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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001a. business card	Sherri Margalit (partial) (1 page)	nd	b(6)
001b. letter	Sherri Margalit to WHCCAMP (partial) (1 page)	02/08/2001	b(6)
001c. email	Sherri Margalit to Ms Gadbois, Mr Meslin (partial) (1 page)	11/13/2000	b(6)
001d. letter	Sherri Margalit to FLOTUS (partial) (1 page)	10/04/2000	b(6)
001e. letter	Sherri Margalit to Karen Antman (partial) (1 page)	02/12/2000	b(6)
001f. letter	Columbia University to Sherri Margalit (partial) (1 page)	07/12/1999	b(6)
001g. letter	Karen Antman to Sherri Margalit (partial) (1 page)	07/02/2000	b(6)
002. testimony	Martha Eddy (partial) (1 page)	02/13/2001	b(6)

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White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

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FOLDER TITLE:
WHCCAM Town Hall Testimony, January 23, 2001

2011-0568-S
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RESTRICTION CODES

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[001a]

Sherri Heitner-Margalit

M.S. SPECIAL EDUCATION, P.D.
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BY APPOINTMENT
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[0016]

Thursday, February 8, 2001

(b)(6)
NY, NY 10024

White House Commission on Complementary and Alternative Medicine Policy
6701 Rockledge Drive, Suite 1010, MS-7707
Bethesda, Maryland 20817-7707

Re: Followup Materials from Jan. 23, 2001 – Panel 3 Coordinator Corinne Axelrod

Dear Dr. Gordon and Members of the Commission:

Initially, I would like to take this opportunity to sincerely thank you for your dedication and thoroughness on these important policy making decisions regarding CAM. Your panel had a profound impact on my experience as a breast cancer patient. For the first time in three years since my transplant, I felt that doctors had actually stopped to listen to what I was saying, regarding After Care as a component to Clinical Trials.

Dr. Fins and I had some conversation during the break and he brought to my attention that PT, OT, and Counseling Support Services were not considered CAM. Yet, that is specifically the point. Breast cancer patients, like me, who participated in non randomized Phase II Clinical Trials which were government funded and administered by renowned medical centers (NY Presbyterian Hospital) could not even get necessary and appropriate standard measures of care to deal with the side effects of HDC treatment.

After Care needs to be built into the grant proposal, so patients can enter into a Clinical Trial with some 'umbrella net of services' as security. It is really a minimum of services to offer patients. If the medical establishment is serious about enrolling patients in Clinical Trials, so answers to cancer questions can be identified more quickly, then patients need to feel that they will be supported when the unpredictable side effects of these 'revolutionary' new drugs occur. I see this as the 'Golden Door' opportunity for CAM to enter into a mutual practice with mainstream medicine. We know CAM techniques are effective. They help people feel better and heal. In some cases I will venture, they even facilitate cures. The timing is ripe for the Commission to give some serious weight to this very specific proposal.

Patients do not always enter into Clinical Trials as 'terminal Stage 4 patients.' Many patients, like myself, look and feel healthy. Our cancers are actually at a microscopic level and generally not measurable by current standards of measurement, until they advance. We are told that we are 'good candidates for HDC/SSR,' by stem cell oncologists due to our age and basic good health (aside from the breast cancer recurrence). Some of our breast surgeons have even stated, "our survival depends on HDC and stem cell transplant," when even the researchers have not made that claim! Some patients realize that undergoing a Clinical Trial with HDC/SSR would be more debilitating, and weigh the odds against that type of treatment, despite the supposed statistical advantage. Others, people like myself, for personal reasons (having young

children or possibly being deluded that this is our cure) were willing to go with this most aggressive route. Yet, I did not realize that I would not be taken care of adequately by either the medical or legal systems, and if we did not survive, just considered a fatality from treatment. The state of affairs is sad and inequitable but CAM can make a difference.

