scratch."
Most of the mothers using the Program work outside the home. They do not need to cook from scratch because the Association provides books listing thousands of brand name processed foods that are acceptable. Many of the major brands of food are available in versions with and without the prohibited additives (i.e., Nabisco, Duncan Hines, Hellmann's, Kraft, Kellogg's, Coca-Cola, Pepsi-Cola, Breyer's, Lender's, Pillsbury).

Criticism: "A child will not receive sufficient nutrition if he is on the Feingold diet."
The contrary is true. Eliminating the above synthetic additives invariably means the child will eat more nourishing foods. Removing oranges for a few weeks will not put the child at risk of becoming deficient in vitamin C. There are many allowed fruits and vegetables that are very good sources of this vitamin.

**The Feingold Association's position on the use of stimulant drugs**

The Association does not take a stand for or against drugs. Instead, we believe that parents and professionals have the right to have complete, accurate information on all of the potential options. We do believe, however, that it makes sense to try the least invasive options first, resorting to drugs if other interventions do not help, or offer only partial help. Some of the children who are using the Feingold program are also on stimulant medicine. In many cases parents report that by using diet, the physician can reduce the dose and the child can achieve the same level of effectiveness. Of course, we encourage families to request an undyed version of any medicines used.

When used appropriately, drugs can offer many benefits, but they are not always used appropriately for children with learning, behavior, or health problems.
We would like to see children receive careful screening to rule out the many things that can trigger attention/behavior problems. We believe that too little attention is given to ruling out illness, and that initiating stimulants without considering them may only mask the symptoms and make them harder to identify.

**Behavior/learning problems can have many causes.**

Some examples of problems that might contribute to overactivity or inattention include:

Sensitivity to food additives
Salicylate sensitivity
Psychological factors
Heavy metal exposure (lead, mercury preservatives in vaccines, excess copper)
Gluten or casein intolerance
Deficiencies – such as low zinc or magnesium levels
Hypothyroidism,
Elevated levels of phenylalanine
Inefficient production of enzymes
Lactose intolerance
Food allergy
Environmental allergy
Essential fatty acid deficiency
Vision problems
Auditory deficits
Language delays
Sensory dysfunction
Fine or gross motor control deficits

The Association believes that children with learning/behavior problems deserve to receive the same careful evaluation provided for children with other symptoms. Underlying sensitivity, deficiency, physical illness or dysfunction should be ruled out.

A brief trial of a simple, inexpensive elimination diet is one such test. It is not an alternative form of treatment, but rather a very traditional, conservative medical approach.

**The current diet of many American children represents a risky experiment.**

There has been a drastic increase in the use of petroleum-based food additives in the United States, along with a dramatic increase in ADHD, yet this important clue to the puzzle is generally overlooked. Unlike drugs, food additives have not been required to be evaluated for behavioral effects before being added to the food supply.

Synthetic dyes that are prohibited from use in foods may still be added to drugs and cosmetics. Small children are the most likely patients to receive medicine with synthetic colors and flavors. Surely, the small child who is sick is at great risk. If a dye is deemed unsafe for use in food, why is it allowed in pediatric medicine? *

Some countries have a low rate of ADHD, and there are significant differences in the diet of the children in those countries compared to the diets of children in the United States. The epidemiological studies that could shed light on a possible connection are not being conducted.

The ingestion of more and more synthetic chemicals by children and infants in the United States is generally ignored despite the published studies that link these additives to disturbed behavior and learning difficulties.

The practice of feeding large quantities of non-nutritive chemicals to young children is neither conservative nor traditional. Likewise, the use of Schedule II drugs on very young children is, in our judgment, neither conservative nor traditional.

* *The New England Journal of Medicine*, October 5, reported three deaths suspected of being caused by the addition of Blue dye No. 1 to the foods of critically ill patients.

## Bibliography

the relationship between foods/food additives and learning/behavior problems


Rowe, Katherine S. and Rowe, Kenneth J.: Synthetic food coloring and behavior: A dose response effect in a double-blind, placebo-controlled, repeated-measures study. JOURNAL OF PEDIATRICS; 125:691-8, 1994

Boris, Marvin and Mandel, Francine S.: Foods and additives are common causes of the attention deficit hyperactive disorder in children. ANNALS OF ALLERGY, 72:462-468, 1994.

Carter, C.M., et al: Effects of a few foods diet in attention deficit disorder. ARCH DIS CHILD; 69:564-568, 1993.

Egger, J; et al: Controlled trial of hyposensitisation in children with food-induced hyperkinetic syndrome THE LANCET, 339:1150-53. May 9, 1992.

Kaplan, Bonnie J.; et al: Dietary Replacement in Preschool-Aged Hyperactive Boys. PEDIATRICS January, 1989.

American Academy of Pediatrics Committee on Drugs: "Inactive" Ingredients in Pharmaceutical Products. PEDIATRICS, October, 1985.

Egger, J; et al: Controlled Trail of Oligoantigenic Treatment in the Hyperkinetic Syndrome. THE LANCET, March 9, 1985.

"Defined Diets and Childhood Hyperactivity", National Institutes of Health Consensus Development Conference Summary. Vol. 4, Number 3. 1982.

Augustine, George J., Jr.; Levitan, Herbert. Neurotransmitter release from a vertebrate neuromuscular synapse affected by a food dye. SCIENCE, 207:28 March 1980.

Swanson, James M , Kinsbourne, Marcel: Food dyes impair performance of hyperactive children on a laboratory learning test. SCIENCE, 207:28 March, 1980.

Weiss, Bernard; Williams, J Hicks; Margen, Sheldon:Behavioral responses to artificial food colors. SCIENCE, 207:28 March 1980.

Shaywitz, B.A.; et al: Effects of chronic administration of food colorings on activity level and cognitive performance in developing rat pups treated with 6-hydroxydopamine. NEUROBEHAVIORAL TOXICOLOGY,1:41-47, 1979.

Levy, F.; et al: Hyperkinesis and diet. A double-blind crossover trial with a tartrazine challenge. THE MEDICAL JOURNAL OF AUSTRALIA,1.61-64,1978.

Feingold, Ben F.: Hyperkinesis and learning disabilities linked to the ingestion of artificial food colors and flavors. JOURNAL OF LEARNING DISABILITIES, 9:551, November 1976.

Feingold, Ben F.: WHY YOUR CHILD IS HYPERACTIVE, Random House, New York, 1975.

Feingold, Ben F.: Hyperkinesis and learning disabilities linked to artificial food flavors and colors. AMERICAN JOUNRAL OF NURSING, 75:797, May 1975.

Feingold, Ben F : INTRODUCTION TO CLINICAL ALLERGY, Charles C. Thomas, Springfield, IL, 1973

# Health Beat

*HB00C008*

## Know the Hidden Asthma Triggers in Children

Asthma among children is increasing at an alarming rate, affecting an estimated five million youngsters in the United States, according to Dr. Philip Landrigan, Senior Advisor to the Environmental Protection Agency (EPA). While there are many possible triggers, many of the culprits named (pollen, pets, pollution) are not new. And they do not explain the sharp increase.

"There are important asthma triggers that are often overlooked, even by health care providers," says Kathy Bratby, M.S.N., R.N., of the State University of New York, "including many synthetic additives being used in foods, especially those designed to appeal to children."

Sulfiting agents are known offenders. The American Lung Association has named synthetic dyes and benzoate preservatives as triggers. The U.S. Food and Drug Administration has acknowledged that yellow dye and monosodium glutamate (MSG) are also a problem for asthmatics. MSG is often hidden in foods under other names.

Foods are not the only source of these additives. Synthetic colors, flavors and sweeteners are used in pediatric medicine, children's vitamins and many types of dental products. Food additives can be made from many different chemicals, including petroleum.

"Because the epidemic of childhood asthma is found in developed countries, but not in underprivileged nations," Bratby suggests, "Americans need to take a closer look at the synthetic chemicals now being added to their foods."

The Feingold Association of the United States (FAUS), a non-profit parent support group, provides information on avoiding additives that can trigger asthma. For a free brochure about their program, send a long, self-addressed stamped envelope to: FAUS-Asthma, P.O. Box 6550, Alexandria, VA 22306. *HB00C973*

# Pure Facts

Newsletter of the Feingold® Associations of the United States

NUTRITION IS A BETTER WAY
FEINGOLD®

This information has been reprinted from the February, 1995 issue of *Pure Facts*, the newsletter of the Feingold Association of the United States, P.O. Box 6550, Alexandria, VA 22306 (800) 321-3287.


## How does a brain work?

Our brain is made up of cells, and the ones which enable us to think are the nerve cells, or 'neurons'. The body of each neuron has one long cable extending from it; this cable is called an 'axon', and is a tube, filled with chemicals. Like the twigs of a tree, the axon branches out into little offshoots, ending in knob-like structures called 'axon terminals'. Each of these terminals can make a connection with other nerve cells, but it does not physically touch the other cell. The space between the axon terminal and the next nerve is incredibly tiny — only about one millionth of an inch. This space separating the two parts is called the 'synapse'.

Thoughts are formed when electrical discharges move from the bodies of nerve cells, down their axons. When the electrical impulse reaches the end of the axon (the axon terminal), chemicals are released. These chemicals are called neurotransmitters. The neurotransmitter molecules travel the tiny distance across the synapse, and fit into receptors, located on the adjacent nerve cell.

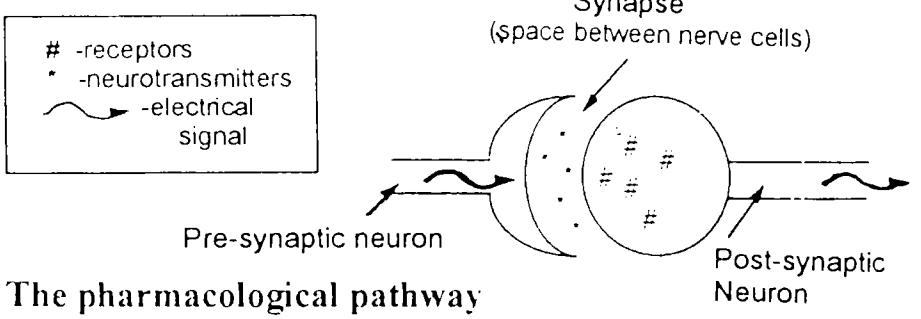
A brain contains billions of neurons, and each has many terminals, so the number of connections which can be made are virtually countless.

# How foods and additives affect the brain

Robert Sinaiko, M.D., addressed Feingold members at our Annual Conference, held in Fort Worth, Texas this past June. He described possible mechanisms by which foods and food additives relate to attention deficit disorder (ADD). Dr. Sinaiko, an immunologist practicing in San Francisco, was privileged to work with Dr. Feingold for several years. He later began a private practice and to date has treated approximately 1300 ADD children.

He is an enthusiastic supporter of the Feingold Association, and feels that Dr. Feingold's work has not only been validated by parents using the Program, but also by the scientific literature. He specifically mentioned studies by J. Egger et al published in *The Lancet* in 1992, and by C.M. Carter et al published in the November 1993 issue of the *Journal of Diseases of Children*. Dr. Sinaiko noted that Carter's group undertook the study to *disprove* previous studies linking diet and ADD, but their own results convinced them of the benefits of dietary treatment. The Carter study also showed the reliability of parental reports of children's behavior.

The workshop focused on "What's happening biochemically inside the body to cause behavior changes when certain foods/food additives are consumed?" There are two major pathways involved.




## The pharmacological pathway

Dr. Feingold called the first pathway the pharmacological or toxic pathway. Small molecules such as artificial food colors or naturally-occurring salicylates can be carried from the intestine to the brain through the bloodstream. In the brain, these molecules interfere with the chemical and electrical functioning of our brain cells. The effects can be produced by drugs, cosmetics, food additives and preservatives, and it takes very little of the offending chemical to produce the toxic effect.

## Immunologically-mediated pathway

The second major pathway Dr. Feingold considered is the immunologically-mediated pathway. This occurs when we eat a food to which we are allergic, such as wheat. Our body identifies the wheat as a foreign substance and responds as it would to an invading infectious microbe. This allergic response has been shown to reduce the levels of neurotransmitters (small messenger molecules) in our brains. When neurotransmitters are in short supply in the brain, behavior can be affected.

*Continued on page 3*

The Feingold® Associations of the United States, Inc., founded in 1976, are non-profit volunteer organizations whose purposes are to support their members in the implementation of the Feingold Program and to generate public awareness of the potential role of foods and synthetic additives in behavior, learning and health problems. The program is based on a diet eliminating synthetic colors, synthetic flavors, and the preservatives BHA, BHT, and TBHQ.

Brain, *from page 1*

## Neurotransmission

Neurotransmission is the method by which our brain and nerve cells communicate and send messages to our body, shown in the simplified drawing.

In neurotransmission, an electrical signal travels down a nerve cell (pre-synaptic neuron) When it reaches the synapse (space between two nerve cells), the electrical signal changes to a chemical one The pre-synaptic neuron (nerve cell which is sending the message) releases chemicals called neurotransmitters into the space between the two cells. The nerve cell receiving the message (the post-synaptic neuron) has receptors on its surface to 'catch' the neurotransmitter molecules being released. When enough neurotransmitters are 'captured' by the receptor molecules, the post-synaptic neuron begins a new electrical signal to be transmitted down the second neuron. The process is repeated along many neurons as they transmit nerve impulses around the brain and to the rest of the body.

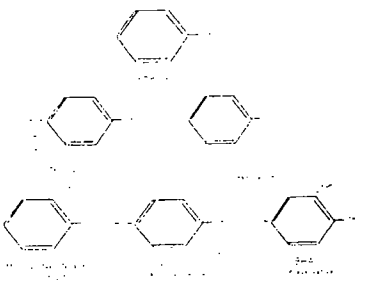
After nerve signals have been transmitted, the excess neurotransmitter molecules in the synapse are almost immediately destroyed by special enzymes. This ensures that the neuron does not continue to send signals when it shouldn't.

At any point in this process, interference with the delicate balance can disrupt the workings of the system.

## Phenols

Many of the additives which trigger problems in children with ADD have a chemical structure based on phenol (see below). Norepinephrine, one of the neurotransmitters, is also based on phenol. Phenolic compounds can dissolve in both water and in fat This is important because cell membranes are composed of both water and fat. This means that phenol molecules can easily cross membrane barriers and can get into the brain

One of the reasons ADD kids are unable to tolerate additives such as vanillin (artificial vanilla) and BHT, Dr. Sinaiko suggests, could be because these molecules can act as 'counterfeit' neurotransmitters. Note how similar the chemical structures of the additives and salicylates are to the chemical structure of the neurotransmitter norepinephrine



Petroleum-based additives such as dyes, BHA, etc. can act as 'neurotoxins', binding themselves to the receptors In other words, instead of a real neurotransmitter connecting with a receptor on the next nerve cell, the BHA molecule takes its place The nerve cell (post-synaptic neuron) thinks that it has received a real neurotransmitter, and fires a false electrical signal. The neuron was 'excitable' and transmitted a signal when it shouldn't have. The result of this is like having static, or unwanted noise in the brain.

**Dr. Sinaiko**

**A word about phenols:** Although some of the chemicals with a phenolic structure cause problems for Feingold members, there are others which do not. Not all phenolic compounds act as neurotoxins. In fact, some naturally occurring compounds, such as the amino acid tyrosine, contain phenolic structures In addition, there are some chemicals that affect ADD children which do not have phenolic structures; an example is Yellow No. 5. So this concept is not simple, nor is it well understood at this time.

## Enzyme Deficiency

Another potential problem is a deficiency in certain enzymes Enzymes are needed to break down the leftover neurotransmitters in the synapse. You might say the enzymes clean up those neurotransmitters that are no longer needed, and dispose of them If the extra neurotransmitters are not disposed of, the nerve may continue to fire randomly, producing 'noise'

Enzymes have another job to do; they get rid of excess phenolic compounds such as those found in the high salicylate foods. Since phenolic compounds can easily get into the brain and cause problems, the body normally produces an enzyme called 'phenol sulfotransferase' to detoxify them and allow them to be eliminated from the body. This means that naturally-occurring phenols (found in apple juice, oil of wintergreen, and many foods) are prevented from interfering in the transmission of nerve impulses.

It is estimated that about half of the children identified as autistic are deficient in the enzyme phenol sulfotransferase. Researchers in England have developed a test to measure the amount of this enzyme in the bloodstream, and many autistic children have almost none of the enzyme at all! It is possible that this inability to detoxify phenolic compounds in the body may disrupt the ability of the brain to send messages, resulting in autistic symptoms [Editor's note: preliminary research suggests that many children with ADD are also deficient in this enzyme. At this time we are not aware of any successful method for adding phenol sulfotransferase to one's system.]

## Receptors

The third area of possible interference in neurotransmission is a change in the number of receptors on the postsynaptic neuron. The number of receptors on the surface of a nerve cell can vary

Earlier in this article, we referred to the fact that ongoing allergic reactions can reduce the availability of neurotransmitters in the brain If we are exposed to an allergen (something to

*Continued on page 4*

**Brain,** *from page 3*

which we are allergic, such as milk or ') over a long period of time, our is compensate for the loss of the neurotransmitter, norepinephrine. Our brain creates more receptors so that even though there are fewer neurotransmitter molecules coming across the synapse, there is a better chance of many being 'captured' — of connecting with a receptor. In other words, someone who was drunk would find it easier to unlock a door if there were twelve keyholes instead of just one.

Although the increase in the number of receptors means that more of the neurotransmitters are caught, there is a down side. With the extra number of receptors, the nerve cells are now more excitable and have a harder time distinguishing between a real message and background 'noise'. For example, imagine that you are trying to listen to a distant radio station with a weak signal; you need to turn the volume way up in order to hear the speaker's voice, but this produces so much extremely loud static that you can barely make out what ing said.

## Neurotransmitters have many roles

When a child's brain is affected in any of the ways described above, there can be many symptoms. Neurotransmitters are involved in a number of essential areas where ADD children have difficulties. They are involved in waking up, in experiencing pleasure and in focusing.

Neurotransmitters are essential for the 'orienting response' which is so important for athletes such as tennis players. When you play tennis, your brain functions in two very different ways — it must constantly switch back and forth between an 'organized' and 'disorganized' state. The organized state is needed for hitting the ball; you are performing a task that has been practiced over and over. But as you wait for your partner to hit the ball back to you, your brain needs to be in a highly disorganized state. You have no way to predict where the ball will come and how you will need to react; in a disorganized state, your brain is ready for whatever action must be taken.

ADD children seem to be able to focus, but they focus on their own dreams and ideas. They have trouble making the shift to the disorganized, open mind which allows learning. This shift to the disorganized, receptive state requires that neurotransmitters be available in sufficient amounts. The use of drugs such as Ritalin locks the brain into the organized state. The reason some children do not seem to learn well on medicine is because they are not able to switch to the receptive (disorganized) state.

## Antifungal drugs

Fungi normally live in relatively small numbers within the intestine, but after repeated courses of antibiotics, fungal populations flourish. Like foods, abundant fungal overgrowth in the intestine can cause an ongoing allergic response, an immunological activation that depletes the available supply of the neurotransmitter norepinephrine, reducing chemical signal amplitude in the brain.

In addition to allergens, fungi produce a wide variety of phenolic compounds, which in the absence of adequate phenol sulfotransferase will accumulate in brain tissue, further degrading brain function by adding to chemical "background noise."

Future research will tell us if the benefit of antifungal treatment (about half the autistic children treated with antifungal drugs were shown to improve) is a combined effect or reducing both allergen and toxin exposures, with improved nerve transmission due to higher signal amplitude *and* reduced chemical background noise levels. Based on what we now know, this seems likely.

## Summary

Dr. Sinaiko discussed many different mechanisms, and it is likely that all of them play a part in the connection between diet and behavior/learning disabilities. Allergies weaken the nerve transmission signal, while toxic effects raise the background noise level of false signals. Both effects disrupt the critical chemical balance at the synapse.

Recent work has not only validated Dr. Feingold's clinical observations, Dr. Sinaiko stressed, but has gone on to implicate the biochemical mechanisms which may be responsible for the effects of food additives and common allergy-inducing foods on behavior and learning disabilities in children. Although many pieces of the puzzle are still missing, research is progressing rapidly in this area and is leading us to a much clearer understanding of behavioral reactions to foods. It is very important to recognize that more than one mechanism is involved here. While diet modifications can help most children significantly, this is too complex a problem for one single answer.

## Editorial note:

Researchers puzzle over the dramatic increase in mental health problems during the past few decades, and over the fact that the greater increase has been in younger people.

Dr. Gerald Klerman of the New York Hospital-Cornell Medical Center noted "I'm pretty convinced that something rather profound happened in our society from about 1950 to 1980 and that it had its greatest impact on young people.

"It could be some virus or some toxin in our food or water..."

Dr. Feingold traced the increase in behavior and learning problems to the years ... wing World War II, when foods began to change from minimally-processed ... additive-laden. Each year, more synthetic chemicals are consumed by more children, experiencing more disturbed behavior.

**References:**

Egger, J. et al. 1992 The Lancet **339**:1150-53.

Carter, C.M. et al. 1993 Arch. Dis. Child **69**:564-568.

Levitan, H. 1977 Proc. Natl. Acad. Sci. USA **74**:2914.