Dr. Fins requested me to recommend the top three or four services which should be covered for people undergoing Clinical Trials in need of After Care. I would include:

1) Bodywork – uncapped number of treatments as required by a health professional. Services could include OT, PT, massage, yoga, water exercise, and acupuncture. Depending upon the extent of injury and the changing needs of the patient would determine what precise services would be required.

2) Nutrition – a consultant to determine what specific foods and supplements would be most beneficial for that patient at that time. These could include traditional Chinese medicine, teas, vitamins and herbal supplements, and homeopathy

3) Social Work Services – to arrange for individual therapy, group sessions, Meditation/mindfulness techniques/music therapy to help deal with the post traumatic shock of treatment.

4) Education – workshops regarding important developments in breast cancer, reconstruction, side effects of treatments, menopausal symptoms and other related topics.

In my experience I have had to run all over NYC to receive these types of services. It would be logical and more efficient if these services were provided on an outpatient basis with the medical center or on a consulting basis with a health care agency. The most important feature to remember is coordination of services. Patients need changing services as they heal. It is vital that there be flexibility of services as their bodies change. It is important to meet those varied needs. For example, the intake could be with a Social Worker, and the Physical Exam could be two part – a standard, medical doctor and an alternative health care practitioner. Each would determine together with the patient what services the patient required. Periodic follow up visits would determine reevaluation of services. This is a rough outline of a possible delivery of service program.

I have enclosed the following materials:

1) Recent article on CAM Directions from Medscape – February 2001
2) Copy of my letter on Report on Ethical Issues in International Research – Nov 2000
3) Copy of article re HDC by Helen Schiff – Oct 2000
4) Copy of my letter to Hillary Clinton – Oct 2000

5) Copy of my Letter to the Editor re HDC – June 2000
6) Copy of my letter to Dr. Karen Antman re my HDC experience at NY Presbyterian Medical Center – Sept 2000
7) Copy of Clinical Trials article in MAMM that discusses my case – Jan 2000
8) Copy of article re HDC by Anne Grant – Sept 1999
9) Copy of the Investigative Report in US News & World Report by Sheila Kaplan that discusses my case – Oct 1999

I sincerely hope that these materials will help drive change in the Clinical Trial/CAM process. We need quicker answers and cancer cures, but in a humane fashion. Thank you in advance for accepting my thoughts and these materials.

Very sincerely yours,

Sherri Heitner-Margalit

Sherri Heitner/Margalit,
Masters in Special Education
Certificate in International Montessori,
License in School Administration & Supervision
Breast Cancer Advocate
Member of SHARE,
NYS Breast Cancer Network,
National Breast Cancer Coalition

Complementary and Alternative Medicine in the Treatment of Cancer: Current Research and Future Directions

Omer Kucuk, M.D., F.A.C.N.

[Oncology Issues 15(6):17-19, 2000.

Introduction

The term "alternative cancer therapy" refers to clinically unproven treatments that are used in place of conventional cancer treatments, while the term "complementary therapy" is attributed to such treatments when they are used as adjuncts to conventional therapy. These treatments may enhance, interfere, or have no interactions with standard cancer therapy. Some complementary and alternative medicine (CAM) treatments may provide symptom control and palliation with minimal or no side effects. However, CAM treatments may have dangerous adverse effects or potentially interfere with standard therapy. In addition, if used alone, they may indirectly harm the patient by delaying clinically proven standard treatments.

Complementary cancer therapies have recently received considerable attention in the scientific and medical community. The National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH) is dedicated to research investigating these therapies. Although CAM therapies have been used for many years, few well-designed, properly conducted clinical studies have investigated their efficacy and adverse effects. Many physicians treating cancer patients have little knowledge of alternative therapies and, therefore, frequently discourage their use by patients. More recently, however, reports of CAM treatments have begun to appear in medical journals, and research programs for CAM therapy have been developed by several comprehensive cancer centers.