*Grateful thanks to Syte Reitz and Debbie Jackson for their assistance.*

# The many effects of food additives

## In 1973 Ben F. Feingold, M.D., presented his findings to the Allergy Section of the annual meeting of the American Medical Association. His work continues to help us understand many different health, learning, and behavior problems.

He described eight years of clinical experience and an impressive track record helping children who he referred to as "the failures of the medical community." Dr. Feingold's credentials were also impressive, and his techniques followed the best medical procedures: treat patients on the clinical level, gather information on successful techniques, relate this to probable causes using information found in respected medical journals. Since he was a clinician, it was his role to help a patient become well. The job of determining why a clinical technique works is the realm of the academician, or researcher. Dr. Feingold called upon his colleagues to begin the complex task of understanding what happens on the molecular level when a synthetically colored or flavored food enters a child's body, and why the result is often profoundly disturbed behavior or inability to focus. Very little has been carried out in this important area; there has never been a double blind study of the Feingold Program.

Dr. Feingold called upon another group. He asked parent volunteers to provide the information and support which enables a family to find suitable food and test the program. For more than seventeen years the Feingold Associations have done this.

Most of the focus of the Association is on helping children with learning or behavior problems, but over the years we have received many reports of other family members experiencing unexpected benefits. The longer the Association has carried out our work, the more diverse the reports of other conditions responding to the program. Dr. Feingold often told us that "any system of the body" can be affected by the additives we eliminate, but it still took us by surprise each time we learned of another condition which was helped by the removal of certain additives and salicylates.

While the research Dr. Feingold called for has not been carried out, work in related fields sheds some light on how symptoms which seem very different from each other are interrelated.

Researchers at MIT have shown that nutrients in food can alter the functioning of the brain. Other researchers have demonstrated the effect that food dyes have on the brains of both animals and humans. Both researchers and consumers report a wide range of negative effects from other additives, notably MSG and aspartame. Presumably, these additives also affect the chemistry of the brain.

Parents of ADD children often hear reference to neurotransmitters; these are chemical messengers that enable nerve cells to communicate with each other. The three neurotransmitters which are repeatedly associated with ADD and related problems are: serotonin, dopamine and norepinephrine.

Serotonin is called an inhibitor. It prevents us from doing things which are inappropriate or dangerous. In his book, *Tourette Syndrome and Human Behavior*, Dr. David Comings states, "Low levels of brain serotinin are associated with aggression, depression, violent suicide, alcoholism, arson, borderline personality, bulimia, and other impulsive behaviors. Low brain serotonin may also cause panic attacks." The Food and Drug Administration connects serotonin with migraine headaches, "Working with other chemicals, serotonin regulates blood vessel constriction and dilation. It can both sharpen and deaden pain." (*FDA Consumer*, Sept. 1992)

Another area where serotonin seems to play an important part is obsessive compulsive disorder, or OCD – when a person feels compelled to repeat an activity over and over, and feels very anxious when they do not. Researchers at Brown University and Yale have found that drugs which increase serotonin can help OCD sufferers. "When utilized by the brain's neurotransmitters at normal levels, serotonin is believed to impart a feeling of certainty, so that people don't experience excessive doubt about what they think and do. If his serotonin level is out of whack, an individual may have no confidence in his decisions or actions, leading him to repeat actions over and over." (*Brown Alumni Monthly*, 12/88)

Considering how vulnerable the brain is to chemicals, it's no wonder the Program helps so many symptoms.

The neurotransmitter, dopamine, is involved in the control of muscle movements, and may play a part in such disorders as Parkinson's disease and Tourette syndrome. The third important chemical, norepinephrine, is formed from dopamine, and helps regulate dopamine.

As the director of the Tourette Syndrome Clinic at the City of Hope National Medical Center, Dr. Comings has collected a wealth of information on symptoms which may be related to Tourette syndrome. They include: hyperactivity, ADD, dyslexia, obsessive-compulsive behaviors, conduct disorders, depression, mood swings, irritability, migraine headaches, short temper, anxiety, panic attacks, phobias, speech problems, sleep problems, addictive behaviors like alcoholism and eating disorders.

Comings has found that the Tourrette patient is far more likely than the average person to have one or more of these symptoms. Apparently they are more closely related than they may seem at first glance. It would follow, then, that a technique which can help one of these problems (such as hyperactivity) might also allieviate depression or headaches, etc.

Because the Feingold Progam asks the entire family to use the same foods, we hear of other problems which have responded to the change. Dad's headaches disappear, Mom is no longer troubled by PMS, and older sister isn't so distracted. The separate pieces of the puzzle begin to fit when you consider that foods and additives can affect brain chemistry, and that altered brain chemistry can result in a wide range of symptoms.

# Pure Facts

Newsletter of the Feingold Associations of the United States

FEINGOLD


Reprinted from Pure Facts November, 1994

## A Review of the Studies on the use of Stimulant Medication for Children with Attention Deficit Disorder

by Syte Reitz, Ph.D.

The use of stimulant medicine for children with ADD offers short-term improvement for the majority of children, but with potential side-effects and no long-term improvement in behavior, learning or social development.

The Council for Exceptional Children has published a comprehensive review of the studies on the long-term effects of stimulant medication for children with Attention Deficit Disorder. The article, by Swanson et al, appeared in *Exceptional Children*, Vol. 60, No 2., 1993.

This article uses a new "review of reviews" methodology to condense the existing findings in recent scientific literature on the use of stimulant medication for children with ADD. Nine review articles (traditional, meta-analytic and general audience categories) were included, as well as other references spanning 1975 to the present.

The methodology used in the article is complicated, and the reading is rough, because the existing literature is filled with conflicting aims, observations and conclusions concerning medication of hyperactive children. Swanson et al attempt successfully to sift facts, effects and observations from aims, predisposition and opinions, and remarkably, they come up with some consensus from the existing literature.

The factual material where the various researchers are in agreement is summarized in one table and one figure.

Table 1 lists and compiles the findings of three individual review papers which are typical of information found in the literature. Despite differing interpretations and recommendations, the eye-opening conclusion all three reviews arrive at is that stimulant medication is seen to have only short term effects on the behavior and attention of children with ADD.

The "effect size" reported in Table 1 is not clearly defined in the article, but presumably it corresponds to the percentage of improvement seen in the children after treatment with drugs. Thus treatment with stimulant drugs produced an average (short-term) improvement rate of 0.83 or 83% in the areas of behavior and attention. In the

*Continued*

## Foods and additives are common causes of the attention deficit hyperactive disorder in children

Marvin Boris, MD and Francine S. Mandel, PhD, ANNALS of ALLERGY, May 1994

"This investigation evaluated 26 children who meet the criteria for ADHD. Treatment with a multiple item elimination diet showed 19 children (73%) responded favorably, $P<.001$. On open challenge, all 19 children reacted to many foods, dyes, and/or preservatives. A double-blind placebo controlled food challenge was completed in 16 children. There was a significant improvement on placebo days compared with challenge days ($P=.003$). Atopic [allergic] children with ADHD had a significantly higher response rate than the nonatopic group. This study demonstrates a beneficial effect of eliminating reactive foods and artificial colors in children with ADHD. Dietary factors may play a significant role in the etiology of the majority of children with ADHD."

The Feingold® Associations of the United States, Inc., founded in 1976, are non-profit volunteer organizations whose purposes are to support their ibers in the implementation of the Feingold Program and to generate public awareness of the potential role of foods and synthetic additives in behavior, ning and health problems. The program is based on a diet eliminating synthetic colors, synthetic flavors, and the preservatives BHA, BHT, and TBHQ. FAUS, P.O. Box 6550, Alexandria, VA 22306.

areas of IQ and achievement, short-term improvements averaged 35%. Considering the fact that Barkley (1977)* reported approximately a 30% placebo response rate, the above figures for stimulant medication translate to real numbers of about 30% short-term improvement in behavior and attention, and about 5% improvement in IQ and achievement (short-term or long term).

No long-term effects of stimulants have been documented, according to Swanson et. al., and most patients discontinue stimulant treatment within two years. The short-term improvement is also not specific to children with ADD, since these drugs exhibit the same effect of improved attention and concentration in normal children.

## In the short-term, stimulant medicine can bring about a significant improvement in some very distressing symptoms.

The disagreement in the literature appears to rest in the interpretation of the above findings — not all authors agree whether the short-term improvements are worthwhile improvements in themselves or whether they interfere with treatment by acting as a short-term crutch, preventing or postponing the use of more effective non-pharmaceutical approaches. Some authors point out that drugs may have greater relevance for stress-reduction in caregivers than intrinsic value to the child.

Figure 1 summarizes what can and cannot be expected from the use of stimulant medication on children with ADD:

**Temporary management of the following symptoms will be expected to occur using drugs:**

a) over activity
b) inattention
c) impulsivity

**This will lead to temporary improvement in the following areas:**

a) deportment (increased compliance and effort will be observed)
b) decreased aggression
c) social interactions (decreased negative behaviors)
d) academic productivity (increased amount and accuracy of work)

**Figure 1 further lists what improvements should not be expected when using stimulant medications to treat ADD:**

1) There will be **no** paradoxical response. This means that the stimulant medications produce the same effects on all children and all adults (improved attention and concentration), regardless of ADD diagnosis or "normal" label. Thus the stimulant drugs cannot be correcting a biochemical defect or physiological or neurological abnormality.

## The researchers are essentially in agreement that stimulant medication does not provide any long-term benefits to the child.

2) There is no way to predict if stimulant drugs will help. Drugs do nothing for 25% to 40% of hyperactive children. The response of a particular child to drug treatment cannot be predicted in advance by any known neurological, physiological or biochemical test.

3) Absence of side effects cannot be expected. Frequent side effects of drug treatment include appearance or increase in tics, problems with eating and sleeping, and possible psychological effects on cognition and attribution (the ability to reason and to understand cause and effect relationships).

4) Major long-term improvement in skills or learning cannot be expected (no long-term improvement in reading, athletic or game skills, or positive social skills occurs).

5) Improvement in long-term adjustment cannot be expected. No improvement in academic achievement is seen, no reduction in antisocial behavior or arrest occurs.

Clearly, when editorializing and opinion are sifted out from the literature, a surprising consensus emerges about the expected benefits and the acknowledged limitations of stimulant medication in children with ADD.

## Some researchers express concern that the use of medicine makes it more difficult to identify the cause(s) or the child's learning problems and to find solutions.

In summary, drug treatment of children with ADD has no long term beneficial effects. Short-term effects are limited to temporary suppression of one subset of symptoms.

Some authors feel that stimulants may be overused in the United States. High doses of stimulants may produce cognitive toxicity (reduced ability to think and reason). Many children have adverse responses to stimulants and most patients discontinue treatment within two years. Clearly the benefits of stimulant treatment of children with ADD are limited.

*Barkley, R.A. (1977). A review of stimulant drug research with hyperactive children. *Journal of Child Psychology and Psychiatry*, 18, 137-165.

*Dr. Reitz received her bachelor's degree in biochemistry from the University of NY at Stonybrook, and her doctorate in biochemistry & molecular biology from Rutgers. She did her post-doctoral work at Princeton and was assistant professor of biochemistry and molecular biology at Oakland University in Rochester, MI.*

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**COLLECTION:**
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

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**FOLDER TITLE:**
WHCCAM Testimony Given, Lighthouse International Conference Center, January 23, 2001 [4]

2011-0568-S
kc890

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# The Application of Traditional Chinese Qigong in Psychiatry in the United States

**Presenter: Huaihai Shan, M.D.**

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CAM approaches that have been applied to psychiatry include Qigong, biofeedback therapy, acupuncture, Chinese herbs, meditation, autonomic training, hypnosis, relaxation therapy and biotherapy. Although the clinical utility of Qigong has not yet been fully evaluated, a large number of practitioners and patients worldwide have accepted it. There is good anecdotal evidence supporting the use of Traditional Chinese Qigong in conventional medical settings for disorders including mild anxiety, depression and, most strikingly, psychosomatic disorders such as asthma. Unfortunately, there are relatively few adequate research studies on the use of Qigong in this field.

Following are some concerns about Qigong that should be considered in order to properly assess the application of Traditional Chinese Qigong in psychiatry.

1. Many Qigong masters do not have extensive knowledge to diagnose

properly medical problems that may be treated by Qigong.
2.The anecdotal evidence of efficacy is not acceptable by conventional medicine because it lacks placebo controls.
3. Qigong has been sometimes been misused in the community and conventional medical settings in China.

What is Qigong? Although Qigong is widely practiced in the world and there is growing number of people and patients who are interested in practice Qigong, there are still some different opinions about its definition. Qigong embodies two principles: Qi is the vital energy of the body and gong is the practice and training of the Qi. Traditional Chinese Qigong, a particular form of Qigong, is also known as medical Qigong.

Traditional Chinese Qigong is the ancient art of health maintenance and healing that originated several thousand years ago in China. Traditional Chinese Qigong has three elements: mind, breathing and movement. The ultimate goal of Qigong is to improve the functions of the Mind/Body in a balanced way. Traditional Chinese Qigong is also one of the psychological rehabilitation techniques. For thousands of years, millions of people have benefited from Qigong practices and believed that improving the function of Qi maintains health and heals disease. It is believed that regular practice of Qigong helps to cleanse the body of toxins, restore energy, reduce stress and anxiety, and help individuals maintain a healthy and active lifestyle.

I hope that psychiatrists and psychologists would consider evaluating Traditional Chinese Qigong as a method of behavioral therapy.

I suggest that NIH establish a focus for research of Traditional Chinese Qigong in NCCAM to evaluate the practice of Qigong including its indications and contradictions.

The practitioner should consider the safety limitations of Qigong in the treatment of medical problems because Qigong may induce some psycho-physiological responses that are not good for health if practiced incorrectly or inappropriately.

I would be pleased to offer some the training courses of Traditional Chinese Qigong in the United States. I hope NCAAM establish a system to license Qigong instructors in the future.

If this is done, the quality of the research in the application of the Traditional Chinese Qigong in psychiatry would be improved.

My colleagues and I are very interesting in the application of Traditional Chinese Qigong for psychosomatic disorders in psychiatry. In particular, we would like to compare Traditional Chinese Qigong with meditation and other relaxation therapies in a Methadone setting for treatment of drug abusers.

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# Huaihai Shan, M.D. Qigong Master

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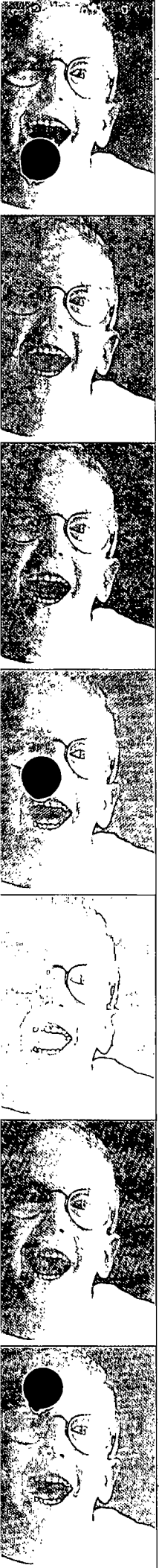
I received M.D in Psychiatry from the Shanghai Mental Health Center of China in 1985. I have trained extensively in general psychiatry, medical psychology, Traditional Chinese Medicine including Qigong, acupuncture and other CAM therapeutic approaches. I had begun to study the research on the psychiatry, medical psychology and CAM in 1985 after I had completed residency program in psychiatry. I founded the several research grant in psychiatry from Chinese government since 1986. I am a principal investigator of Chinese Health Center grant for in Qigong and psychology. The Several articles have been published in Chinese journals on the Complementary and Alternative Medicine. I also have been training in psychiatry and complementary and alternative medicine in the United States since 1996.

I also received a certificate of medical Qigong instructor from Shanghai Traditional Chinese Medical University of China, School of Qigong in 1989. I have taught Qigong at Shanghai Mental Health Center, in Qigong clinic and the community. Over the past 10 years, I have successfully integrated complementary approaches into my clinical practice. I have completed the project of the application of Traditional Chinese Qigong-based stress reduction program in the treatment of Anxiety disorders that has been published.

My research interests are focused on the use of complementary and alternative medicine including Qigong therapy, acupuncture, Chinese herb medicine and mind/body medicine and relaxation therapy, to treat stress-related disorders. I have been dedicated to helping people heal themselves, increase vitality, cultivate spiritual growth by complementary and alternative medicine. I am currently working on the research of the comparing Traditional Chinese Qigong with Biofeedback therapy for psychosomatic disorders and other medical problems as postdoctoral fellow in psychophysiology lab at UMDNJ. I am also training the faculty and staffs learning Qigong practice in medical school and treat the patients by Qigong therapy. I believe that Traditional Chinese Qigong is one of the Complementary and Alternative Medicine that is very helpful for Americans in the future.





My story begins in 1996 when my son Jacob was born, and then six months later diagnosed with Canavan disease, a fatal neurological genetic disorder. After being told Jacob would never hold up his head, sit, crawl, walk or say a single word, I was horrified to further learn that he would develop seizures, loose his ability to see, hear, swallow and would die within the first decade of his life. Even worse than the diagnosis, was the reality that there was no treatment to save my baby. I was told to take my baby home, make him comfortable and watch him die.

What I thought would be an endless journey, to search the world for any hope of a treatment, was not that at all. Within a month, I had located researchers from Yale University and the Auckland School of Medicine who had successfully treated two Canavan children with gene-therapy (in New Zealand) and were planning to treat 15 Canavan children in a US Phase I Clinical Safety Trial. Jacob was enrolled.

In January of 1998, after an extremely lengthy review process through the NIH, FDA and the Internal Review Boards at Yale, Jacob was finally treated and treated once more in September 1998. Jacob improved dramatically, but most impressive was his ability to generate new white matter in his brain.

As I sit before you today, Jacob again waits for the approval of yet another gene-therapy protocol that according to the researchers is safer, less toxic and technologically advanced. Where the prior therapy successfully reached a few areas of Jacob's brain, data indicates that the new procedure will deliver the gene, critical in saving Jacob, to all the areas of his brain.

With the excitement of this potential treatment comes the reality that Jacob deteriorates before your eyes as we wait for a review process that began back in May. While I am told by FDA officials that the review process is to ensure the safety of my child, I often respond by saying, "Why isn't the FDA equally concerned that Jacob could die because of lengthy reviews?" Equally concerning is that the FDA wants to ensure that patients and family members are fully informed, but yet we are kept at arms length from the review process.

Because of the orphan disease status of Canavan, there is zero federal funding that supports research in this horrific disorder. In addition to the emotional and physical toll taking care of my child has taken, I have also been given the responsibility of raising the funds necessary to support research with the potential of treating Canavan. Money is scarce, so I have become a very informed parent only able to support solid research. While I have been treated by officials at the FDA and NIH like a desperate mother willing to try any snake oil, the reality is that there simply is not enough money to support everything, so my choices must be made based on informed, concise information. And most importantly on evidence that the research I support has the potential of benefiting my son.

For an agency that prides itself on working hard to provide the public with safe, effective treatments, I am amazed at the snails pace and lack of regard the FDA has for terminally ill patients (and their families) who have no alternatives. They seem at rest with the fact that because they are taking an unethical amount of time to ensure safety, and patients may die while doing so, there is some sort of justification. I can assure you that there is never justification for a parent who must bury a child.

In my summation, Jacob's ethical right to receive a treatment that may stop the progression of Canavan, improve his quality of life and potentially treat or cure him is denied with each passing day he waits for an approval from the FDA. In addition, my right to choose what is best for my child is taken away as well. The same freedom this country prides itself on is the same freedom that has been taken away from Jacob and I.

It is my belief that protocols involving terminally ill patients must be reviewed more expeditiously and with different standards. Presently, the FDA must respond within 30 days of submission, but

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there is no limit for how many times they can ask for re-submissions, for which another 30-day response is allotted. I would propose the following:

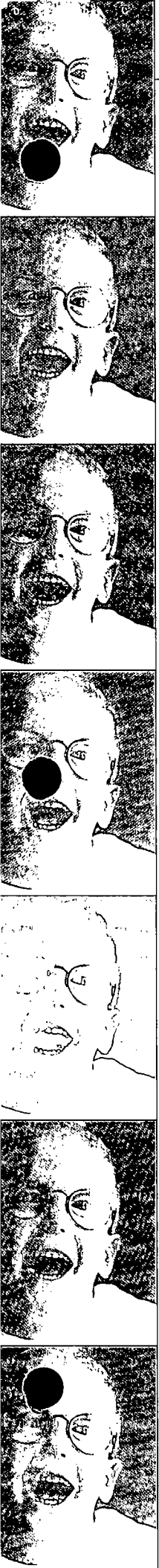
1. For experimental research in preparation for clinical trials involving patients quickly deteriorating from terminal illness (with a small window of opportunity) there must be prior knowledge of the FDA's demands, a review process that begins prior to submission. Researchers and patients and patient representatives should be able to have open dialogue with the FDA to discuss protocol intensions, collection of data and risk/benefit ratios.

2. The FDA needs to have more interaction with the patients of the protocols they are reviewing to understand the magnitude and the necessity for treatment, the patients knowledge of the alternatives (in our case death) and the desire of the patients choice of treatments.

3. Upon submission, the FDA should be required to respond within two weeks. If there are further requests from the FDA that the researchers and patients seem unreasonable and would create an unnecessary delay, then the patients and/or family members should be able to waive the approval from the FDA and sign an informed consent to proceed with the treatment.

4. An oversight committee must be created to protect patients and oversee the FDA. There must be a balance. As stated by our local congresswoman, Nita Lowey, "If there is a level of comfort, parents or patients are informed and know the risks and there are no other options than we must move ahead and treat the patients."

I thank you for this opportunity to share with you my precious Jacob and the struggles we live though every day. I hope that our testimony will make a difference and most important save lives.



# JACOB'S CURE

## A Fight Against Canavan Disease

In September of 2000, I created Jacob's Cure, a non-profit foundation, because of my passion to save the life of my son, Jacob, who is afflicted with Canavan disease, a devastating genetic brain disorder. Because of an enzyme deficiency, Canavan demyelinates the brain. Without myelin or white matter, Jacob never reached his first milestone...lifting his head. He is essentially trapped in his body. Without intervention, Jacob will lose his sight, his ability to swallow, may be stricken with seizures, become too weak to fight off illness and die within the first decade of his life.

In 1998, my efforts resulted in Jacob's enrollment in a Phase 1 Gene-Therapy Clinical Safety Trial. Jacob, along with 14 other Canavan children exhibited positive results and miraculously, Jacob developed new myelin. There was now hope where none existed before.

With these exciting results, it is my goal and that of Jacob's Cure to continue to support the continuation and advancement of research in gene-therapy. Because Canavan is so rare, zero federal funding supports research in Canavan disease, so it is through the help of friends, family and a philanthropic community that Jacob and children like him may be cured.

As it is the goal of Jacob's Cure to help the children dying of Canavan today, an additional project supported by Jacob's Cure is Neural Stem Cell Transplantation at Boston Children's/Harvard, at the direction of Dr. Evan Snyder. This research has exhibited great hope in curing Canavan and most brain disorders because of the unique ability of stem cells to provide what the brain is lacking, while also repairing any damage that has occurred. Dr. Snyder and his team aim to treat Canavan children with stem cells by the end of 2001.

Currently, Jacob and 24 other children suffering from Canavan desperately wait for a second, more advanced gene-therapy procedure that is under review for approval at the FDA. The goal to begin this critical gene-therapy treatment is by February 2001.

- *Jordana Sontag, "Jacob's Mom"*
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GIULIANI CHIC
By Dan Barry

..KUMENTARIES
DEVOUR
PRIME TIME
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Photographs by
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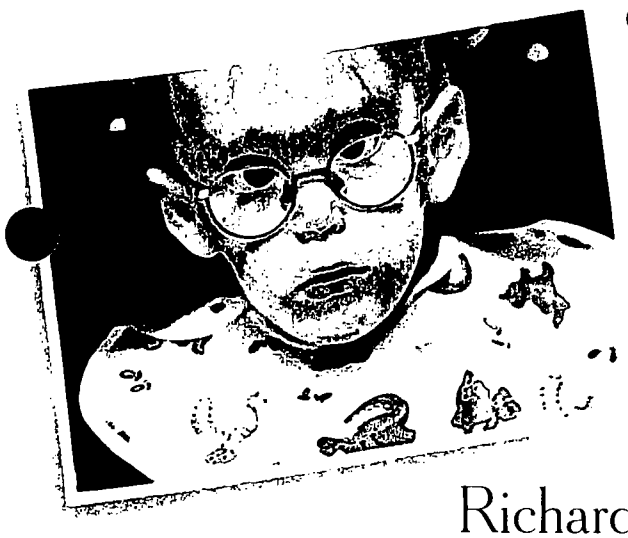
The New York Times Magazine

DECEMBER 6, 1998 / SECTION 6



Their 19-month-old boy was deteriorating, and Richard and Jordana Sontag had come to Yale, desperate and angry. An experimental gene therapy was their only hope, but the scientists were not sure it was safe. The couple spotted Dr. Margretta Seashore in the lobby. 'Look at him,' Richard said, thrusting Jacob in her face. 'You tell him why this protocol is delayed while he's dying. ...You look at my son dying. Tell it to him.'

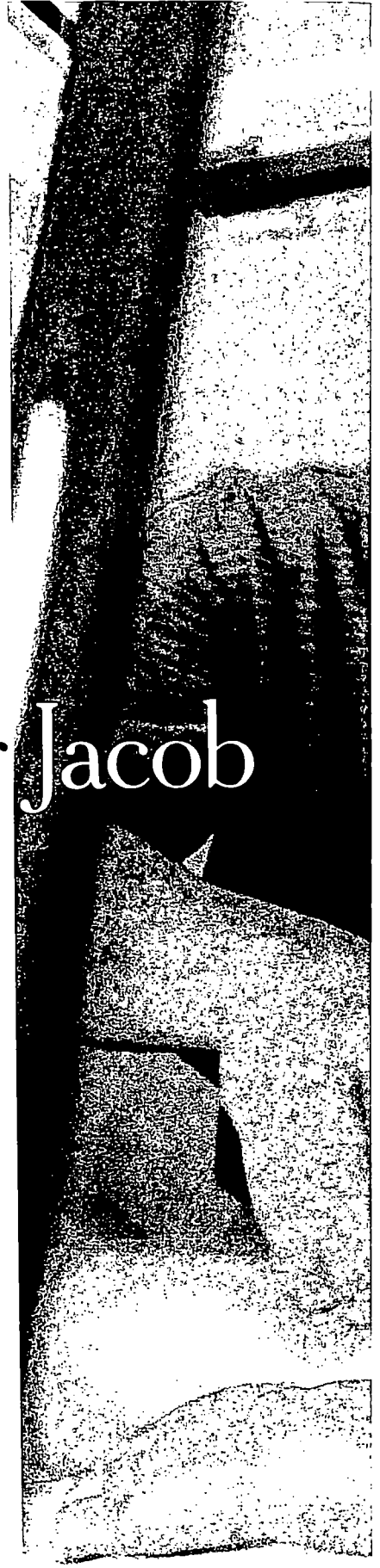
# Keeping Jacob Alive

By Michael Winerip

Until recently, there was no hope for a child with Canavan disease. But when the Sontags learned that their only child was born with it, they were prepared to sacrifice anything to get him the experimental treatment he needed. They didn't know that might include their marriage.

# Fighting for Jacob

By Michael Winerip



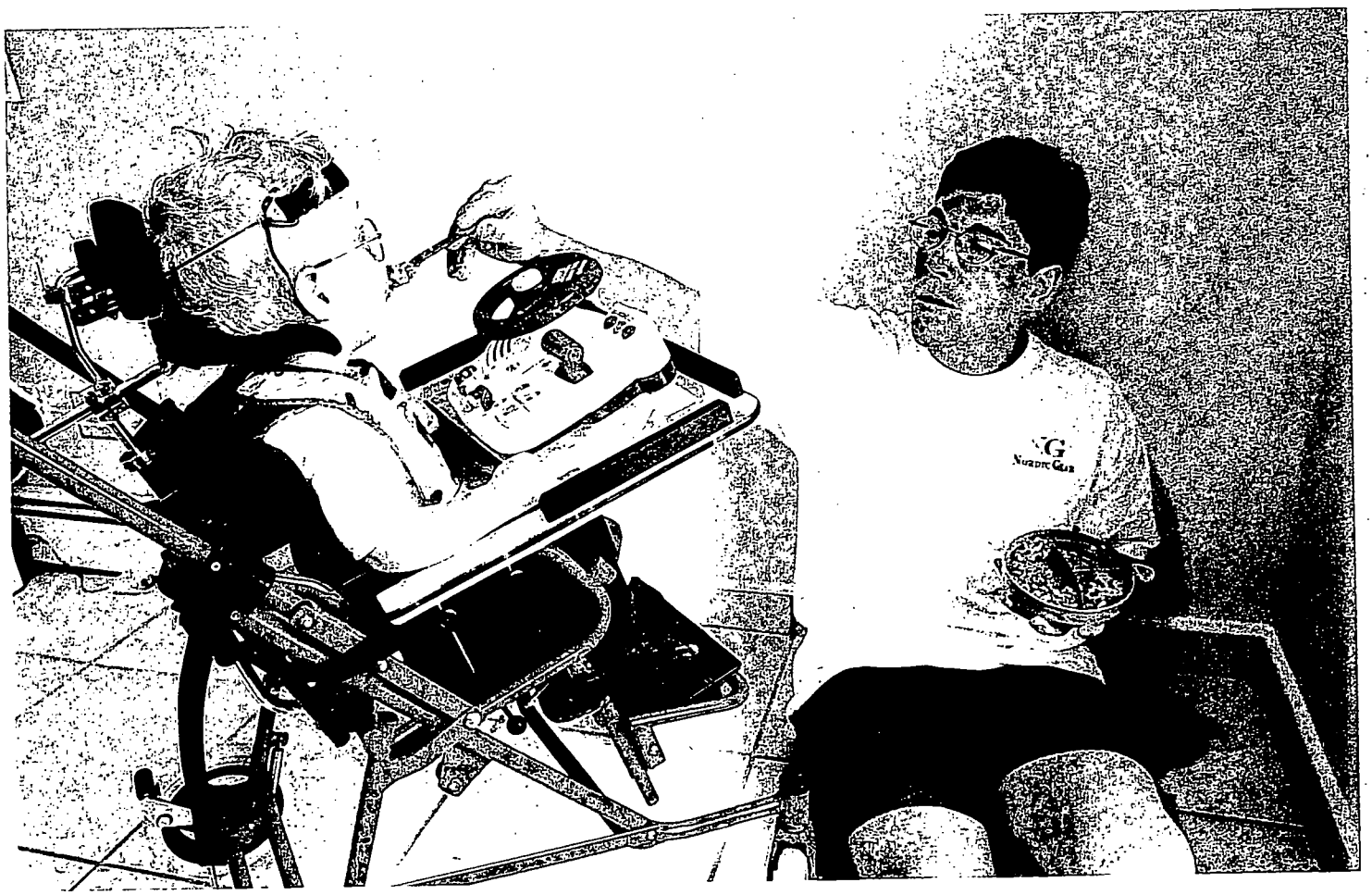
Jordana and Richard Sontag were speeding toward Yale University, angry, desperate, ready to unleash their secret weapon, which they had carefully loaded into the back of their Grand Cherokee. For a year, they had done everything in their power to save their dying baby boy, Jacob. The well-to-do young couple and relatives had donated more than $200,000 to Yale to underwrite experimental gene-therapy research aimed at curing the rare genetic disease that plagued Jacob. They had helped pay to bring two leading researchers from the other side of the world to Yale and to transport from a lab in Germany the precious concoction of healthy genes that might save their son and a dozen other dying children with Canavan disease. They had hired lawyers and enlisted United States Senators to lobby the medical oversight committees for approval of the experimental procedure.

And then they waited. Week after week, Yale officials assured them that the medical school's review committees and the governmental agencies would soon take action. But spring had given way to summer, and summer to fall, and still nothing. Jacob's adorable blond head had grown too heavy for him to hold up, and he had little control of his limbs, which hung at his sides, making him floppy like a rag doll.

In hopes of speeding the review, Jordana had assembled two notebooks full of records documenting the complete medical history of 1½-year-old Jacob Ross Sontag, starting with the first sonogram. The names of all those committees and agencies that had to approve the experimental treatment made her head throb and at night turned her dreams dark and anxious: the Human Investigation Committee and Biological Safety Committee at Yale; the Recombinant DNA Advisory Committee at the National Institutes of Health; a staff review at the Food and Drug Administration. All had to say "yes" before the children could be treated. But as the

*Richard and Jordana with Jacob, after he was hospitalized with a 103-degree fever.*

Photographs by James Estrin



*Above: Richard and Jacob at mealtime. Right: Jordana in a moment of quiet anguish.*

Sontags knew, H.I.C. wouldn't act until B.S.C. did; B.S.C. preferred R.A.C. to give an expedited approval first; and R.A.C. was waiting until H.I.C. ruled. And how did the Sontags explain that to friends who asked, "How's it going?"

"We plan to see anyone who will see us," said Richard on the drive to Yale. "We'll look into offices, the cafeteria — we'll find them!" That fall day in 1997, as they hurried through the lobby of Yale-New Haven Hospital wheeling the secret weapon, they couldn't believe their luck. There was Dr. Margretta Seashore! The enemy! To the Sontags, Dr. Seashore epitomized all the bureaucratic delays that were killing them. She is an internationally known genetics professor, appointed by Yale to shepherd the experimental procedure through the review process. At 59, Seashore is careful, thorough, academic — precisely the type of person who was driving the Sontags crazy. Seashore was a generation older than the bold team of junior Yale researchers who had actually developed the new gene therapy, tested it on 300 rats, 4 monkeys and 2 children in New Zealand and pronounced it ready to go for its first trial in the United States.

As far as the Sontags were concerned, Seashore represented the establishment, when they needed a firebrand to shake up Yale.

Seashore was waiting in the lobby to meet a group of medical students for a tutorial and was surprised to see the Sontags. She tried to make small talk, but they would not be distracted. "I'm sorry I can't sympathize," said Jordana. "We're living with a dying child the past 18 months."

Richard unfastened the secret weapon and began yelling. "You look at him!" he screamed, lifting Jacob out of the stroller and pushing him at Seashore. "You tell him why this protocol is delayed while he's dying!" The father was speaking so loud, people in the lobby were staring. Seashore noticed that her four medical students had arrived and appeared to be in shock.

"How could you prevent our child from treatment?" Richard yelled. By then, Richard was crying, Jordana was crying, Jacob was howling and Seashore looked ready to burst into tears.

"I do understand your desperation," Seashore said. "You have to understand, the biosafety committee is trying to be safe." She suggested that they consult the medical-school dean about the delays. "I'm under tremendous pressure the past months, overseeing this protocol."

"That's a luxury compared to being parents of a terminally ill child," said Jordana.

Seashore's hands were trembling. She warned she'd take herself off the protocol if this pressure continued: "If I do, this trial is dead."

"You look at my son dying," Richard screamed. "Tell it to him!"

Seashore would later call that Sept. 24, 1997, showdown a watershed. "I was shocked at their behavior in public," she said. "What that said was: We have desperate people here; they're going to blow the place up; we have to make a deci-

*Michael Winerip is a staff writer for the magazine.*

PHOTOGRAPHS BY JAMES ESTRIN/THE NEW YORK TIMES

sion." After the Sontags' visit, the assistant to the medical-school dean spoke to members of the Yale biosafety committee and told them that it was time to decide — yes or no— but soon. The next week, the committee approved the therapy, and in the following months the other committees did, too. The Sontags' desperate plan had worked. On Jan. 2, 1998, Jacob Sontag was scheduled for surgery at Yale, the first time doctors in this country planned to treat a genetic disease by shooting a syringe full of healthy genes directly into the brain.

The four medical students who witnessed that confrontation have told Seashore it's the best clinical lesson they've had at Yale, and indeed, many of the forces shaping medical practice and research converged that day in the lobby to detonate the nasty explosion. For the Sontags, the experimental therapy was the sole hope they had to reverse the degeneration of their only child, precious Jacob, suffering from a rare disease that eventually leads to paralysis, blindness, severe retardation and death, typically between ages 5 and 10. To the Sontags, gene therapy — introducing healthy genetic material into malfunctioning cells so that they can produce a missing enzyme Jacob's body needs — was brilliant, and they knew from news articles that the approach was being used in hundreds of trials on cancer, cystic fibrosis and heart disease.

In the Sontags' corner were two junior Yale researchers, Dr. Matthew During, 41, and Paola Leone, 34, a neurobiologist. Since 1995, when parents of another dying child had begged During and Leone to apply their skills to Canavan, the two had moved at a breakneck pace. The Sontags understood these researchers had their own reasons — there will be great rewards for the scientist who figures out how to deliver large amounts of healthy genetic material to the right cells. For During and Leone, Canavan could be the template for other genetic therapies, revolutionizing medicine; the dying children promised to be the perfect human subjects. As for the parents, they just thanked God that anyone would take on such a rare "orphan" disease.

On the other side were Seashore and three dozen colleagues on Yale's oversight committees, many of them fearful that in this era of deregulation safety standards are being lowered, allowing treatments like the fen-phen diet drugs to reach the public without adequate testing. "The heart of the question," Seashore said, "is when is it time for something in a scientific lab to be made available to people?" Seashore had seen the career of one of her colleagues, the geneticist Dr. Reuben Matalon, upended by moving too quickly from the test tube to humans. In the early 1990's, Matalon thought he had developed a pregnancy screening test for Canavan. And then, to his horror, four pregnant women who had tested negative gave birth to babies with the disease. "I wasn't going to let anything like that happen to me," Seashore said.

I first met Jordana and Richard Sontag in May 1997. Richard's sister, Deborah Sontag, is a friend and colleague (the Jerusalem bureau chief of The Times) and had told me of her younger brother's quest. She was skeptical, but also in awe of how determined her brother and sister-in-law were to find a cure and how open they were about Jacob. A few months before, in Feb-

*Richard comforting Jacob as Dr. Charles Duncan, center, and his assistant, Dr. Sung Lee, inject the new genes.*

ruary 1997, to celebrate Jacob's first birthday, Richard and Jordana had rented a restaurant banquet room, hired a Musical Munchkin and invited 50 friends and relatives to the party.

Until recently, there was no hope for a child with Canavan, which is most prevalent among Ashkenazi Jews like the Sontags — affecting 1 in 6,000 Jewish infants. Both parents must be carriers for the disease to manifest in the offspring. Children have a defective gene that can't produce a key enzyme needed to break down an acid in the brain known as NAA. Scientists hypothesize that a surplus of NAA develops, which in turn interferes with the formation of myelin, the white coating that covers nerve cells. Without myelin, the brain's nerve cells can't relay messages to the body, eroding motor control to the point of paralysis. Autopsies reveal spongy brains full of tiny holes.

At birth, the baby appears normal. But by 3 months, parents notice a lack of responsiveness. Misdiagnosis is common. Jacob was first thought to have developmental and vision problems. At 4 months, he was fitted for glasses. At 5 months, a specialist said it was Leigh's disease. By the time Canavan was identified, Jacob was 7 months old.

Most families had only bleak things to tell the Sontags. They met parents who medicated their children around the clock, who felt any physical therapy was a waste. A mother from Philadelphia said: "Don't get him glasses. It won't matter to him, and you don't want people staring." There were parents who confided that they quietly let the children die instead of rushing them to a hospital during a seizure. "The best thing you can do," they said, "is have another child who is healthy." To Jordana and Richard, this was Canavan's defeated old guard speaking.

The couple was not used to failure. In 1992, when Richard was 30, he bought out a two-man firm that produced battery-heated socks and in five years built it into Nordic Gear, a multimillion-dollar outdoor accessory company with three factories and 350 employees. At an age when many are still deciding what to be, Richard was flying to the Orient first class on business and arranging meetings with his bankers. For her part, Jordana was a creative public-relations executive, savvy enough to get one of Richard's items featured on an Oprah Winfrey pre-Christmas show highlighting great gift ideas.

In the spring of 1997, in the midst of their quest for treatment, they bought a seven-bedroom, seven-bathroom home with a pool on 1.75 acres in a wealthy Westchester County suburb. That enormous house made Jordana uneasy, but Richard saw it as a testament to his business success.

They were determined to treat their son as normally as possible. When I first met Jacob, at 15 months, if his head fell onto his chest, Richard would say: "Pull up your head Jacob. Come on Boo." And slowly, Jacob did. "Say hi," Richard coached, and light came into Jacob's eyes, a smile appeared, his mouth opened and a tiny "Hi" came out. Then Richard would kiss him all over, turn him upside down and make gassy noises against his neck while Jacob beamed.

"Other Canavan families are amazed by Jacob," said Jordana. "They've never seen a Canavan child so advanced." The Sontags made sure Jacob had extensive weekly therapy — physical, speech, occupational — all publicly financed as part of a Federal early-intervention program for disabled preschoolers. They constantly read to him. On a trip to Philadelphia, Jordana sat in the back seat and read and sang the entire two hours while Jacob was mum, staring through his blue-rimmed glasses: "Is Clifford in his doghouse? Is that where Clifford is? Little Man, how come you're so smart?"

They were delighted he was already 25 pounds, while a 7-year-old Canavan girl they'd met, Morgan Gelblum, weighed *Continued on page 61*



PHOTOGRAPHS BY JAMES ESTRIN/THE NEW YORK TIMES

The genes they had been waiting so long for, the genes that could change their son's life, had arrived in an ice bucket that looked borrowed from a Motel 6.

just 30. Instead of giving him a mushy diet — he had limited chewing control — they fed him Cheerios, waffles, chicken soup with matzoh balls. Canavan children tend to have trouble sleeping — imagine not being able to shift your body for 10 or 12 hours — and most parents sedate them. "They put them to sleep with one pill and wake them with uppers," said Richard. If Jacob cried, they checked on him, but let him cry himself to sleep.