NIH listed the following CAM research areas in a recent Request for Applications (RFAs):

- Alternative medical systems, which include traditional oriental medicine (acupuncture, herbal medicine, oriental massage, and qi gong, or vital energy); ayurveda (India's traditional system of medicine that places equal emphasis on body, mind, and spirit, and strives to restore the innate harmony of the individual); other traditional medical systems such as those developed by Native American, Aboriginal, or African cultures; homeopathy; and naturopathy

- Manipulative and body-based systems, such as chiropractic, osteopathic, or unconventional applications of integrated conventional and physical therapies, including massage therapy
- Biofield therapy, such as energy healing and intentional effects on living systems
- Bioelectromagnetics, such as diagnostic and therapeutic application of electromagnetic (EM) fields, including pulsed EM fields, magnetic fields, direct current fields, and artificial light therapy
- Pharmacologic therapies, such as metabolic therapies and immunoaugmentative therapies as used by CAM practitioners or the public, including antineoplastons (medium- or small-size peptides and amino acid derivatives that are taken orally or injected, and are said to form a defense against cancer), enzyme therapies, the Revici system (which focuses on improving the balance between anabolic and catabolic activities, using injectable selenium, calcium, and copper), or 714X (a camphor rich in nitrogen) therapy
- Herbal medicine, such as echinecea, gingko biloba, and other herbals
- Mind-body medicine, such as transcendental meditation, imagery, hypnosis, biofeedback, music therapy, yoga, spirituality, and biological effects of consciousness
- Orthomolecular medicine, such as the use of products that may be used as nutritional and food supplements, such as ultra-high doses of magnesium, co-enzyme Q-10 (an antioxidant), carnitine (an amino acid), melatonin, or vitamins, when investigated for therapeutic or preventive purposes.

Despite the widespread use of CAM treatments,[1] little data are available to demonstrate the safety, efficacy, and mechanisms of these therapies. The U.S. Office of Technology Assessment issued a report urging a systematic analysis of alternative treatments and their effects on major disease, health, and wellness (U.S. Office of Technology Assessment, OTA-H-405, 1990, p. 225). To promote high-quality research of CAM, the National Center for Complementary and Alternative Medicine (NCCAM), the National Cancer Institute (NCI), and the National Heart, Lung, and Blood Institute (NHLBI) recently funded 11 centers for CAM research. Such centers will provide the resources necessary for the rigorous scientific investigation of CAM. Research conducted at these centers is expected to examine the potential efficacy, effectiveness, safety, and validity of CAM practices, as well as the physiological or psychological mechanisms underlying or contributing to the effects of these practices.

Some of the research topics for CAM therapies listed in the NIH RFA include: prevention; modification of disease course; supportive care or symptom management (including pain control); management of chemotherapy, surgery, or radiation induced side-effects; and issues involved in improving quality of life of cancer survivors. Multidisciplinary approaches to study the molecular and cellular basis of the mechanism of action of CAM therapies in cancer are needed, and collaborations between clinical investigators and basic scientists are crucial. Areas of CAM research include:

- Unconventional adjuvant nutritional approaches that either augment the therapeutic effect of conventional therapies or ameliorate side effects
- Elucidation and systematic evaluation of the mechanisms of action and potential clinical significance of drug-botanical interactions
- Comparative analyses of therapeutic indexes of whole botanical products versus specific isolated compounds from these products with known anticancer activity

- Studies of the potential effect of mind-body modalities (e.g., relaxation, imagery, meditation, psychosocial support groups, or psychotherapy) on physiologic end points (e.g., immune parameters) or disease parameters, such as response rate to conventional therapy, disease-free survival, or overall survival

- Cancer chemoprevention studies that are oriented to unpurified, whole natural substances, such as soy products or herbal extracts

- Studies to evaluate the potential interaction of antioxidant compounds and conventional chemotherapy and/or radiation therapy.