Strangers saw Jacob's stylish glasses and his polo shirts and commented on how much he looked like the boy, Ray, in the film "Jerry Maguire." "People don't realize he's handicapped," said Jordana. But the Sontags were no fools. Jordana was constantly downloading articles, and one described how much of the brain's development is completed by age 2. "Every month he doesn't have the surgery, he's losing," she said. "At 6 months, he wasn't far behind other children. Now at 15 months, he should be walking, and the distance from where he should be and where he is gets larger. He'll have to do so much more to catch up after the surgery." While the Canavan literature lists retardation as a symptom, it is not clear at what age mental deterioration becomes irreversible. Jordana and Richard were convinced there was a bright little boy trapped in that body, and they based that on the light in his eyes and his beautiful smile. They were in a race against time to reach that trapped person before he disappeared forever.

THEY WERE NOT THE FIRST. THE KARLINS of New Fairfield, Conn., were. In 1994, Canavan was diagnosed in Lindsay Karlin. Her father, Roger, an internist, and mother, Helene, a psychologist, began a frantic hunt for scientists doing gene therapy and found During and Leone nearby at Yale. At the time, the researchers were using Parkinson's disease to investigate ways to deliver genes into brain cells of rats. They were testing a nonharmful virus that could be loaded with replacement genes and would then transport those genes through the membranes of brain cells.

The Karlins brought Lindsay to meet During and Leone. After several visits, the researchers agreed to focus on Canavan. The disease offered an objective measure of gene therapy's effectiveness. If, after gene injection, a brain scan showed the children's NAA decreased and their myelin increased, it would be evidence that the implanted genes had done the job. There were human reasons, too, in the Karlins' favor. Like the Sontags, they were educated people who understood the ethics of offering up their daughter and promised to be able fund-raisers.

At that time, During, a native New Zealander, was being wooed to return to Auckland. While scores of labs in the United States were doing gene therapy, in New Zealand he would be first. He saw a chance to do more, faster, with greater resources. Indeed, shortly after returning to New Zealand, the pioneer geneticist was fielding phone calls from reporters. On March 6, 1996, he oversaw his first human gene trial — on Lindsay Karlin and on a second American child, Alyssa Mushin.

Though results were mixed, the Karlins were excited. Within weeks, they say, their daughter seemed to see more and do a better job holding up her head. Brain scans seemed to indicate a decrease in her NAA and increase in her myelin (although not for the other child). The Karlins were now anxious to have their daughter treated again and agreed with During that they should inject twice as much genetic material.

*Dr. Margretta Seashore, the noted genetics professor at Yale.*

That fall of 1996, the Sontags were just beginning to confront Jacob's illness when they heard of the New Zealand experiment. In their usual take-charge style, Jordana and Richard were soon coordinating the next round of injections in New Zealand, on eight more children, including Jacob. To insure that every family could make the trip, the Sontags offered to underwrite any expenses the others could not afford. When New Zealand officials sent questionnaires asking parents if they understood the risks, Richard faxed sample answers to each family, urging them to slightly change the wording to the responses. The experiment was described as testing only the safety of gene injection: "The best we can hope for is that the procedure is safe; anything over and above that will be a bonus." In Richard's advisory to parents he warned, "Do not say that you expect the gene therapy to save your child's life," although that was what most hoped. Three times the Sontags had plane tickets for New Zealand, and three times they canceled as committees there raised objections. A backlash was setting in. Articles had appeared in Science and Lancet, and letters were sent to Washington regulators questioning whether During was using a distant country to circumvent United States oversight.

Night after night, Richard and Jordana phoned and E-mailed New Zealand. But the treatment was slipping away. By June, that country's officials were accusing During of pushing through the first trial without sufficient public debate, while he questioned their ethics. Sitting on this side of the world, Richard took the long view: "They don't give a damn about our kids. These aren't New Zealand kids dying."

The day they got the word, Richard and Jordana took Jacob to the playground. They wanted to be alone. Richard held Jacob in his lap as they went down slides. A woman watching asked, "Is he getting physical therapy?" She wasn't being intrusive; she simply wanted to be sure they knew it could help. "Some people try to ignore it," said the woman.

Later, Richard said, "She was nice."

"Yeah," said Jordana.

"That's the first time a stranger realized," said Richard. Jordana nodded.

THEY STARTED OVER AGAIN IN THIS COUNTRY. Richard flew to Washington with Roger Karlin to meet with lawyers about how to best pressure officials at Yale and the National Institutes of Health. The Institutes' next quarterly review was in mid-September; the Yale committees would have to act by late August for the protocol to be considered at that mid-September Federal review. "We don't know if we should get politicians involved or give Yale lots of money or go to the press," said Karlin.

"That could backfire," said Barbara Mishkin, an attorney at the firm Hogan & Hartson who specializes in human experimentation. "You could just get the committee upset."

Bob Brady, another attorney, said: "We have to lower the decibel level, focus on the science. Inadvertently, the protocol has become notorious, both here and in New Zealand."

Richard favored being aggressive: "What we tried to do is call Yale's president and thank him for letting us deposit $250,000 in the Canavan research account and say to him, 'Who do we contact about giving more?'"

Mishkin replied: "The research budget at Yale is multimillions. To influence them, you'll need much more than a couple hundred thousand."

"You want us to tone it down," said Richard. "We want to bring it up." After two hours, he and

Karlin rose to leave. Karlin pulled out a photo to show the lawyers. "My daughter, Lindsay," he said. Richard pulled Jacob from his wallet. "The consequences if this is postponed?" Brady asked.

"They may go blind, become vegetables, die," Karlin said.

JORDANA HAD STOPPED WORKING AND WAS watching Jacob like a hawk for signs of changes. Was she the only one who could feel time slipping away? "He'll get to the point of no return," she said. "The gene therapy might prolong his life, but won't help him."

Sunday morning, July 20, Richard got him out of bed. Jacob looked pale and unhappy. "A cranky baby here," Richard announced and brought him downstairs. Jordana rubbed his arms, but couldn't get a smile. His lips were chalky white. He began making jerky motions; she tried to bend his legs, couldn't, then noticed his eyes rolling. "He's seizuring!" she screamed.

Doctors hospitalized Jacob for several days, but couldn't find a cause for his 103-degree fever. Not even Jordana could coax a smile from him. A dizzying parade of specialists visited. At one point, when Jordana asked a doctor a question, Richard started to answer, but she cut him off.

"You always do that," she said to Richard. "You jump in and answer my questions. I have important questions I don't get to ask."

"Write them down," Richard said.

"I don't have to write them down!" said Jordana. "I just don't want my son being dead because some doctor doesn't know how to treat a child with Canavan." Doctors said there should be no damage from the seizure, but the Sontags worried. Who was Jacob? A little boy with light in his eyes and a delicious smile, who liked best to be rocked in his mother's arms. There was no sign of that Jacob. Was he still in there?

For weeks they weren't sure. He was crankier, often seemed in pain. For the first time, he was having trouble sleeping, and they argued over how to handle it. When his crying persisted one night, Jordana picked him up. "Why'd you bring him out here?" said Richard. "Of course he's sweating when he's crying; he's crying himself to sleep. What's wrong? He's fine. Put him back."

He was having trouble lifting his head, too. On Aug. 15, Jordana said: "Something's definitely not the same. I can't pinpoint it yet. Richard thinks one of his eyes is starting to turn; the muscle has weakened. None of the therapists noticed anything, but it seems he used to see me sooner when I came into a room. If he was on the couch and I walked from the kitchen to the front door, he'd see me, want me and cry."

*Romping with Jacob — aka Boo, Bubbles, Mr. Head or Little Man — at home.*

Jordana knew the optical nerve can degenerate without myelin and on Aug. 20 took Jacob for a checkup. The ophthalmologist found significant deterioration and strengthened Jacob's glasses. This scared her. "I can't imagine what it would be like if he couldn't see my face or Richard's," she said. "If something started to go wrong with his eyes — it's unacceptable to me."

Jordana got United States Senators involved. One Canavan child was from South Dakota, and an aide to that state's senior Senator, Tom Daschle, was particularly aggressive about pressing Yale. Still, many at Yale did not feel the same urgency. At a Sept. 2 biosafety meeting, members said there were still too many questions and postponed a decision. The earliest Federal action would now be the December quarterly meeting. Jacob would be nearly 2.

"Jordana's going to explode," said Richard. "She's holding everything in. She's talking about chaining herself to the White House fence."

Little things were destroying her: a 2-year-old niece asking when Jacob would stop being a baby. Even his pockets depressed her. "A little boy his age starts enjoying his pockets," she said, "putting different things in there, and he doesn't even know they are there." Richard would come home from work and there was nothing in the refrigerator. She had stopped grocery shopping. "It made me crazy," said Richard. "I'd say, 'Jordana what's going on — no food in the house?' She'd say to Jacob, 'Your Daddy thinks I'm crazy.'"

She had tried to explain how difficult it was taking Jacob shopping, but Richard always had an answer: "Put him in the baby seat. What's the problem?" She didn't tell Richard, but she couldn't do that to Jacob, a 1½-year-old sitting flopped in an infant seat. "It's not that I care what people think," she said. "It's making Jacob a spectacle when I'm shopping."



PHOTOGRAPH BY JAMES ESTRIN/THE NEW YORK TIMES

Jacob would wake at 4 A.M., they'd struggle to get him to sleep and then were up until morning, arguing. They began seeing a marriage counselor. Jordana complained Richard bullied her; Richard complained Jordana was running from life.

In mid-September, she asked for a divorce. Richard wanted to know if there was someone else. Jordana said there was not a soul — that was the problem. She was finding she couldn't talk to anyone about Jacob. "Every day there's some stupid new development, we're so immersed," she said. "It's so lonely. Even when Richard and I talk, we have totally different views." They disagreed about things as basic as the gene therapy. Richard was hardheaded: he expected the small improvements Lindsay Karlin's parents had reported, but felt a cure was years away. "I'm not in la-la land on this," he said.

Jordana thought Jacob would thrive, because he'd been an advanced Canavan child and would get twice the dose of genes that the first two girls received in New Zealand. "At some point, not right after, I see him lifting his head," she said. "Maybe he'll say the words he knows now, loud and clear.

"What I envision is this little boy coming out of his shell — 'I'm here! Hi! Here I am!' I want him to be set free in a way. I hope he'll walk. He has the desire to walk. I put him down, he tightens his leg. You know, I'll be grateful if he can just sit up, play on his own, grab things.

"If he could just roll over. I put him to bed at night on his belly. In the morning, I come in, he's in the same position. I think about how nice it would be for him, if he could roll over and stretch — so there are my hopes."

Knowing those hopes, it was easier to understand why each new delay seemed the cruelest. On Sept. 18, Yale's biosafety committee again met without deciding. On Sept. 19, the Sontags were invited to attend a memorial service at the Jewish Guild for the Blind in Manhattan for 7-year-old, 30-pound Morgan Gelblum, who died over the summer. On Sept. 24, Jordana told Richard that whether or not he came, she and Jacob were going to Yale to confront Seashore and anyone else she could find. Richard would later say, "I was on the fence about going," but he went, as much to save his marriage as his son.

SEASHORE DIDN'T TELL THE SONTAGS, but she, too, thought Yale's biosafety committee was stalling, afraid to make the leap. However, she also saw a need for caution. "If you just tell people we're putting foreign DNA into the brains of small children, jaws drop," she said.

There were other reasons members did not feel an urgency: many doubted it would work. While gene therapy had captured the imagination of the public and media (most hometown newspapers had done a hopeful feature on their local Canavan child), the scientific community was skeptical. An article in Nature that fall of '97 reviewed all gene protocols to date, including treatments for cancers, heart disease and immunodeficiencies and put it bluntly: "Although more than 200 clinical trials are currently under way worldwide with hundreds of patients enrolled, there is still no single outcome that we can point to as a success."

It wasn't a question of whether they could deliver genes to the cells. They could. It was how many and how long they'd work. Matthew During estimated that the new genes would reach 10 million of the 100 billion brain cells, or 1 in 10,000. Delivery was primitive: They shot the genetic fluid into a liquid cavity of the brain known as the ventricle and hoped it would be absorbed by adjoining brain cells. This was like pouring it into a river and seeing how much was absorbed by the surrounding land; you'd find a lot in the riverbed, some along the banks, but not much inland. The low "hit" rate was the major misgiving voiced by committee members. Even if inserting the genes proved benign, the surgery had a risk. Implanting the plastic reservoir in the brain to pump genes into the ventricle carried a 5 percent risk of serious infection, possibly death. Put another way: for the 16 children waiting, there was a 1-in-20 chance of a life-threatening crisis.

Complicating matters was During's status. He was a hero to parents, but because the protocol had bounced from Yale to New Zealand and back and was publicly criticized, some at Yale regarded him as a cowboy. Committee members questioned how successful the procedure really was in New Zealand. While both girls had a temporary decrease in NAA, the more important indicator, myelin growth, was less clear-cut. To ensure uniformity, the committees decided that all M.R.I.'s would be done in one place, Children's Hospital of Philadelphia.

With During still in New Zealand, Yale had taken the unusual step of asking Seashore to shepherd the protocol, though she was not involved in the research. "Acrimonious things were said about Matt During that weren't fair," she said. "But I would not let that happen to me. If I had to be the bad guy to parents, I'd be the bad guy."

Seashore remembered too well what had happened to her longtime friend and colleague, Dr. Reuben Matalon. At Miami Children's Hospital in the 1980's, Matalon made the key breakthroughs in Canavan research, including identifying the mutation responsible for the disease. Canavan parents considered him a godsend. In 1990, he thought he had another score, a Canavan screening for pregnant women. What happened next has never been reported in the media, but it stunned geneticists who pieced the facts together. In a 1992 issue of the Journal of Inherited Metabolic Diseases, Matalon published a paper detailing how his test on pregnant women had correctly predicted whether a baby would be born with Canavan 13 of 13 times. His conclusion: "It is possible to determine Canavan disease prenatally." But then, in a last-minute postscript, came the shocker: "Note Added in Proof: Subsequent to the submission of this manuscript, we determined that one *Continued on page 78*

CANAVAN

*Continued from page 63*

of the pregnancies predicted to be normal resulted in an affected baby."

That affected baby was Molly Green, born June 18, 1991, in Arlington, Va. Molly's parents, David, a lawyer, and Wendy, a psychologist, had already buried one Canavan child, Eli, in 1990. After hearing of Matalon's new test, Wendy got pregnant again. "He told us it was experimental," said David, "but there was nothing like an informed consent procedure or peer review. We were desperate to have a child. Our attitude was, sounds good enough to me." The pregnant Wendy sent a fluid sample to Matalon. "We were informed the results were sparkling," said David. "We were having a healthy baby."

Molly seemed perfect at birth and was even chosen as the poster baby for the National Tay-Sachs and Allied Diseases Association, which was undertaking its annual fund-raiser. Three months later, after Molly had gone floppy and her parents knew the truth, one of the first calls the father made was to the foundation. "Rip up all those postcards of Molly," he said. "She has it." She died March 1, 1992. Three more women with sparkling screenings gave birth to Canavan babies, and two of those sued and later settled. "Reuben made a mistake," Seashore said, "but he was pressed very hard by the families to bring something into clinical service before it was ready."

In the end, the Canavan protocol was approved at Yale for very human reasons. The children were as disabled as any on the planet, and they probably would not be harmed and might benefit, or at least provide insight for researchers. I asked Dr. Charles Duncan, one of the nation's pre-eminent pediatric neurosurgeons and the man slated to operate on Jacob, "Would you do it if it were your child?" "Oh yes," he said. "I wouldn't be doing the surgery if I didn't think so."

There was more good news. The National Institutes of Health had recently made a policy change: under streamlined guidelines, Yale's approval meant the Federal committee did not have to give its go-ahead.

Seashore, however, insisted that the protocol go for that Federal review anyway. "I don't want to be the first protocol that doesn't," she said. Leone, who had worked so closely with the parents, fought her. "They saw me as an obstacle," Seashore conceded. "I saw them as loud. It was only a couple more weeks."

THAT NOVEMBER, THE Sontags hired divorce lawyers and put the house up for sale. The previous spring it had felt to Richard like a symbol of his power, but now, as winter neared, he seemed to have lost control of things that mattered, and the big house embarrassed him. Many rooms were still unfurnished.

Just before Thanksgiving, Jacob had a brain scan scheduled in Philadelphia to establish a baseline for myelin before gene therapy. Richard and Jordana took separate cars — agreeing to meet there. On the George Washington Bridge, Richard spotted Jordana and Jacob and waved. He knew she'd be nervous about driving alone, and sure enough, she pulled behind him. As they caravaned south on the New Jersey Turnpike, he picked up his car phone and dialed her in the Cherokee. They talked for 20 minutes, their first conversation in weeks.

Trying to get the IV in for the anesthetic was always the worst moment of an M.R.I. Jacob's arms were flaccid and nurses had trouble pricking a vein. He cried as Richard and Jordana held him. Soon they were sobbing, too, their tears falling together on their son. The nurse tried to comfort them, saying that the IV really didn't hurt Jacob much, but that was not why the Sontags were crying.

That night, they left Jacob with their sitter and took a hotel room.

BY DEC. 18, THE FEDERAL agencies had given their approval. Jacob's therapists prepared evaluations, to measure changes that might come later. Vivian Kahn Adler, the speech therapist, noted deterioration in recent months. When she started, "he used at least five different sounds — 'hi,' 'more,' 'ma.' At that age it was very encouraging; he was a baby. Now he's not

using many." She didn't know why Jacob had lost speech. It could be physical — his breath support had weakened. Or maybe, she said, cognitive. She was trying to get him to communicate by gazing at the food he wanted on his tray. During her Dec. 18 lesson, he sneezed and his head fell on his chest; he couldn't lift it. His eyes were crossed now, too. "A lot of kids you feel are stuck at the 3- to 6-month level," Adler said. "With Jacob, I feel there's a bright little kid in there. Sometimes he can wave. It'll take a while. If you don't have patience, you'll miss that wave."

The researchers decided the Sontags or Karlins would go first. They'd worked the hardest and raised the most money. At a diner, they flipped a coin. Jacob won. Jordana felt like a pioneer. She was hearing from families from around the world. "I feel great," she said, "like we've spared them the pain of all the fighting we've been through. I saw a video this family in Canada sent of their baby — his name's Jacob, too. He's 5 months, lifting his head, looking around. Can you imagine what this could do for him?"

SURGERY WAS TO BE done in two phases. On Friday, Jan. 2, at 8 A.M., Duncan used an air drill to cut a 9-millimeter hole in Jacob's skull. A tube was lowered into the ventricle; then a plastic, egg-shaped reservoir was attached to the tube and imbedded below the scalp, making a bump over Jacob's forehead. The reservoir would remain to facilitate future injections. This took less than an hour. Then Jacob was to be observed that weekend for signs of infection, and on Monday the genes would be implanted.

It was not to be. Sunday night he had a 103-degree fever, and Richard slammed the nearest table. "Twelve hours away!" he said. Duncan came to the hospital past midnight to get a sample of Jacob's brain fluid to test for infection. While Richard held his son, a young doctor assisting Duncan put the syringe into the reservoir to withdraw a specimen. Jacob's brain fluid came rushing out, splashing on the floor. Richard's eyes widened; brain surgery wasn't like he'd envisioned. Duncan felt Jacob just had the flu, but didn't want to take chances. He said he'd have to consult Seashore before deciding when to proceed.

"If Dr. Seashore makes the call," Richard moaned, "we'll be waiting another year." At 10 the next morning, Leone wheeled in a cart with a black plastic container. Richard could not stop staring. The genes they had been waiting so long for, the genes that could change their son's life, had arrived, in an ice bucket that looked borrowed from a Motel 6.

For days, Jacob was too sick with flu for the injection. On Jan. 9 at 6 A.M., Jordana was watching him sleep when she noticed his pinkie finger tremble, then his arms, then the whole body. His eyes opened wide and she thought he was dying. The nurses could not stop the seizure and moved him to intensive care. Would there be anything left of him to save?

Not until Jan. 22 was he strong enough. The actual procedure was so simple that it was done in an examination room. Jacob was laid on his stomach, screaming, Richard and Jordana holding him down. Duncan took a syringe and inserted it into a pin in Jacob's scalp that looked like the needle used to blow up a football. With his left hand he injected the syringe's fluid and with his right thumb he pumped the implanted reservoir 16 times. After 14 months, it was over in three minutes. The new genes were floating down the river Jacob.

"RICHARD AND I HAVE this joke," Jordana said. "Jacob will sit up and say, 'I don't know about this gene therapy.'" Jordana's mother urged, "Keep your camera out for when he lifts his head." They upped physical therapy to five days a week to capitalize on any improvement and thought they saw a million little things. "I was feeding him," said Jordana. "He put his hand on the spoon three or four times. He's done that before, but it was like right on my hand." When Richard held him, Jacob seemed to lift his head off Richard's chest more to look around. "Every day is exciting," said Jordana. "Lots of hope."

What was not encouraging was Jacob's sleeping patterns. He was constantly waking at night now and often would not go back to bed. "We're exhausted," said Jordana in mid-February. "We haven't had a good night's sleep in a month and a half." Their pediatrician prescribed a sedative for Jacob, but Jordana resisted. "We didn't want to do that," she said. "I hate giving in to this disease." For his part, Richard had surrendered. His attitude was, "Get the chloral hydrate!" The researchers told the Sontags his wakefulness might be positive, a sign gene therapy was working. They reasoned the new genes had so stimulated his brain, a sensory rush was keeping him awake.

Or it could be that Jacob was experiencing the classic sleep problems of an aging Canavan child.

Exhausted, Jordana no longer cared. The researchers didn't have to get up with him at 4 A.M. On Feb. 20, she was in tears. "Jacob did not sleep at all," she said. "I'm sorry we did the procedure. The only thing we got out of all this — he can't sleep! It's so cruel."

Plus, they were pushing

him for any physical gain while the new genes were fresh. With Jacob screaming, his physical therapist put on his stiff leg supports and led him a few steps. Richard placed him on the floor, legs crossed in a yoga position, his head flopped on his chest, and pleaded, "Lift it — come on Boo," but the head did not budge.

On Feb. 24, Jacob turned 2. They celebrated quietly, the three of them. At one point, Richard left the room so Jordana would not see him cry.

That week, Jordana gave in. She explained her decision to medicate Jacob this way: "I think we're better off as a family if the baby sleeps." They began giving him Klonopin, a muscle relaxant. It was the turning point. The muscle relaxant relaxed the parents, too.

Jacob's stiffness decreased; he stopped grinding his teeth. "Jacob is doing phenomenal," Richard said in mid-April. "He is in a fabulous mood." Why? "He's stoned," said Richard. "It's hard to know how much is Klonopin or the gene therapy or physical therapy five times a week. There are so many variables."

Jordana's fantasy, that he'd sit up, hadn't happened. "Not yet," she said. "In the past, I'd be devastated. But I feel I don't have to worry now. We got him the gene therapy; we've done all we can. I guess if I had to choose between motor skills and the cognitive, I'd choose this. He'll hang out in bed with us. We just lay him flat and play with him. Everything is funny to him now. Richard brought him in the other morning. I said, 'Little Man.' He starts smiling. 'Hi, Little Man.' He says, 'Hi.' I heard him!"

Jordana did not wait for During's lab to call with the latest results; she phoned Philadelphia herself and wormed it out of the M.R.I. people. "They gave me an unofficial report that Jacob has myelin!" she said on June 5. "They still have to do a comparison with the last M.R.I., but I have a feeling it's in the area that controls cognition."

Four days later, she left a message: "Wanted to let you know we received the report, and it says there have not been significant changes. He does have myelin, but it's the myelin he had prior to gene therapy."

JORDANA RETURNED to work part time. They sold the big house and moved to an attractive ranch house that was half the price. It was a nice fit, on one floor, easy for Jacob. All the rooms had furniture.

She was busy raising money for the Canavan Research Fund the families had founded. She spoke with rabbis and doctors about publicizing the new prenatal screening test for Canavan that was developed in the mid-1990's after Matalon's failure.

On June 19, the Sontags met with a lawyer about a "wrongful birth" lawsuit they had filed against the doctors Jordana used when she was pregnant with Jacob. In the lawsuit, Jordana claims she had repeatedly requested all relevant prenatal screening tests and had been given several but not the new one for Canavan. During the meeting, Jordana held Jacob and explained how they had struggled to enrich his life. So it wasn't until the end that the lawyer, Bruce Clark asked the awkward question, "You would have had an abortion had you known?"

"Absolutely," said Jordana. "Even with this little man in my arms, I would."

"It's not fair," said Richard. "Trapped in that body."

THE PREVIOUS YEAR, RICHard had dismissed the National Tay-Sachs and Allied Diseases conference as too touchy-feely, but this year they went and were the last to leave a seminar on how people with a disabled child can hold a marriage together. The therapist had couples take a personality test, and it turned out Richard was a "fixer" while Jordana was a classic "turtle." And when the turtle complained, the fixer felt he had to make everything all right, scaring the turtle instead of just giving that little turtle a hug. "I know this sounds totally ridiculous," Jordana would say later, "but it made perfect sense at the time."

The next day, the three Sontags were at a deli getting Jacob his matzoh-ball soup when Jordana realized she'd forgotten an appointment to visit a school for Jacob. "I know why," she told Richard. They had run into three families just back from a Little League game, all these messy, jumpy, little noodgie boys, and here the Sontags were heading to some depressing handicapped school. "I don't know why you're feeling that way," Richard started, but Jordana cut him off. "We're not even away from this marriage seminar for 24 hours," she said, "and you're trying to fix everything, Mr. Fixer," which made Richard laugh. The turtle was out of her shell, snapping.

ON SEPT. 9, JACOB WENT to Yale for his second injection. He was home in two days. Thomas Jefferson University Hospital, in Philadelphia, where During and Leone now work, was also doing the procedure.

THAT MONTH, NINE THERapists and social workers gathered to discuss the new program Jacob was starting at the Saint Agnes rehabilitation center, where the typical disabled child receives $33,000 a year in government-financed services. Jacob's home

*Continued on page 112*

CANAVAN

*Continued from page 82*

therapists were there to advise the school therapists who would be taking over.

Richard and Jordana took turns rocking their 2½-year-old and giving him a bottle. "He has been making tremendous strides," Richard said. Adler, the speech therapist, explained how much of her time was spent working on chewing and swallowing. She didn't say it, but most Canavan children wind up on feeding tubes. "He'll drink from a cup, but there's still spillage on the sides," she said. She warned that he sometimes choked on solids, "a bit of a safety issue." As if on cue, Jacob began gagging on a waffle Jordana was feeding him, coughing and turning red. The room went dead. "Breathe," said Jordana. There was a moan and Jacob's normal color returned.

"He never used to cough so well," said Nancy Wolff, his physical therapist. "This is good."

Someone asked if he could flip a switch, and his occupational therapist said no. When the center's medical director, Dr. Maria Pici, asked what gains he had made, the physical therapist said he could roll on his side if she helped. "If I give him minimal facilitation depending on his mood and I tell him, 'Jacob bring your arm over, bring your leg over,' and of course I'm aligning him, he can roll," Wolff said.

They asked what Jacob liked. "Human contact," said Wolff. "And silliness. He loves silliness."

"Gassy noises, he loves them," Richard said.

"He's there," his physical therapist said. "Definitely," his occupational therapist said.

Jacob's Oct. 21 report from Children's Hospital in Philadelphia showed no new myelin. While researchers kept the other children's results confidential, parents talked, and Jordana learned that none of the children's M.R.I.'s showed myelin. Or, as Jordana put it, "at least not yet." Still, she saw potential in another new development. Jacob's ophthalmologist had found evidence of new myelin in his eyes. It wasn't likely to help Jacob see better, but the doctor found it "fascinating."

Some families grew discouraged. One dropped out, and even Helene Karlin had mixed feelings. "I don't even want to talk to the other parents," she said. "I don't want them to hear any discouraging note. They need to fight." There was another setback. The 5 percent risk from implanting the reservoir — it happened. In September, one child developed a serious complication and the reservoir was removed. Doctors sought to determine if there was brain damage.

SOME STORIES DO NOT END AS YOU expect. A year and a half ago, I could see the two central themes clearly. First, the curse of science: how a new medicine like gene therapy could seem to offer so much hope and yet cause so much pain, because it is still only promise. And second, the blessing of science: how the pursuit of new medicine could lead to a prenatal screening that would allow the Sontags to have a healthy baby the next time. I envisioned the story closing joyously, with Jordana giving birth to a new child.

What I witnessed instead was the hardships of the pioneer family. At the Sontags' meeting with the lawyer last summer, he asked if they would try to have another child. "We've only started to discuss that," Richard said softly.

Last month, Richard called as I was finishing the article. He was concerned I hadn't seen Jacob in weeks. "He's a whole new child," said Richard. "They love him at school," said Jordana.

On Nov. 5, I spent the day with Jacob. That morning at Saint Agnes, a well-staffed, bright, state-of-the-art rehab center, Jacob fell asleep while two speech therapists were having him practice eating a Ritz Bits cracker. In class, it took more than an hour to feed him a puréed lunch. His teachers and aides talked about how much he loved the computer, but when placed in front of it, he fell asleep again.

Then at home that night, Jacob was another child. His face lit up when Richard returned from work and kissed him hello. For two hours, the Sontags roughhoused. They called him Boo and Bubbles, Mr. Head and Little Man, and the noisier and louder and sillier they all grew, the more Mr. Stinky Butt beamed and his eyes shone. It was wonderful to see, and for once I stopped trying to guess how much was going on inside. This was medicine more remarkable than new genes, Klonopin or physical therapy five times a week — a parent's love. ■

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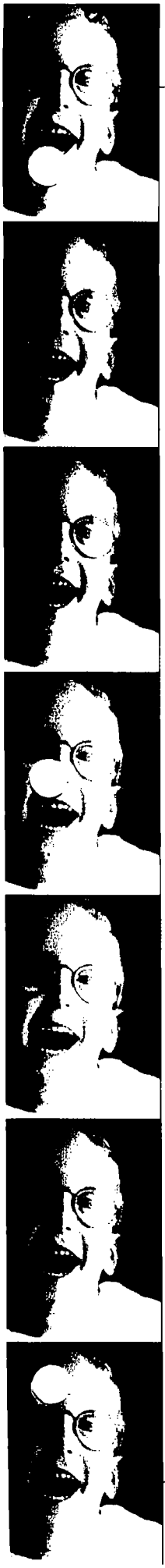

[003]

# JACOB'S CURE

## A Fight Against Canavan Disease

*- A copy of a letter from Ms. Ilyce Randell, mother of Max Randell who suffers from Canavan disease. This letter documents the plea of a parent for help in ushering an approval for a treatment for her son.*

My name is Ilyce Randell. I live at [(b)(6)] Palatine, IL 60067. I have a 3 year old son, Max, who is dying of a rare and fatal brain disease.

Because Canavan disease (CD) is progressive, he is running out of time, and declining physically every day. Due to a lengthy and, in this case, too stringent review process by the FDA; medical treatment that Max has an ethical right to seek is being kept from him by a regulatory agency that is effectively protecting him to death.

I would like to explore the possibility of suing the FDA. To force them to allow my son, and fourteen other dying children to have access to a treatment that may slow down the progression of this devastating disease. These children are literally running out of time, and they deserve to get medical help even if it is only "experimental."

I realize that the FDA has been under a tremendous amount of pressure from Congress and the public to be extra cautious in approving gene therapy trials due to the unfortunate death of Jesse Gelsinger, he was enrolled in an unrelated clinical trial using gene therapy. Our children are now paying the price of this negative backlash. But, this has been going on for a year now, and I want my son to at least have a chance at a better quality of life.

Max received an injection of healthy genes by the same research team we are currently working with in a previous gene therapy Phase 1 Safety Trial in September of 1998, at Yale University. He did remarkably well. If that IND was being held to today's higher standards, and the negative view towards gene therapy, Max never would have been treated, or had the benefit of demonstrating such amazing improvements.

I only want the best for my child, and a chance at a better life, this is his only chance in the world. It is not as if there are other treatments that I am unwilling to try...this is our ONLY hope. It helped before and I want to try it again. I know the minimal risks and am willing to give full consent. I am not an uninformed parent.

Dr. Paola Leone at Thomas Jefferson Medical College has developed a better, safer, less toxic, and more effective means of delivering the corrected genes to our children's brains, and I want my son to have that treatment. All our tests show it is actually safer that the old method.

It is my understanding that the FDA, as a regulatory agency, still must answer to the law. My son has a right to seek medical treatment. He is

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suffering from a 100% fatal and PROGRESSIVE disease, and this is his only option for treatment. Is there anything I can do, legally, to force the FDA to release the "clinical hold" they have placed on our IND? We can't wait any longer.

Several Senators and Congressman are already working on this matter, but they are getting nowhere. The Principle Investigator for the protocol, Dr. Leone, has explained to me that she has done all she can do on our behalf. The FDA is "acting conveniently too conservative" How can they use stall tactics when my child is trapped in a body that is deteriorating more and more everyday? Once he is placed on a feeding tube and becomes completely paralyzed... it will then be too late for treatment!

If you think we have a case, I will of course be able to furnish you with any and all information regarding the specifics of our situation, and the IND (proposed protocol). I am sure Dr. Leone would be willing to speak with you as well.

This case is precedent setting because we can prove that when Government is too big their protection can potentially kill people waiting for medical treatment. People, who otherwise have no hope, and no other option. Regulatory agencies do not have absolute authority, especially when they are under pressure to look good, and are overworked. In this scenario people like Max are slipping through the cracks. This is when the law needs to step forward and force the FDA's lengthy review process to be reassessed.

I run a public charity dedicated to funding medical research to cure Canavan disease, I can sue either on behalf of the foundation, or as a parent (there are also 14 other families involved in this struggle).

For more information about Canavan disease please visit our website at http://www.canavanresearch.org/ Thank you for your time and consideration of this important matter.

Cordially,

Ilyce Randell
Canavan Research Illinois
President
And Mother of a dying child
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Topic One :
Promoting integration of CAM practices with traditional medical professionals.
With the objective of educating and promoting CAM to allopathic professionals there should be readily available concise, scientific and factual based literature written in a context that would appeal to the medical professional. Some of the facts that should be included would be, statistics on the popular demand of a complementary practice by the public at large. We also need more co-represented conferences where CAM practitioners and traditional medical practitioners can share information side by side combing the best of both worlds and encouraging and promoting the acceptance of CAM by medical professionals in a friendly setting, these conferences should be composed of well known practitioners of both traditions.

Topic Two:
The American Holistic Nurses Association was established in 1987 in an effort to organize and support nurses who believe in treating the body, mind and the spirit incorporating the various CAM practices with the guidance and provisions to assist in providing and promoting the maintenance of professionalism that would uphold using these approaches and provide guidelines for practice with integrity. We more funding and individual, financial support provided to aid and promote education and college courses about CAM within the institutions of higher learning. And we need more funding that would make it easier for nursing CAM practitioners to promote and participate in CAM practice models for research without the criteria of being attached to an established institution; in other words, funding for private practitioners to do research that can develop a comprehensive plan.

Topic Three:
There is one brief statement I would like to have noted by the commission regarding practitioner guidelines. And that is simply, that it does not take a bachelors or doctorate to practice CAM but should involve some basic knowledge of anatomy and physiology and simple understanding of the disease process of the body.

There is so very much to consider in these processes, my proposal to you in closing is that along with considering all things we need to do to bring CAM up to the acceptance level we desire, we also must consider that it should be done in a timely and expeditious manner.
Thank you all for your time and attention.

Elaine Stern, L.Ac.
150 Fifth Avenue #706
New York, NY 10011
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January 23, 2001

I am a licensed acupuncturist, national board certified in acupuncture and Chinese herbal medicine. My education includes formal training and apprenticeship both here and in China. I have been in private practice for 17 years and have taught Chinese medicine throughout my career. My practice is primarily internal medicine, with a focus on women's health.

Chinese medicine is very effective in the treatment of women's health problems. Some of the more common gynecologic conditions seen in my practice include: amenorrhea, dysmenorrhea, irregular menstruation, premenstrual syndrome, menopausal complaints, menorrhagia, infertility and polycystic ovary syndrome[1].

I do not have statistics for "success rates" in treatment, however, many women experience significant improvement, or complete alleviation of the presenting problem. The measurement of success ranges from subjective reduction or disappearance of symptoms, to objective changes in sonography and/or hormone levels.

Chinese medicine is by no means a panacea for women's health, but we do have a valuable contribution to make. Many women are able to avoid, reduce or eliminate medications with uncomfortable or dangerous side effects. Many babies are conceived without the need for strong hormonal medications, to say nothing of the expense.

In my practice, some patients are treated completely with complementary medicine, whereas some are treated in conjunction with biomedical interventions such as medication or surgery. In most cases the best situation **for the patient** would be a cooperative effort between the biomedical and complementary branches of their treatment. It is not uncommon for me to direct a patient to her gynecologist either to rule out a concern or because the Chinese medicine alone is not sufficient. It would be a tremendous boon to my practice, and to the practice of complementary medicine in general, were this cooperation more prevalent and easier to effect.

My recommendations to this commission focus in two areas.

The first is to foster cooperation between practitioners of biomedical and complementary medicine. This point must be addressed in several ways.

1) Complementary practitioners cannot afford to "vilify" mainstream medicine; nor can mainstream physicians continue to ridicule and dismiss complementary practitioners.
2) Both biomedical and complementary practitioners should be aware of each others'capabilities. Biomedical practitioners should understand when complementary treatment is useful and complementary practitioners should learn how to interact with and refer patients for biomedical treatment.

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[1] See " Polycystic Ovary Syndrome: three cases treated with acupuncture, herbs and nutrition" *Clinical Acupuncture and Oriental Medicine* pp19-29, Vol.1, No.1,1999

I recommend we develop a series of seminars. These would be classes designed by practitioners for practitioners. The curriculum should be assembled as a joint effort and the seminars presented in a way that it is possible for busy, overworked professionals in both fields to attend. These seminars, in addition to providing much-needed education for practitioners, would act as a meetingplace and a forum for further discussion and cooperation. Perhaps this type of seminar would yield good research concepts as well.

My second recommendation concerns reasearch in complementary medicine. Both interest and funds for this purpose are increasing, but there is so much to be done and so much controversy about how best to go about conducting this research.

I recommend that we create a board of complementary practitioners that advises biomedical researchers and reviews research projects. This would help to bridge the gap between complementary practitioners and biomedical researchers.

I hope to be able to participate further in this discussion, in the future. Thank you for your consideration.

My name is Renate Siekmann and I am the mother of 4 children. All of my children have benefited tremendously from alternative forms of medicine, especially homeopathic treatment. One of my son's came down with a double ear infection and double conjunctivitis when he was just a toddler. He was given a powerful antibiotic by our pediatrician. The result was such bad diarrhea that he began bleeding from his anus. For a year and a half after that he had daily stomach cramps, diarrhea and regular vomiting. My pediatrician had no solution. I finally found a homeopath who was able to cure him and return him to the old self he had been before his ordeal began. Another one of my sons came down with a bad case of eczema as an infant. My pediatrician suggested using Hydrocortisone cream, an option unacceptable to me. I would not use that type of medicine on myself and I will certainly not put in on my 3 months old son. Again, homeopathy came to the rescue and within 10 days of treatment all eczema disappeared. I would be happy to give you many more examples where Homeopathy in particular has been a wonderful and effective form of treatment for my family and myself.

I feel that allopathic medicine is doing a wonderful job in trauma care and we would certainly never want to be without everything it has to offer. However, there are many illnesses where treatment is either ineffective or can even be harmful. There are wonderful, gentle alternative therapies, which have survived the test of time. Homeopathy, for example, has been used successfully in Germany for over 200 years, longer than most forms of allopathic treatment In Germany as well as many other countries in the world natural alternative forms of treatment are available to the patient by specialized practitioners as a complement to allopathic medicine. It is up to the patient to decide which type of treatment he or she prefers. Freedom of choice is what it is all about. I feel that it is important that the patients are given the choice. Let the different forms of medicine work hand in hand and allow the consumer to choose freely without breaking the law. Let the trained practitioners practice freely without breaking the law. This type of system works beautifully in many other countries and it can work in this country as well. Let's all work together towards one common goal – a healthier population.

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# Chinese Herbal Medicine - Education, Research and Science

**Presented by:** **Phyllis Tan**
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**Presented to:** **The White House Commission on Complementary and Alternative Medicine Commission**

**Date:** **January 23, 2001**

Allopathic medicine has made great stride in its development. These strides have mainly developed during wartime have been in the eradication of diseases and surgery. Hence its strength lies in critical care and emergency care. With less than 100 years of history, allopathic medicines research and development in chronic disease and prevention is still in its infancy.

Chinese herbal medicine has 5,000 years of history. It's strengths lie in chronic disease and prevention. Unlike many other forms of medicine, the development of Chinese medicine did not stop when Allopathic medicine was introduced to Asia. Indeed in China, Chinese and Allopathic medicine is an integrated/parallel system of medicine that complements each other. The advantage we have with Chinese herbal medicine it is a "working model" that we can touch, feel and see. Thus, for Integrative medicine, Chinese herbal medicine is not a leap into the unknown. It is a leap into a field of medicine that we have yet to learn of.

Having said that, it is easy to fear what we do no know. I believe there are three important steps to overcoming fear and move towards integration:

1. Science
1. Research
2. Education

## Science:

Recently the FDA requested companies to recall herbal products as a result of the FDA action regarding the isolated chemical Aristolochic Acid and 63 herbs, which the FDA says, may cause cancer or kidney failure. The Belgium case on which to FDA is largely basing the recalls was published on June 8, 2000 in The New England Journal of Medicine (NEJM). The abstract did not mention the diet clinic's combination use of:

- Amphetamines
- Fenfluramine and Diethylproprion (FEN-PHEN)
- Tranquilizer, meprobamate
- Actetazolamide
- Artichoke extract and euphyllin injections

- Cascara sagrada
- Belladonna
- Magnolila cortex
- fangchi (mistakenly replaced the herb Stephania tetrandra.)

While the abstract concludes that a Chinese herb of the aristolochia species is responsible for high rates of kidney failure and cancer, the article notes that there is still much debate over the matter. Furthermore, four physicians wrote letters of complaint to the NEMJ. They were concerned that the article laid unfair blame on the Chinese herb, when the real culprit could have been any of the previous mentioned drugs and the clinics diet program.

I have worked with pharmacologist on the Aristolochic Acid issue and am concerned with the inconclusive science behind the FDA actions. If we are to progress in integration model, good science has to be used by all parties to develop a better healthcare system.