Oncologists are aware that their patients use CAM. As cancer incidence rates and survival time increase, use of CAM will likely increase. Richardson and colleagues[2] assessed the prevalence and predictors of CAM use among cancer patients attending the outpatient clinics at The University of Texas M.D. Anderson Cancer Center, Houston, Tex. Of the 453 participants, 99 percent had heard of CAM. Of those, 83 percent had used at least one CAM approach. Use was greatest for spiritual practices (81 percent), vitamins and herbs (63 percent), and movement and physical therapies (59 percent). The researchers found that women, younger patients, and those who had undergone cancer surgery or who were poor were more likely to use alternative treatments. Most of the participants expected CAM to improve their quality of life (77 percent), boost their immune system (71 percent), prolong life (63 percent), or relieve symptoms (44 percent). However, about 38 percent expected CAM therapies to cure their disease. Despite high hopes for CAM, about 60 percent of participants said that they had not discussed the topic of alternative and complementary medicine with a physician. The authors concluded that "given the number of patients combining vitamins and herbs with conventional treatments, the oncology community must improve patient-provider communication, offer reliable information to patients, and initiate research to determine possible drug-herb-vitamin interactions."

Nam and colleagues[3] determined the prevalence and patterns of the use of complementary therapies among patients with prostate cancer and those at high risk for the disease. Of the patients presenting to urology clinics and the support group, 27.4 and 38.9 percent with, and 25.8 and 80 percent at high risk for prostate cancer, respectively, used some form of CAM. Since some CAM therapies used by prostate cancer patients may include herbs, such as PC-SPES,[4] and phytochemicals, such as lycopene[5] and soy isoflavones[6] with potent biological effects, obtaining accurate information from patients regarding their CAM use is important.

Phytochemicals in Cancer Prevention and Treatment

One area of active CAM research is the use of phytochemicals in the prevention and treatment of cancer. The rationale for the use of phytochemicals in cancer prevention comes from epidemiological studies demonstrating decreased cancer risk associated with increased consumption of fruits, vegetables, and specific phytochemicals. Fruits, vegetables, and other plants contain many potentially cancer-preventive compounds.

Large clinical studies have been conducted and more trials are planned to study the cancer-preventive effects of specific micronutrients and phytochemicals. Well-designed clinical trials are necessary to determine whether a micronutrient confers benefit or risk in the target population. The importance of conducting clinical chemoprevention trials has become very clear recently when several clinical trials showed that the agents hypothesized to prevent cancer did exactly the opposite.[7,8] A large chemoprevention study conducted to determine whether beta-carotene and/or alpha-tocopherol would prevent lung cancer showed that beta-carotene supplementation increased the risk of lung cancer.[7] These unexpected results highlight the importance of conducting well-designed, prospective, randomized clinical trials before making recommendations to the public regarding the use of supplements.

Beta-Carotene Paradox

Epidemiological studies have consistently shown that increased intake of fruits and vegetables, which are rich in carotenoids, is associated with decreased risk of lung cancer. Since lung cancer is caused by smoking, which is a pro-oxidant, and since smokers have decreased serum levels of beta-carotene and other antioxidants, supplementing the diet with beta-carotene in smokers to prevent the development of lung cancer was a reasonable strategy. However, a well-designed, large clinical study conducted in Finland found just the opposite.[7] This unexpected result might have been due to the paradoxical pro-oxidant effect of beta-carotene in lungs where the oxygen tension is high. This information became available only recently and was not known at the time the study was designed. Studies have shown that beta-carotene, at high concentrations, has a pro-oxidant effect when the oxygen pressure is also high.[9] Therefore, in lungs where the oxygen tension is high, administering large doses of beta-carotene may lead to oxidative DNA damage and higher incidence of cancer. Furthermore, beta-carotene and tobacco smoke interact to increase activator protein-1 (AP-1) production in ferret lungs.[10] Overexpression of AP-1 is positively associated with squamous metaplasia in lung tissue. This increased production of AP-1 may also explain the increased risk of lung cancer with beta-carotene supplementation in current smokers but not in current non-smokers.