**Research**

For good science we need good research. Funding for research in Integrative medicine is extremely important. To Progress funding is needed for clinical investigation and clinical trials. Moreover, we should evaluate the empirical evidence of safety and efficacy. Although the studies done in the past have not bee rigorous double-blinded placebo studies, these studies do show evidence of efficacy that we can build on for Integration.

**Education.**

People fear what they do not know. To educate is to overcome fear and learn about the unknown.

Almost every paper I have read in medical journal discuss the problem that patients do not disclose with the primary care physician about their visits to Complementary and Alternative Medicine (CAM) practitioners. If we education our physicians I believe we can overcome this problem.

Rather than feeding on the fear of the unknown, we need to build confidence in education. Funding education program in medical, nursing and pharmacy schools is important. So to is government support in funding continuing education programs for healthcare professionals that have completed their educational training.

**Conclusion.**

Science, Research and Education. I believe these are three key factors to the development of CAM.

In conclusion, I would like to share a story with you. A veteran internist from a teach hospital told me. "Every year she would see hundreds of patients come in with virus infections. She would treat the patients with antibiotics, a few days later the patients would return with upper GI discomforts. She would the prescribe Prilosec, then the patients would return with another infection, and the cycle would begin again. After a while you forget what you are treating. One day she had an epiphany and thought there must a better form of treatment. Is she treating a disease or is she giving health care." If we are to progress, let us not try to reinvent the wheel. The working model of Allopathic and Chinese medicine system in Asia is a model that we can touch, see, and feel. Thus, for Integrative medicine, Chinese herbal medicine is not a leap into the unknown. It is a leap into a field of medicine that we have yet to learn of.

**Recommendations to the White House Commission on Complementary and Alternative Medicine Policy**
**January 23, 2001**

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I appreciate the opportunity to present my recommendations to you. I am a family doctor, working at Montefiore Medical Center and a faculty member in the Department of Family Medicine and Community Health at Albert Einstein College of Medicine. For the last 15 years as a clinician, I have been integrating a number of different complementary medical approaches into the primary care of the medically underserved in the Bronx and lower Westchester. As a teacher, I have been presenting these modalities and their underlying philosophy to residents and medical students. Presently, I chair a group on CAM for the medical school's Department of Education where we have begun to integrate CAM education into all 4 years of the curriculum.

My experience has shown me that complementary and alternative medical education is critical to the education of health care professionals but we must acknowledge that education in CAM presents a significant challenge to our present medical and educational systems. Many schools now offer electives in CAM, but we need this training to be required and integrated into all areas of the curriculum. Often students hear an introduction to CAM, but they may hear this introductory talk many times without ever going deeper. We do need to teach some specific techniques to the students. Which area of CAM you choose to teach, whether it be mind/body approaches, the use of some Western herbs, or beginning bodywork techniques, is less crucial than approaching the techniques in a hands-on way, emphasizing self-care as crucial to health and healing. Use the best teachers you have available and let them teach from their expertise.

What is important is that we don't just substitute one of these techniques for a Western medical one. We don't just use an herb in place of a drug. We need to integrate conventional and unconventional medicine, but we also need to change the whole approach to patient care. We need to teach the deeper philosophical base of CAM. We need to teach about health and healing, about working with another person to help the body heal itself in order to reach harmony of mind, body, and spirit. When we bring CAM to medical education, we need to bring a change in the paradigm of conventional medicine. We have to move away from a focus of curing diseases to one of healing individuals within the context of their community and family networks. We should encourage research and evidence-based CAM practices, but we also need to endorse the connection between patient and provider that many people seek when they turn to CAM

practitioners. We need to emphasize, along with CAM techniques, the compassionate and loving embrace of each individual by the health care professional. This provides the basis for healing to occur.

In conclusion we must acknowledge that we need to change the paradigm of conventional Western medicine and CAM education needs to be a required, not elective, part of health care professionals' curriculum.

Ellen Tattelman, M.D.

Recommendations

A. CAM education requires a paradigm shift in medical education
   Emphasize listening, connection, and love between provider and patient
   Diseases may be cured, but people require healing–Janet Quinn, nurse educator (1)
   Work with a patient to allow their body to reach a healthier balance

B. CAM education must be a **required** part of health care professionals' education

C. CAM must be integrated into all aspects of medical education, pre-clinical and clinical
   For example, in the first year anatomy course, add a massage therapist, a chiropractor, or an osteopath to show how the knowledge of anatomy is used in these disciplines. Then you could use the stressful nature of anatomy lab to teach the students about stress reduction from the very start, using let's say, yoga, self-hypnosis, or meditation

D. Self-care is crucial to the health and healing of one's self and then others
   Teach in a hands-on way
   Pay attention to the stresses of medical education

1. Quinn JF. On healing, wholeness, and the Haelan Effect. Nursing and Health Care 1989;10:553-6.

# The Role of Ayurveda in 21st Century US Healthcare

*Presented to* ***WHCCAMP*** *by*

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Mr. Chairman and commission members, my name is Swami Sada Shiva Tirtha. I am the president of the AHC & School of Ayurveda offering consultations, pancha karma spa therapies and certification & Ph.D. programs. I hold a Doctor of Science in Ayurvedic Medicine.

It is spirit that we are talking about here, not herbs or yoga or drugs. Spirit is the core therapy. Ayurveda unlike any science offers a spiritual dimension. Love, care & compassion are the essence of Ayurvedic healing– more than mundane therapies.

Healthcare must fit into a spiritual paradigm. We cannot mold traditional medicine into the allopathic system without destroying its spiritual effectiveness.

Therefore it is crucial that an Ayurvedic expert be represented on your commission or at the very least on a secondary panel. If you are to be effective and taken seriously, the commission must include representatives of the original healing sciences or run the risk of overlooking the essence of healthcare.

Along with love, care & compassion, Ayurveda contains a complete & profound science.

It diagnoses the root cause of illness with unique pulse taking methods and treats in an individualized manner with herbology, nutrition, aromatherapy, yoga, massage, etc. More than 2,000 research studies have proven Ayurveda effective, safe and inexpensive.

In my center we have consistent success with
OB-GYN: PMS, menopause, bone-loss, cysts & natural hormone balance
Seniors: age-reversal, memory loss, brittle bone, arthritis
Special: Parkinson's, MS, Fybromyalgia

Ayurveda is cost-effective: Medicare & Medicaid patients won't have to choose between paying for food or medicine.

My pilot research study on seasonal allergies found a savings of 2 billion dollars for a 6-month allergy season compared to allopathic treatment-costs. Apply this comparison to digestive diseases, & we would save hundreds of billions of dollars a year.

There should be as much press coverage for alternative medicine as there is on allopathic drugs – pass an 'Equal Air Time Bill'. In a time when western medicine has no answers for many diseases, causes deadly side effects and exorbitant pricing, it is a crime that people can't hear about these alternative medicine successes. Create proactive holistic-health laws. Don't just fight unfair label and freedom of information law attempts. Create bills that punish the truly criminal injustices of current healthcare.

Set up a website database for practitioners to submit their case studies and research findings to inform practitioners & citizens. Use these databases to report to the press.

I encourage a national & state "practitioner regulatory committee" based on the Minnesota model. In NY we are not allowed to practice Ayurvedic massage without undergoing a lengthy, costly process to obtain a license in Swedish massage. Yet a licensed masseur can practice Ayurvedic massage with only superficial training.

Increase alternative medicine funding and set up an office to help practitioners write research grants and choose the best statistical analysis methods (e.g., regression, t-test).

## Other Suggestions & Thoughts

Whole herbs are safer than allopathic medicine. JAMA reported that 4th leading cause of death in the US is due to prescription drugs. This is 2½ times more deaths than is caused by AIDS.

Hold educational symposiums several times a year for holistic and allopathic professionals to meet to bridge the semantic gap.

There should be an equal partnership between traditional and allopathic decision-makers. Rigorous research methods and spiritual integrity must both be maintained.

The essence of alternative medicine, to use a computer industry label, is an open platform, that is you cannot patent herbs or healing and thus deters pharmaceutical companies from investing in or supporting alternative medicine. There needs to be a paradigm shift away from the old views of how to make money on the sick, and find new ways to make money from the healthy. The use of spas, prevention, rejuvenation etc. will bring people for the pleasure of it and the cost-savings of prevention will still be better than compared to treating disease, side effects and complications.

There should be more research on cost-effectiveness comparisons between traditional and modern medicine therapies for each disease. These can include prevention costs vs disease-treatment costs.

**Research Study:**
**Cost Comparison between Ayurvedic & Allopathic Methods in Treating Seasonal Allergies**
**By Swami Sada Shiva Tirtha, D.Sc.**

**Abstract**

Background: Seasonal allergy symptoms affect almost 10% of all Americans. The treatment of these pervasive symptoms often require decongestants and antihistamines to control allergic rhinitis with or without ocular involvement. Treatment is costly and adverse drug reactions are common with these medications, some of which may be quite serious.

Method: In a preliminary study on the cost-effectiveness of Ayurvedic treatment of seasonal allergies, 5 subjects received a combination of herbs and nutritional therapies according to their constitutional profiles and their specific symptoms.

Results: In all cases significant or complete allergy relief occurred within two days to two weeks, and eventually reporting complete relief. Long-term follow-up evaluations in two subjects for four and five years showed that as long as the subjects followed their Ayurvedic nutritional regimens, no seasonal allergy symptoms recurred. The allergy symptoms did return, however, only when the subjects discontinued their therapies. Cost comparisons showed that over a six month allergy season, Ayurveda-treated subjects spent between $0 and $147, while the average cost for physician visits and OTC or prescription drugs cost approximately $535 for the same 6 month allergy season provided no adverse drug reactions occurred. The costs rose significantly when drug side effects occurred, ranging from $735 to $1,070. [Costs based on estimates from two allergists]. 10% of Americans (27+ million people) with seasonal allergies translates into more than $2 bill extra costs in allopathic care.

Conclusions: The Ayurvedic treatment of seasonal allergies based upon one's constitutional profile and specific symptoms is safe, effective, and considerably less costly than traditional western therapies. Future studies including larger groups of subjects are needed to further evaluate this cost-effective holistic approach to allergy treatment.

# Research Study Cost-Effective Comparison Data

| | **Allopathy** | **Ayurveda** |
|---|---|---|
| Cost of Initial Visit | $125 | $50-100 |
| Cost of Follow-up | $50-85 | $25-50 |
| Follow-up Time | 2-3 weeks | 2-3 weeks |
| Number of Visits | 2 visits minimum | 1-2 visits minimum |
| Cost of Therapy | $60-80/month | nominal - $12/month |
| Lost Days of Work/School | 1-2 days | 0 days |
| Side effects | Possible | None |
| Cost of Side Effects | Dr. Visit: $125<br>Cortisone injection: $25-45<br>Follow-up Visit 3-5 days later: $50-150<br>Prednisone (if required): $35-40<br>Emergency (if rushed to hospital with serious reaction): $300-500 (x-rays, lab tests, injection)<br>Next day Primary care Dr. visit: $85-150 | n/a |
| **Cost: 6-month sample** (April-Sept) Allergy patient with no side effects | **$535** | **$0 - $147** |
| Cost for a 6-month sample (April-Sept) Allergy patient with **side effects** | **$735-$770**<br>with hospital **1,035-$1,070** | **n/a** |

## Sampling of Ayurvedic Scientific Research



amalaki-acute pancreatitis-10
amalaki/haritaki/bibhitaki-cholesterol-induced atherosclerosis-10a
amalaki/bibhitaki/haritaki/amlavedasa (yellow dock)-HIV-24/antimicrobial-24a
arjuna-antianginal,cardioprotective-13 & 13a/angina pectoris 13C/cardiac tonic and current uses include treatment for angina, hypertension, arrhythmias, and congestive heart failure. 21
arjuna/guggul-ischemic heart disease (inadequate blood flow to heart leading to angina pectoris/heart attack)-13d
cancer-13b/arjuna, nirgundi-anti-bacterial-9
ashwagandha and shilajit cognition enhancing, memory, Alzheimer's-2a/antioxidant-2b
bakuchi-nutritional source of genistein and daidzein isoflavones-18/asthma-18a
bhuamalaki-HIV 30 & 30a
bilwa-antifungal-16
black pepper-anti-bacterial/penicillin-15/antioxidant-15a
black pepper, cumin-colon cancer-36
brihati-antitumor-38
chirayata-antimicrobial-1/hypoglycemia-1a/12b
cinnamon/cumin-anti-bacterial-11
coriander-cholesterol/triglicerides-11a
cumin/basil-anti-carcinogenic-12
cumin and turmeric-antiatherosclerosis, anti-inflammatory, antithrombotic-40
fenugreek-diabetes-32
ginger-nausea, vomiting, headache, arteriosclerosis-41, 41b/rheumatism-41a
ginger, pippali, coriander, musta, cumin, cinnamon, asafoetida, triphala-indigestion-41c
gotu kola - psoriasis - 22/ antioxidant/memory enhancing, epilepsy, insomnia, sedative-22a
gotu kola, shank pushpi, ashwagandha, licorice, vacha, sarpagandha-schizophrenia-22b
guduchi-immunity-26/ liver disease 26a/jaundice 26b/diabetes type II -29/ joint swelling in adjuvant arthritis-37
guduchi, turmeric, bilwa, karella-urinary tract infections-26c

guggul-cholesterol/atherosclerosis-19, 19a/superior to nitroglycerin-reducing chest pain and dyspnea of angina-21
gurmar-suppression of sweet tastes-12a, 12b/diabetes-27
gurmar, neem, shilajit-diabetes-27a
haritaki, bhringaraj, tulsi-antibacterial-23
ishabgol-irritable bowel syndrome-17
kapikachu-Parkinson's-8/ diabetes-33
kushta-anti-tumor-7/hepatitis B-7a/kutki- hepatitis B-31
licorice- antimicrobial-42/atherosclerosis-42a/anti-viral-encephalitis-42b
manjishtha-anti-tumor-6-6a/ antioxidant-6b/ antiviral-6c
neem-malaria, anti-parasitical-4
nirgundi-anti-inflammatory-5a
punarnava, guduchi, haritaki, ginger, barberry-immunity/T-cells-25/liver-25a
punarnava, bhringaraj, chirayata, arogyavardhini, mandur bhasma-liver/bile-25b
saffron-antitumor-35
shatavari-gastric emptying time-3
shilajit-peptic ulcers and anti-inflammatory-2, 28
trikatu -absorption/bioavailability-14
turmeric-gallstones, cholesterol-20/ibuprofen substitute, anti-inflammatory-20a/ anti-carcinogenic-20 B/anti-inlfammatory, antispasmodic, liver/bile-39
turmeric and cumin-cancer lesions-20c/antitumor-20d

*Citations on next page*

## Citations

1-Omoregbe RE, Ikuebe OM, Ihimire IG. Antimicrobial activity of some medicinal plants extracts on Escherichia coli, Salmonella paratyphi and Shigella dysenteriae. Afr J Med Med Sci 1996 Dec;25(4):373-5

1a-Karunanayake EH, Welihinda J, Sirimanne SR, Sinnadorai G. Oral hypoglycaemic activity of some medicinal plants of Sri Lanka. J Ethnopharmacol 1984 Jul;11(2):223-31

2-Goel RK, Banerjee RS, Acharya SB. Antiulcerogenic and antiinflammatory studies with shilajit. J Ethnopharmacol 1990 Apr;29(1):95-103

2a-Schliebs R, Liebmann A, Bhattacharya SK, Kumar A, Ghosal S, Bigl V. (Indian Ginseng) and Shilajit differentially affects cholinergic but not glutamatergic and GABAergic markers in rat brain. Systemic administration of defined extracts from Withania somnifera. Neurochem Int 1997 Feb;30(2):181-90

2b-Bhattacharya SK, Satyan KS, Ghosal S. Antioxidant activity of glycowithanolides from Withania somnifera. Indian J Exp Biol 1997 Mar;35(3):236-9

3-Dalvi SS, Nadkarni PM, Gupta KC. Effect of Asparagus racemosus (Shatavari) on gastric emptying time in normal healthy volunteers. J Postgrad Med 1990 Apr;36(2):91-4

4-Dhar R, Zhang K, Talwar GP, Garg S, Kumar N. Inhibition of the growth and development of asexual and sexual stages of drug-sensitive and resistant strains of the human malaria parasite Plasmodium falciparum by Neem (Azadirachta indica) fractions. J Ethnopharmacol 1998 May;61(1):31-9

5-Chawla AS, Sharma AK, Handa SS, Dhar KL. Chemical investigation and anti-inflammatory activity of Vitex negundo seeds. J Nat Prod 1992 Feb;55(2):163-7

6-Takeya K, Yamamiya T, Morita H, Itokawa H. Two antitumour bicyclic hexapeptides from Rubia cordifolia. Phytochemistry 1993 Jun;33(3):613-5

6a-Adwankar MK, Chitnis MP. In vivo anti-cancer activity of RC-18: a plant isolate from Rubia cordifolia, Linn. against a spectrum of experimental tumour models. Chemotherapy 1982;28(4):291-3

6b-Tripathi YB, Sharma M, Manickam M. Rubiadin, a new antioxidant from Rubia cordifolia. Indian J Biochem Biophys 1997 Jun;34(3):302-6

6c-Ho LK, Don MJ, Chen HC, Yeh SF, Chen JM. Inhibition of hepatitis B surface antigen secretion on human hepatoma cells. Components from Rubia cordifolia. J Nat Prod 1996 Mar;59(3):330-3

7-Cho JY, Park J, Yoo ES, Baik KU, Jung JH, Lee J, Park MH. Inhibitory effect of sesquiterpene lactones from Saussurea lappa on tumor necrosis

factor-alpha production in murine macrophage-like cells. Planta Med 1998 Oct;64(7):594-7
7a-Chen HC, Chou CK, Lee SD, Wang JC, Yeh SF. Active compounds from Saussurea lappa Clarks that suppress hepatitis B virus surface antigen gene expression in human hepatoma cells.
Antiviral Res 1995 May;27(1-2):99-109
8-An alternative medicine treatment for Parkinson's disease: results of a multicenter clinical trial. HP-200 in Parkinson's Disease Study Group. J Altern Complement Med 1995 Fall;1(3):249-55
9-Perumal Samy R, Ignacimuthu S, Sen A. Screening of 34 Indian medicinal plants for antibacterial properties. J Ethnopharmacol 1998 Sep;62(2):173-82
10-Thorat SP, Rege NN, Naik AS, Thatte UM, Joshi A, Panicker KN, Bapat RD, Dahanukar SA
Emblica officinalis: a novel therapy for acute pancreatitis--an experimental study. HPB Surg 1995;9(1):25-30
10a-Thakur CP, Thakur B, Singh S, Sinha PK, Sinha SK. The Ayurvedic medicines Haritaki, Amala and Bahira reduce cholesterol-induced atherosclerosis in rabbits. Int J Cardiol 1988 Nov;21(2):167-75
11-Agnihotri S, Vaidya AD. A novel approach to study antibacterial properties of volatile components of selected Indian medicinal herbs. Indian J Exp Biol 1996 Jul;34(7):712-5
12-Aruna K, Sivaramakrishnan VM. Anticarcinogenic effects of some Indian plant products. Food Chem Toxicol 1992 Nov;30(11):953-6
12a-Ota M, Shimizu Y, Tonosaki K, Ariyoshi Y. Synthesis, characterization, and sweetness- suppressing activities of gurmarin analogues missing one disulfide bond. Biopolymers 1998 Aug;46(2):65-73
12b-Arai K, Ishima R, Morikawa S, Miyasaka A, Imoto T, Yoshimura S, Aimoto S, Akasaka K.
Three-dimensional structure of gurmarin, a sweet taste-suppressing polypeptide. J Biomol NMR 1995 Apr;5(3):297-305
13-Dwivedi S, Agarwal MP. Antianginal and cardioprotective effects of Terminalia arjuna, an indigenous drug, in coronary artery disease. J Assoc Physicians India 1994 Apr;42(4):287-9
13a-Bharani A, Ganguly A, Bhargava KD. Salutary effect of Terminalia Arjuna in patients with severe refractory heart failure. Int J Cardiol 1995 May;49(3):191-9
13b-Pettit GR, Hoard MS, Doubek DL, Schmidt JM, Pettit RK, Tackett LP, Chapuis JC. Antineoplastic agents 338. The cancer cell growth inhibitory. Constituents of Terminalia arjuna (Combretaceae). J Ethnopharmacol 1996 Aug;53(2):57-63

13c-Dwivedi S, Jauhari R. Beneficial effects of Terminalia arjuna in coronary artery disease.
Indian Heart J 1997 Sep-Oct;49(5):507-10
13d-Seth SD, Maulik M, Katiyar CK, Maulik SK. Role of Lipistat in protection against isoproterenol induced myocardial necrosis in rats: a biochemical and histopathological study. Indian J Physiol Pharmacol 1998 Jan;42(1):101-6
14-Atal CK, Zutshi U, Rao PG. Scientific evidence on the role of Ayurvedic herbals on bioavailability of drugs. J Ethnopharmacol 1981 Sep;4(2):229-32
15-Perez C, Anesini C. Antibacterial activity of alimentary plants against Staphylococcus aureus growth. Am J Chin Med 1994;22(2):169-74
15a-Nakatani N, Inatani R, Ohta H, Nishioka A. Chemical constituents of peppers (Piper spp.) and application to food preservation: naturally occurring antioxidative compounds. Environ Health Perspect 1986 Aug;67:135-42
16-Rana BK, Singh UP, Taneja V. Antifungal activity and kinetics of inhibition by essential oil isolated from leaves of Aegle marmelos. J Ethnopharmacol 1997 Jun;57(1):29-34
17-Nayak AK, Karnad DR, Abraham P, Mistry FP. Metronidazole relieves symptoms in irritable bowel syndrome: the confusion with so-called 'chronic amebiasis'. Indian J Gastroenterol 1997 Oct;16(4):137-9
18-Kaufman PB, Duke JA, Brielmann H, Boik J, Hoyt JE. A comparative survey of leguminous plants as sources of the isoflavones, genistein and daidzein: implications for human nutrition and health. J Altern Complement Med 1997 Spring;3(1):7-12
18a-Fu JX. [Measurement of MEFV in 66 cases of asthma in the convalescent stage and after treatment with Chinese herbs]. Chung Hsi I Chieh Ho Tsa Chih 1989 Nov;9(11):658-9, 644
19-Verma SK, et al. Effect of Commiphora mukul (gum guggulu) in patients of hyperlipidemia with special reference to HDL-cholesterol. Indian J Med Res. 1988 Apr;87:356-60.
19a-Singh RB, Niaz MA, Ghosh S. Hypolipidemic and antioxidant effects of Commiphora mukul as an adjunct to dietary therapy in patien ts with hypercholesterolemia. Cardiovasc Drugs Ther 1994 Aug;8(4):659-64
20-Hussain MS, Chandrasekhara N. Effect on curcumin on cholesterol gall-stone induction in mice. Indian J Med Res 96:288-291; 1992.
20a-Srivastava R, Srimal RC. Modification of certain inflammation-induced biochemical changes by curcumin. Indian J Med Res 81:215-223; 1985.
20b-Nagabhushan M, Bhide SV. Curcumin as an inhibitor of cancer. J Am Coll Nutr 11:192-198; 1992.

20c-Kuttan R, Sudheeran PC, Josph CD. Turmeric and curcumin as topical agents in cancer therapy. Tumori (ITALY) 73:29-31; 1987.
20d-Retardation of experimental tumorigenesis and reduction in DNA adducts by turmeric and
curcumin. Krishnaswamy K, Goud VK, Sesikeran B, et al. Nutr Cancer 1998;30:163-166.
21-Miller AL. Botanical influences on cardiovascular disease. Altern Med Rev 1998 Dec;3(6):422-431
22-Natarajan S, Paily PP. Effect of topical Hydrocotyle Asiatica in psoriasis. Indian J Dermatol 1973 Jul;18(4):82-5
22a-Tripathi YB, Chaurasia S, Tripathi E, Upadhyay A, Dubey GP. Bacopa monniera Linn. as an antioxidant: mechanism of action. Indian J Exp Biol 1996 Jun;34(6):523-6
22b-Parikh MD, Pradhan, PV, Shah LP, Bagadia Vn. Evaluation of Indigenous Psychototropic Drugs- A Preliminary Study. Journ. Res. Ay. Sid. Vol 5; no. 1-4 1984.
23-Phadke SA, Kulkarni SD. Screening of in vitro antibacterial activity of Terminalia chebula, Eclipta alba and Ocimum sanctum. Indian J Med Sci 1989 May;43(5):113-7
24-el-Mekkawy S, Meselhy MR, Kusumoto IT, Kadota S, Hattori M, Namba T. Inhibitory effects of Egyptian folk medicines on human immunodeficiency virus (HIV) reverse transcriptase. Chem Pharm Bull (Tokyo) 1995 Apr;43(4):641-8
24a-Ahmad I, Mehmood Z, Mohammad F. Screening of some Indian medicinal plants for their antimicrobial properties. J Ethnopharmacol 1998 Sep;62(2):183-93
25-Sohni YR, Bhatt RM.
Activity of a crude extract formulation in experimental hepatic amoebiasis and in immunomodulation studies. J Ethnopharmacol 1996 Nov;54(2-3):119-24
25a-Rawat AK, Mehrotra S, Tripathi SC, Shome U. Hepatoprotective activity of Boerhaavia diffusa L. roots--a popular Indian ethnomedicine. J Ethnopharmacol 1997 Mar;56(1):61-6
25b-Deshpande PJ, Singh R, Bhatt NS, Clinical Efefct of an Ayurvedic Drug L2002 on Hepatobiliary Disorders. Journal of NIMA, Dec 1994
26-Thatte UM, Rao SG, Dahanukar SA. Tinospora cordifolia induces colony stimulating activity in serum. J Postgrad Med 1994 Oct-Dec;40(4):202-3
26a-Nagarkatti DS, Rege NN, Desai NK, Dahanukar SA. Modulation of Kupffer cell activity by Tinospora cordifolia in liver damage. J Postgrad Med 1994 Apr-Jun;40(2):65-7

26b-Rege N, Bapat RD, Koti R, Desai NK, Dahanukar S. Immunotherapy with Tinospora cordifolia: a new lead in the management of obstructive jaundice. Indian J Gastroenterol 1993 Jan;12(1):5-8

26c-Deshpande PD, Singh R, Bhatt NS, Clinical Trial of Ayturvedic Drug U-144 (K-4 Tablets) in Urinary Tract Infections. The Medicine & Surgery. Vol 32; no. 10/11. Oct - Nov 1944

27-Baskaran K, Kizar Ahamath B, Radha Shanmugasundaram K, Shanmugasundaram ER. Antidiabetic effect of a leaf extract from Gymnema sylvestre in non-insulin- dependent diabetes mellitus patients. J Ethnopharmacol 1990 Oct;30(3):295-300

27a-Pal KNC. Effects of a Herbomineral Compound on Diabetes. Ayurved Samachar: Issue 8; vol 10 2 Feb. 1988

28-Goel RK, Banerjee RS, Acharya SB. Antiulcerogenic and antiinflammatory studies with shilajit. J Ethnopharmacol 1990 Apr;29(1):95-103

29-Noor H, Ashcroft SJ. Pharmacological characterisation of the anti-hyperglycaemic properties of Tinospora crispa extract. J Ethnopharmacol 1998 Aug;62(1):7-13

30-Qian-Cutrone J, Huang S, Trimble J, Li H, Lin PF, Alam M, Klohr SE, Kadow KF. Niruriside, a new HIV REV/RRE binding inhibitor from Phyllanthus niruri. J Nat Prod 1996 Feb;59(2):196-9

30a-Ogata T, Higuchi H, Mochida S, Matsumoto H, Kato A, Endo T, Kaji A, Kaji H. HIV-1 reverse transcriptase inhibitor from Phyllanthus niruri. AIDS Res Hum Retroviruses 1992 Nov;8(11):1937-44

31-Mehrotra R, Rawat S, Kulshreshtha DK, Patnaik GK, Dhawan BN In vitro studies on the effect of certain natural products against hepatitis B virus. Indian J Med Res 1990 Apr;92:133-8

32-Alarcon-Aguilara FJ, Roman-Ramos R, Perez-Gutierrez S, Aguilar-Contreras A, Contreras-Weber CC, Flores-Saenz JL. Study of the anti-hyperglycemic effect of plants used as antidiabetics. J Ethnopharmacol 1998 Jun;61(2):101-10

33- Akhtar MS, Qureshi AQ, Iqbal J. Antidiabetic evaluation of Mucuna pruriens, Linn seeds.
JPMA J Pak Med Assoc 1990 Jul;40(7):147-50

34-Chithra P, Sajithlal GB, Chandrakasan G. Influence of Aloe vera on collagen turnover in healing of dermal wounds in rats. Indian J Exp Biol 1998 Sep;36(9):896-901

34a- ez B, Avila G, Segura D, Escalante B. Antiinflammatory activity of extracts from Aloe vera gel. J Ethnopharmacol 1996 Dec;55(1):69-75

35-Nair SC, Pannikar B, Panikkar KR. Antitumour activity of saffron (Crocus sativus). Cancer Lett 1991 May 1;57(2):109-14
36-Nalini N, Sabitha K, Viswanathan P, Menon VP. Influence of spices on the bacterial (enzyme) activity in experimental colon cancer.
37-Duwiejua M, Zeitlin IJ, Waterman PG, Chapman J, Mhango GJ, Provan GJ. Anti-inflammatory activity of resins from some species of the plant family Burseraceae. Planta Med 1993 Feb;59(1):12-6
38-Chiang HC, Tseng TH, Wang CJ, Chen CF, Kan WS. Experimental antitumor agents from Solanum indicum L. Anticancer Res 1991 Sep-Oct;11(5):1911-7
39-Ammon HP, Wahl MA. Pharmacology of Curcuma longa. Planta Med 1991 Feb;57(1):1-7.
40-Srivastava KC. Extracts from two frequently consumed spices--cumin (Cuminum cyminum) and turmeric (Curcuma longa)--inhibit platelet aggregation and alter eicosanoid biosynthesis in human blood platelets. Prostaglandins Leukot Essent Fatty Acids 1989 Jul;37(1):57-64.
41-Bone ME, Wilkinson DJ, Young JR, McNeil J, Charlton S. Ginger Root-a New Antiemetic. The Effect of Ginger Root on Postoperative Nausea and Vomiting after Major Gynaecological Surgery. Anesthesia 45:8, 1980 Aug. 669-71
41a-Srivastava KC, Mustafa T. Ginger in Rheumatism and Musculoskeletal Disorders. Med Hypothesis 39:4, 1992 Dec. 342-8
41b-Grontvend A, Brask T, Kambskard J, Hentzer E. Ginger Root Against Seasickness. A Controlled Trial on the Open Sea. Acta Otolaryngology (Stockh) 105:1-2, 1988 Jan-Feb 45-9
41c-Thakur M, Bhatt NS, Mishra S, et. al.Effects of Ayurvedic Drug (AB + R) in Indigestion. Medicine & Surgery. May - August 1996/23
.42-Li W, Asada Y, yoshikawa T. Antimicrobial flavonids from Glycyrrhiza glabra hairy root cultures. Planta Med. 1998 Dec; 64 (8): 746-7
42a-Belinky PA, Aviram M, Fuhrman B, Rosenblat M, Vaya J. The antioxidative effects of the isoflavan glabridin on endogenous constituents of LDL during its oxidation. Atherosclerosis 1988. Mar; 137 (1): 49-61
42b-Badam L. In vitro antiviral activity of indigenous glycyrrhizin, licorice and glycyrrhizic acid (sigma) on Japanese encephalitis virus. J. Comun. Dis. 1997 June; 29(2): 91-9

# Swami Sada Shiva Tirtha, D.Sc.
## Curriculum Vitae

**1974 Initiated into Indian meditation**
**1975 BA Interdisciplinary Studies**
**1976 Certified meditation teacher**
**1980 MA Non-Verbal Communication Research**
**1988 Ayurveda Certificate - Ayurvedic Institute**
**Opened Ayurvedic Holistic Center**
**Advanced private study with Benares Hindu University professors in India**
**Met spiritual teacher (guru) in India**
**1989 Ayurveda Certification - American Institute of Vedic Studies**
**Founded Hindu non-profit monastery in US -**
**named Swami Narayan Tirtha Math to promote spirituality and Ayurveda**
**1990 Published spiritual book, Yoga Vani by Swami Shankar Purushottam Tirtha**
**Advanced private study with Ayurvedic doctors in Himalayas**
**Developed one of the first line of Ayurvedic herbal products in US**
**1991 Founded the International School of Ayurveda–**
**(One of the first Ayurveda schools in US)**
**Advanced private study with Ayurvedic doctors in Himalayas**
**Received initiation into monkhood (sannyas) as swami from Guru in India**
**1995 Published second spiritual book, Guru Bani by same author**
**1997 Created one of the first online Ayurveda websites – now a top-3 Ayurveda site.**
**1998 Wrote the Ayurveda Encyclopedia**
**Completed Ayurveda scientific research study on cost-comparisons**
**1999 Earned Doctor of Science (D.Sc.) in Ayurvedic Medicine (first in the US)**
**2000 Research study published in the American Ayurveda Journal – July**
**Wrote the Ayurveda Primer E-Book/interactive multimedia CD-ROM**

**Miscellaneous**

**Ayurveda Encyclopedia – Amazon.com top 3 bestseller in Ayurveda category in US, UK, Japan & France. 8,000 copies sold through Dec. 2000**
**Government advisor – US Senate, NCCAM, Nat'l. Council for Alternative Medicine**
**University lecturer – John Hopkins University, Penn State**
**Special advisor to the Ayurveda Acupuncture Board of Accreditation of Australia**

**THE WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY**

STATEMENT:

PLEASE ALLOW ME TO INTRODUCE MYSELF. I AM ELIZA TOWNSEND,N.D., PROPRIETOR OF "RELAX FOR HEALTH", A HOLISTIC (ALTERNATIVE)HEALTH CENTER LOCATED IN WYANDANCH, NEW YORK.

AS AN ALTERNATIVE HEALTH CARE PROVIDER, I TEACH LIFESTYLE CHANGE AND RECOMMEND THE USE OF ALL THE FORCES, WHICH ARE FOUND IN NATURE SUCH AS LIGHT, WATER, AIR, PLANTS, AND FOOD TO STIMULATE THE BODY'S NATURAL HEALING ABILITIES. THESE SERVICES ARE NOT MEDICAL NOR ARE THEY INTENDED TO REPLACE MEDICAL TREATMENT.

MY PRACTICE PRIMARILY IS WORD OF MOUTH, REFERRALS FROM OTHER ALTERNATIVE CARE PRACTITIONERS, AND SOMETIMES MEDICAL DOCTORS FOR A SPECIAL NEEDS PROGRAM. I DO NOT ADVERTISE OR SOLICIT.

I RECEIVE CALLS FROM PEOPLE WHEN THEY FEEL THAT HAVE RUN OUT OF MEDICAL OPTIONS.

MANY OF MY CLIENT DO NOT TELL THEIR PRIMARY CARE PHYSICIANS THAT THEY ARE SEEKING ALTERNATIVE HEALTH SERVICES DUE TO THE NEGATIVE FEED BACK AND WARNING THAT THESE SERVICES HAVE NOT BEEN VALIDATED.

**WHY DO PEOPLE COME TO ME?**

WHEN ASKED THIS QUESTION, ONE OF MY CLIENTS RESPONDED "I FEEL VERY COMFORTABLE WITH THE SERVICES YOU OFFER. I GET RESULTS. YOU SPEND TIME ANSWERING MY QUESTIONS. AFTER THE CLEANSING PROGRAM MY SKIN CLEARED UP."

AS AMERICAN CITIZENS, I SHOULD HAVE A RIGHT TO MAKE CHOICES ABOUT MY HEALTH/WELLNESS CARE.
WE ARE ALL AWARE OF THE FACT THAT NATURAL REMEDIES HAVE BEEN PART OF OUR CULTURE FOR HUNDREDS OF YEARS, WITHOUT SIDE EFFECTS.

AS A PRACTITIONER, I BRING A VALUABLE SERVICE TO THE TABLE AND I SHOULD BE RECOGNIZED AS A VALID ACCEPTABLE SERVICE PROVIDER.

THE CHALLENGES I FACE AS AN ALTERNATIVE CARE PROVIDER:

1. CONSTANT CRITICISM BY THE MEDICAL PROFESSION.

2. LACK OF HEALTH INSURANCE COMPANIES COVERAGE.

3. TO PUBLICLY ADVERTISE MY SERVICES AS AN ACCEPTABLE ALTERNATIVE HEALTH CARE SERVICE.

**THE FEDERAL AND STATE GOVERNMENT SHOULD PROVIDE POLICIES THAT ARE INCLUSIVE AND NOT EXCLUSIVE IN PROVIDING ALTERNATIVE HEALTH CARE TO OUR EVER CHANGING SOCIETY.**

Greyston Health Services

Good afternoon. My name is Joe Tribbie, Assistant Vice President of Greyston Health Services in Yonkers, New York. We are in our third year of providing medical and social services including a wide array of complementary and alternative approaches to persons living with AIDS.

As the AIDS epidemic enters the 21st century, persons living with AIDS, through increased education about their illness, are making more informed decisions about their course of treatment. Approximately 25% of our patients consistently access holistic services on a weekly basis while approximately 50% access these services at least once each month. Additional funding sources would enable programs such as ours to enhance service provision and increase our research efforts to report more precisely the effects of complementary and alternative therapies on special populations such as PLWAs.

It is expected that enhanced treatments, vaccines, and perhaps one day a cure for HIV/AIDS will be the result of western based medical research, however, the person living with the virus cannot be ignored. In utilizing holistic therapies, we work with the body, the mind, and the spirit to restore and strengthen the whole person whereby the immune system along with other bodily functions is better supported. Our patients often comment on the healing component of alternative health care and its ability to promote wellness, to relieve stress (which studies have shown can weaken immune response), and to assist the body in stabilizing and managing an impaired immune system. Through a partnership involving both holistic and standard medical approaches, we address not only HIV infection but other health issues effecting PLWAs such as hepatitis C, depression, fatigue, physical rehabilitation, substance use, and cognitive skills. As a result, we have seen increases in T-cells and decreases in viral loads, we have seen a lessening of anxiety and stress, we have seen a decrease in drug use, we have seen patients who have an inability to trust and difficulty in being consistent in their treatment come

back again and again and again. We have seen a community form and we continue to see this community grow and flourish.

How much do the alternative therapies play a part in this development? We know that our attendance is higher on days when we offer alternative therapies. So we know our members believe in the course of treatment that they have chosen, which is a core issue in learning to care for oneself, learning to take better care of your own well being. The healing process begins in the mind, moving into a contemplative state and from there into a position of action. Our experience has shown us that the integration of standard medical procedures with complementary and alternative care can greatly enhance a person's ability to move in this direction. To continue to enable our patients to get to that point, we must provide them and ourselves with the largest array of ammunition possible. Thank you.

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Anthony Vera

White House Commission on Complementary and Alternative Medicine Policy
New York City Town Hall Meeting
January 23, 2001

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Statement by Ms. Wanda Evans
Executive Director,
Betances Health Center

Complementary or alternative medicine, in the form of home remedies or new self-care discoveries amidst the cultural diversity of New York City, has for generations been the first line of care for the many Latinos and African Americans served by Betances Health Center. Located in the Lower East Side, New York City's traditional settling community for new immigrant groups, Betances provides health care with 30 years of service commitment to integrate the healing wisdom of Eastern and Western cultures.

Ninety-one (91) percent of our 3,840 patients are Latino and African American, and our experience has been that all have utilized at least one complementary care remedy for acute or chronic conditions. Last year 1,096 patients made an estimated 3,822 visits for acupuncture, massage therapy, and nutrition counseling and dietary supplementation. These visits, however, were made for medical necessity; and only 2% of the visits were paid directly by patients. Betances also provides primary care services to approximately 400 Latinos and African Americans with HIV/AIDS. About 12% of our HIV patients have opted for complementary care for a variety of reasons. For many African

Americans, choosing complementary care is their way of responding to medical treatment fears rooted in the legacy of the Tuskegee Study. Among a significant number of our HIV patients complementary care is consistent with a belief system that embraces holistic health and self-healing.

Our experience with complementary care also confirms the finding (Dole, et. al.[1]) that Latinos adopt traditional patterns of use when it comes to herbal remedies compared to the faddish appeal such remedies have for Non-Latino white populations. Among Latinos, for example, the "botanica" continues to be more than a place for spiritual healing, one where herbal remedies are intricately connected to belief systems that are only now being uncovered by conventional medicine to be a critical predictor of positive medical outcomes. It is, therefore, very easy for Latinos to accept healing practices, such as acupuncture, massage therapy or therapeutic touch alongside conventional medical remedies.

Regrettably, the barriers posed by Western medicine are complicated by a market place culture that unrelentingly promotes complementary health care the way it peddles beauty and fashion. There is no scientific method behind culturally-driven remedies that show their efficacy with the power of tradition and

[1] Ernest J. Dole, Robert L. Rhyne, Carla A. Zeilmann, Betty J. Skipper, Melvina L. McCabe, Tieraona Low Dog. The Influence of Ethnicity on Use of Herbal Remedies in Elderly Hispanics and Non-Hispanic Whites, ***Journal of the American Pharmaceutical***, 40(3):359:365, 2000.

use over countless generations. Moreover, quality assurance methodologies, managed care, and medical reimbursement practices are locked into the paradigm of Western medicine and the scientific method. A paradigm shift is needed to make room for complementary care that is truly integral to the benefits that are derived from the ways of Western medicine.

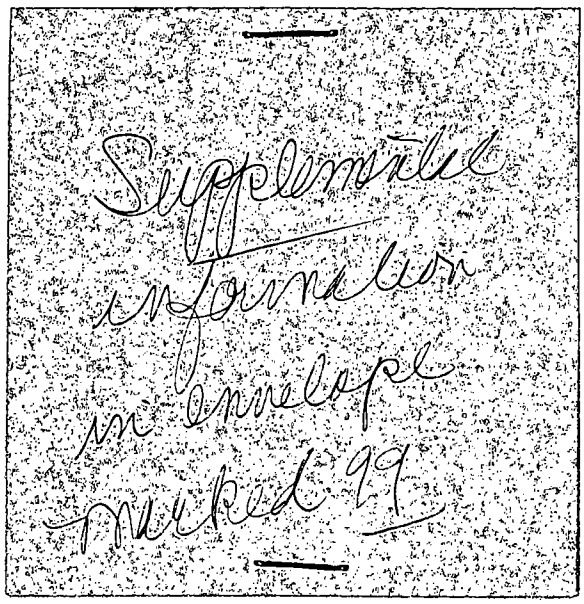
While we wait for such a revolution in Western medicine, there are some practical ways that community health centers can be allowed some room to practice good medicine using holistic approaches that embrace conventional medicine with culturally syntonic complementary care practices.

We suggest two systemic changes that will promote the adoption of established complementary care practices in a Medicaid managed care service future.

1. Standards of care should be established that will permit patients to receive acupuncture, massage therapy, nutrition therapy, and herbal remedies as medical services within state licensed medical care facilities with adequate Medicaid and Medicare reimbursement rates.
2. Managed care plans should treat complementary care services as a "carve out" product that supports the self-care and wellness benefits such plans promote as health maintenance goals.

Respectfully submitted,

Wanda Evans
Executive Director
Betances Health Center


Supplément
au Journal
de l'enveloppe
Mardi 99

AmSAT American Society for the Alexander Technique

Ladies and Gentlemen of the Commission:

My name is Missy Vineyard, I represent the American Society for Teachers of the Alexander Technique. We are especially concerned about how CAM is being defined and about how the Alexander Technique is frequently misdefined. And we want to tell you about AmSAT, and what we are doing to voluntarily self-regulate our profession.

The first consideration must be: on what basis does a discipline become defined as a type of CAM? Everything from tai chi and meditation, to aromatherapy and colonic irrigation is suddenly CAM. Is every modality that claims to offer health benefits, but isn't yet regulated, thrown into the CAM grab-bag? The differences among these diverse practices must be considered. Toward this end, a critical question should be: is the discipline primarily a treatment modality, administered to a passive recipient who has little role in how the treatment is administered; or is it an educational modality, in which the recipient is consciously engaged in gaining knowledge and skill enabling him to make new choices and change behavior? Western medicine is principally treatment oriented. So too, are many non-traditional disciplines.

On the other hand, the Alexander Technique is an educational discipline. It promotes health and well-being by teaching people how to change unconscious habits of malcoordination. If you slump for hours in your chair, walk with your shoulders hunched in and your head down, you are malcoordinating yourself. If you do this for years, eventually you will affect your health. You'll have back and neck pains, shoulder pains, and eventually your spine may become fixed in its curvature. For over a century, Alexander teachers have been teaching students to become aware of maladaptive habits and behaviors and to prevent them. In time, the student learns to maintain his improved coordination independently, without the teacher. But it isn't only for those with physical complaints. Teachers work in performing arts departments and arts festivals around the world, including Juilliard and Yale, helping students achieve the highest levels of muscular control and artistic expression.

We are an educational discipline that sometimes produces therapeutic benefits, depending on the student's habits and ability and motivation to learn new behaviors. We aren't medicine, traditional or otherwise. We don't treat, diagnose, or make claims for cure. We aren't an alternative to appropriate medical care, and we aren't complementary to it. AmSAT-certified Alexander teachers receive an intensive, three-year, 1600-hour course of instruction. Only highly experienced Alexander teachers can assess the competency of new teachers, and only teachers can assess if the Alexander Technique is an appropriate choice for an individual. Since 1987, our Society has been working to responsibly protect the public we serve by maintaining

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professional standards through voluntary self-regulation. We are affiliated with a network of 23 societies worldwide, comprising a membership of over five thousand teachers, sharing the highest standards for teacher training, evaluation of training courses, professional conduct and adjudication of complaints, and continuing education. Most teachers are self-employed; we do not seek insurance reimbursement. We strive to chart a path of growth, development, and independence for our profession and to educate the public about its benefits. We are autonomous, and we adamantly maintain our right to remain so. The only circumstance under which we might appropriately be considered CAM, is if this were to encompass a sub-category for 'health education,' as opposed to 'health care.'

On the regulatory side, we would emphasize that until CAM is better delineated, and the disciplines within it distinguished from each other, regulation of any type is premature. And, no single type of regulation can possibly be appropriate for all. Treatment modalities should require a different type of regulation than those that are educational. We urge you to consider offering guidelines for voluntary self-regulation, as we have done, and consider that many of these modalities should be permitted to maintain their autonomy so long as they adequately regulate themselves.

In closing, we hope you will consider that it isn't only 'treatments', applied by a practitioner to a passive patient, that can and do effect beneficial changes in health. Educational approaches, which teach people how to understand and change their behavior also produce significant health benefits. But such systems aren't treatment and don't belong within the medical model or squeezed within the narrow confines of a single, over-arching type of regulation. Further, to genuinely understand non-traditional modalities, you must begin with non-traditional thinking and develop new ideas that address the many complex questions before you. Only in this way can you achieve your aims of genuinely protecting the public interest, investigating the validity of health claims, and expanding our understanding of human health and behavior.

Thank you for your time and consideration.

Missy Vineyard, Director
The Alexander Technique School of New England
Founding member and past chairman,
The American Society for Teachers of the Alexander Technique

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GARY I. WADLER, MD, FACP, FACSM
INTERNAL MEDICINE
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**Testimony before the**
**White House Commission on Complementary and Alternative Medicine Policy**
**January 23, 2001**
**by**
**Gary I. Wadler, M.D. FACP, FACSM, FACPM, FCP**
**Associate Professor of Clinical Medicine**
**New York University School of Medicine**

**I AM HERE TODAY IN A VARIETY OF ROLES THAT ARE LINKED BY THEIR RELATIONSHIP TO THE CASCADING PROBLEM OF PERFORMANCE ENHANCING DRUGS AND DIETARY SUPPLEMENT USE IN SPORTS.**

**IT'S A CRISIS THAT OBSERVES NO BOUNDARIES, AS IT RANGES FROM THE GRASS ROOTS TO THE ELITE LEVEL.**

**MY TESTIMONY TODAY IS AS AN INTERNIST AND SPORTS MEDICINE EXPERT, SERVING AS MEDICAL ADVISOR ON DRUGS IN SPORTS TO THE WHITE HOUSE OFFICE OF NATIONAL DRUG CONTROL POLICY.**

**MY TESTIMONY IS ALSO AS A MEMBER OF THE WHITE HOUSE TASK FORCE ON DRUG USE IN SPORTS AND A MEMBER OF THE HEALTH, MEDICINE AND RESEARCH COMMITTEE OF THE WORLD ANTI-DOPING AGENCY.**

**FOR THE PAST TWO DECADES, I HAVE WORKED TO FOCUS ATTENTION ON THE INCREASINGLY PERVASIVE AND MULTIDIMENSIONAL PROBLEM OF DRUGS AND SPORTS, A SUBJECT OF IMMENSE – AND EVER-GROWING SCIENTIFIC AND ETHICAL COMPLEXITY.**

IT IS IMPERATIVE THAT WE RECOGNIZE THAT THE ABUSE OF DRUGS IN SPORTS IS NOT LIMITED TO INDIVIDUALS OR THE EXCLUSIVE DOMAIN OF ATHLETES. IT IS A BURGEONING PROBLEM THAT IS THREATENING OUR YOUTH AND AS SUCH THREATENS THE PUBLIC HEALTH.

GIVEN THE BREADTH OF THE SUBJECT, I WOULD LIKE TO NARROW YOUR ATTENTION TO THE ISSUE OF DIETARY SUPPLEMENTS AND PARTICULARLY THE SO-CALLED STEROID PRECURSOR DIETARY SUPPLEMENTS.

EVER SINCE MARK McGWIRE'S HOME ROOM RECORD WAS CLOUDED BY THE REVELATION THAT HE HAD USED THE DIETARY SUPPLEMENT ANDROSTENEDIONE, THERE HAS BEEN A PREDICTABLE EXPLOSION IN THE SALE OF ANDROSTENEDIONE AND RELATED SUBSTANCE, SUCH AS 19-NOR-ANDROSTENEDIONE.

THESE SO-CALLED STEROID PRECURSORS ARE NOT ONLY A PROBLEM FOR ELITE ATHLETES.

THEIR USE REPRESENTS A FAR BROADER THREAT TO THE PUBLIC HEALTH BECAUSE THE PHYSIOLOGICAL IMPACT OF STEROID PRECURSORS GOES WELL BEYOND THEIR EFFECT ON MUSCLE.

TO UNDERSTAND THEIR DANGER, WE NEED TO UNDERSTAND THE SHORT AND LONG-TERM EFFECTS, OF ALL THINGS, THE FEMALE HORMONE, ESTROGEN.

YOU MAY ASK WHY ESTROGEN? THE SIMPLE REASON IS THAT THE HUMAN BODY CONVERTS ANDROSTENEDIONE INTO ESTROGEN IN BOTH MALES AND FEMALES ALIKE. IN FACT, A RECENT STUDY HAS SHOWN THAT 300MGS DAILY OF ANDROSTENEDIONE CAN INCREASE ESTROGEN LEVELS BY 80 PERCENT.

WHY SHOULD THIS PANEL BE CONCERNED ABOUT ESTROGEN LEVELS? THE ANSWER LIES IN THE FACT THAT JUST ONE MONTH AGO, AN EXPERT ADVISORY PANEL OF THE NATIONAL TOXICOLOGY PROGRAM OF THE UNITED STATES NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

RECOMMENDED THAT ESTROGENS BE LISTED AS A "KNOWN" CAUSE OF CANCER IN HUMANS. LET ME PUT THIS ESTRGOEN/TESTOSTERONE PARADOX IN SOME PERSPECTIVE.

BECAUSE ANDROSTENEDIONE IS CONVERTED TO TESTOSTERONE, THIS DIETARY SUPPLEMENT IS OF INTEREST TO ATHLETES WHO ARE SEEKING TO INCREASE THEIR LEVELS OF TESTOSTERONE WITHOUT PURCHASING ANABOLIC STEROIDS AND THUS VIOLATING THE VERY STRICT CONTROLLED SUBSTANCES ACT OF 1990.

AS WE ALL KNOW, TO ATHLETES, TESTOSTERONE MEANS LARGER AND STRONGER MUSCLES, LESS BODY FAT, AND INCREASED ASSERTIVENESS.

TO YOUNG MEN AND WOMEN WHO ARE NOT ATHLETES BUT ARE VICTIMS OF OUR "PERFECT BODY" CULTURE, IT MEANS A LEANER, MORE CONTOURED OR CUT PHYSICAL APPEARANCE.

ALARMINGLY, RECENT STUDIES HAVE REVEALED THAT AS MANY AS THREE PERCENT OF TEENAGE BOYS AND THREE PERCENT OF TEENAGE GIRLS HAVE USED CONTROLLED ANABOLIC STEROIDS. THE RATE OF INCREASE AMONG TEENAGE GIRLS IS PARTICULARLY ALARMING.

THE MARKETING OF ANDRO IS NOTHING LESS THAN FLYING UNDER THE LEGAL RADAR SCREEN TO ACHIEVE A STEROID EFFECT WITHOUT VIOLATING THE LAW.

IT'S A DANGEROUS LOOPHOLE. THERE IS NO TELLING HOW MANY TEENAGERS HAVE USED THE OVER THE COUNTER DIETARY SUPPLEMENT ANDROSTENEDIONE -- AND RELATED SUBSTANCES -- UNKNOWINGLY PLACING THEMSELVES AT THE CENTER OF ESTROGEN'S CARCINOGENIC EFFECTS -- AND WHO KNOWS WHAT OTHER HEALTH THREATS – FOR THE REST OF THEIR LIVES?

AND HERE'S ANOTHER TWIST IN THE ROAD. WHILE ANDROSTENEDIONE HAS BEEN PRIMARILY MARKETED TO ATHLETES AND YOUNG PEOPLE, ITS IMMEDIATE PRECURSOR,

DEHYDROEPIANDROSTERONE, -- KNOWN AS DHEA -- HAS BEEN MARKETED TO THE OLDER POPULATION AS YET ANOTHER ANTI-AGING MIRACLE. CLAIMS HAVE BEEN MADE THAT DHEA IS A "FOUNTAIN OF YOUTH," ABLE TO TURN BACK THE CLOCK, TO INCREASE ONE'S SENSE OF WELL BEING, AND BOOST THE IMMUNE SYSTEM.

NOT SO FAST.

I MUST EMPHASIZE THAT DHEA IS METABOLIZED TO ANDROSTENEDIONE, ULTIMATELY EXPOSING THOSE WHO TAKE IT TO THE VERY SAME RISKS ASSOCIATED WITH ELEVATED LEVELS OF TESTOSTERONE AND ESTROGEN.

THE DIETARY SUPPLEMENT AND HEALTH EDUCATION ACT OF 1994 (DSHEA), WAS INTENDED TO INSURE CONSUMERS THAT SAFE AND APPROPRIATELY LABELED PRODUCTS REMAIN ON THE SHELF – AND TO ENCOURAGE MANUFACTURERS TO LIVE UP TO THESE GUIDELINES.

THE FACT THAT DSHEA HAS SO DRAMATICALLY LIBERALIZED THE LANDSCAPE WITH RESPECT TO STEROIDS IS SOMETHING – I AM CERTAIN – THAT WAS NEVER EVISIONED OR INTENDED WHEN THE LAW WAS ENACTED.

TAKING THIS FURTHER, WE ARE LIVING UNDER THE TERMS OF A SCARY CONTRADICTION.

ON ONE HAND, WE HAVE A LAW -- THE CONTROLLED SUBSTANCE ACT -- THAT PUTS SERIOUS CONSTRAINTS ON THE PURCHASE OF TESTOSTERONE, ALONG WITH A COMPANION REGULATORY SYSTEM THAT REQUIRES A PRESCRIPTION FOR THE PURCHASE OF ESTROGENS.

ON THE OTHER HAND, WE HAVE A LAW THAT AUTHORIZES THE PURCHASE OF THE PRECURSORS OF BOTH TESTOSTERONE AND ESTROGEN WITHOUT ANY PRESCRIPTION WHATSOEVER.

TO ME THIS IS UNACCEPTABLE AND POTENTIALLY DANGEROUS.

LAST YEAR, 343 ELITE ATHLETES FROM AROUND THE WORLD HAD POSITIVE URINE DRUGS TESTS FOR THE METABOLITES OF ANDROSTENEDIONE. VIRTUALLY ALL WERE BELIEVED TO BE RELATED TO THE INGESTION OF DIETARY SUPPLEMENTS. IN SPORTS THESE ARE LEGAL TO BUY, BUT GENERALLY NOT TO USE, YET ANOTHER PARADOX THAT HIGHLIGHTS THE NEED FOR RE-REGULATION.

MY VIEW REGARDING THE PUBLIC HEALTH THREAT OF THE STEROID-BASED DIETARY SUPPLEMENTS IS NOT MERELY PERSONAL OR CURMUDGEONLY.

SPORTS MEDICINE EXPERTS AND SCIENTISTS FROM AROUND THE WORLD SHARE IT. THEY SEE UNITED STATES LAW AS HAVING BIRTHED THE EXPLOSION OF THESE SUPPLEMENTS AND NOW THEY LOOK TO THE UNITED STATES TO CLOSE THE LOOPHOLE.

IT IS ESSENTIAL THAT THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994 BE REVISITED FORTHWITH WITH AN EYE TOWARD RECLASSIFYING THESE SO-CALLED STEROID PRECURSORS AS WHAT THEY ARE: PRESCRIPTIVE DRUGS.

I THANK YOU FOR YOUR ATTENTION AND I WOULD BE HAPPY TO ANSWER ANY QUESTIONS.

**January 23, 2001**

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***White House Commission on Complementary and Alternative Medicine Policy***
***January 23, 2001, New York City***

Oral Comments by David P. Yens, Ph.D., New York College of Osteopathic Medicine,
New York Institute of Technology, Old Westbury, NY 11568

For many Complementary and Alternative Medicine therapies it is difficult to assemble a sufficient number of patients in one place who have the same kind of problem and require the same kind of treatment. For other therapies, such as osteopathic manipulation, a given problem may be treated in different ways by different physicians depending upon collateral conditions that may exist. For both of these situations, some kind of National data collection and analysis mechanisms need to be developed and supported so that a sufficient number of cases can be assembled for scientific analysis. The creation of an osteopathic electronic SOAP note will be used to illustrate what is needed and the problem that must be addressed.

**About osteopathic medicine**

The philosophy and science of osteopathic medicine were first described in 1874 by Andrew Taylor Still, MD, DO, a physician who lived from 1828 to 1917.In 1892, Dr Still founded the American School of Osteopathy in Kirksville, Mo. The members of the osteopathic medical profession are designated as "physicians and surgeons, DO." They are qualified to render complete healthcare. Osteopathic medicine is a complete system of medical care with a philosophy that combines the needs of the patient with the current practice of medicine, surgery and obstetrics. Osteopathic philosophy also emphasizes the interrelationship of structure and function, as well as the body 's ability to heal itself. Osteopathic medicine cooperates with all other branches of medical science. It maintains its independence to develop and perpetuate for everyone this unique and inclusive system of medicine.

D.O.s understand how all the body's systems are interconnected and how each one affects the others. They focus special attention on the musculoskeletal system, which reflects and influences the condition of all other body systems. D.O.s know that the body's structure plays a critical role in its ability to function. They can use their eyes and hands to identify structural problems and to support the body's natural tendency toward health and self-healing.

What is "alternative" about osteopathic medicine? The National Center for Complementary and Alternative Medicine considers the manipulation component to be "alternative." D.O.s are widely recognized for their incorporation of manipulative medicine into their spectrum of care. However, it is this manipulation component that is hard to study.

While manipulative medicine is commonly associated with physical ailments such as low back pain, this far-reaching treatment modality can also be used to relieve the discomfort or musculoskeletal abnormality associated with a number of disorders, including Asthma, Sinus Disorder, Carpal Tunnel, Migraines, and Menstrual Pain. OMT can relieve muscle pain associated with a disease, and can hasten recovery from illness by promoting blood flow through tissues. A large variety of manipulative techniques can be used to treat these, and other, problems, and the specific technique or techniques used depend upon the physician's training and what they sense through their musculoskeletal examination. Thus, a diagnosis of otitis media may be treated in different ways depending upon the severity of the condition, identification of collateral problems, and the nature of the cranial bones and passages the ear and nose.

**The Problem and The Need**

Scientific research, designed to determine the most effective treatment for a given problem, requires that a

consistent technique be used to treat the problem. Appropriate outcome measures, or dependent variables, must be selected to evaluate the effectiveness of the treatment. However, the complexity of the situation makes this hard to do. With the growing need for outcomes based research in the osteopathic profession, there is an increasingly urgent need for a standardized format for reporting the incidence, severity, treatment of and outcomes related to somatic dysfunction. If the profession is to compete in the increasingly competitive arena of health care provision, it must provide information on those concepts which are central to its treatment and how the disturbances it professes to treat almost uniquely in the health care field, are distributed in the population.

The Louisa Burns Osteopathic Research Committee of the Academy of Osteopathy has designed a form (osteopathic SOAP note) that is to be used by practicing osteopathic clinicians to gather data on their osteopathic examination, the somatic dysfunctions found, the treatment regime used and the response obtained to treatment. This form is designed to capture subtle nuances of the diagnosis and treatment process. The process to be studied is the provision of osteopathic evaluation and treatment as part of the management of a patient's health care. The outcomes being sought are a modification of the somatic dysfunction and the patient's health problems. The data sought will come from the patient records and the physician's description of the treatment performed

To be usable, all the data collected via these forms must be collected together, or aggregated, to permit analysis. However, this requires uniformity in description of the problem(s), in description of the treatment, and measurement of the outcomes. How can this be done?

The only viable approach to solving this problem is the use of a computer record that provides sufficient precision for input that these variables can be accurately identified and aggregated for analysis. With a very large number of levels of variables and shades of meaning this is a difficult task that can only be handled by gathering very large numbers of cases. Thus, some kind of computer network, with a centralized database, is required. The Louisa Burns Committee is initially addressing this task by creating a computerized SOAP note that replicates the paper SOAP note mentioned above. The plan is to create a standardized program whereby uniform data can be gathered from private physician's offices, residency programs, and hospitals that is transmitted to a central data storage facility for analysis. Of course, many security issues must be addressed; this is being done. The major problem is the expense of developing and maintaining such a system. The osteopathic profession is not able to support a project of this magnitude. Identifying other funding sources for such a project has been difficult; we are still searching. Although medical information databases have been developed, we are aware of none of the complexity required for our purpose.

I believe that the problems we are addressing are not limited to the osteopathic profession; similar problems are probably faced by other complementary and alternative approaches to health care. The magnitude of the problem, combined with the potential for providing effective outcomes analyses for a variety of CAM therapies, implies that Federal support for such programs would facilitate the creation of reliable and valid knowledge about these therapies. I urge the establishment of a funding program for this purpose.

Thank you for permitting me to make these comments.

*Sections of these comments were adapted from a grant proposal prepared by the Louisa Burns Osteopathic Research Committee

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