Antioxidant Use During Chemotherapy or Radiation

Recent articles have cautioned and discouraged the use of antioxidant supplements during radiation and chemotherapy primarily because of the theoretical possibility that antioxidants may interfere with the therapeutic efficacy of radiation and chemotherapy.[11] Since antitumor effects of radiation therapy and certain chemotherapeutic agents have been attributed to generation of oxygen free radicals, there is some concern regarding potential interference that may be caused by antioxidant micronutrients taken by patients during therapy. Although theoretically plausible, no reported human clinical trials have yet shown this potential adverse effect. To the contrary, there are examples of antioxidants preventing the toxicities of radiation[12] or chemotherapy[13] while not affecting their antitumor effects. Since supplement use is prevalent among cancer patients and there is potential for negative interactions between supplements and anticancer therapy, clinical trials investigating these potential interactions should be conducted. Until clinical data become available, recommendations should not be made one way or another, and caution should be exercised in the use ofany high-dose chemical that has the potential to interact with chemotherapy or radiation therapy.

Soy Isoflavones: To Use or Not?

Similarly, some physicians discourage the use of soy products by women who have breast cancer, because of possible estrogenic effect of soy isoflavones. However, many physicians prescribe tamoxifen and/or estrogen replacement therapy for the same women. The concerns about soy phytoestrogen use in the breast cancer setting are not based on clinical data, since no clinical studies have shown increased risk of cancer or poor outcome in women with breast cancer who are taking dietary soy products. To the contrary, in Japan, where soy consumption is much higher than the United States, the risk of breast cancer is lower, and the outcome of treatment is better than that in the United States in similarly treated women.[14]

Because of the U.S. Food and Drug Administration approval of soy products as "heart disease preventive" foods in October 1999, the consumption of soy products is likely to increase in the U.S. population. This increase will likely include a substantial number of women who are at risk for breast cancer or have active breast cancer or had cured breast cancer. Some women will be on tamoxifen or raloxifene for prevention or treatment of breast cancer. Since soy isoflavones bind to estrogen receptors, potential interactions with tamoxifen, raloxifene, or other molecules that bind to estrogen receptors are possible. Thus, it is important to investigate the soy isoflavone compounds in breast cancer as well as prevention and treatment in other cancers. Keep in mind that

oy isoflavones are not only antiestrogenic/proestrogenic, but they also have antioxidant, antiproliferative, anti-inflammatory, and pro-apoptotic effects in cancer cells, which may provide additional mechanisms for their potential anticarcinogenic effects. Current recommendations to healthy individuals as well as patients include caution in using soy isoflavone supplements until clinical trials are completed. However, there is no good reason to discourage people from eating whole soy products, such as roasted soy nuts or tofu, or drinking soy milk. Clinical research with soy foods and/or soy isoflavones in patients with breast cancer or in individuals at high risk for breast cancer should be a high priority.

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Subj: Report on Ethical Issues in International Research
Date: Monday, November 13, 2000 12:15:48 AM
From: Shuli10024
To: nbac@od.nih.gov

Dear Ms. Gadbois and/or Mr. Meslin:

I had requested a copy of the NBAC draft on Ethical Issues about one month ago, and received it Friday, November 10th,2000. Thank you for forwarding this important document. I read and skimmed through most of the draft. I commend you for the first recommendation points d and e - to address the need for 'adequate care and compensation for injuries sustained in research.' Yet, no where in the draft is this discussed at all. How and who will pay for this care? Whose responsibility and liability is this? Is the pharmaceutical company responsible, or is it the doctors and the hospital, or is it the insurance company or the government who are sponsoring these projects?

I was in a Phase II Clinical Trial for a local breast cancer recurrence two and one-half years ago where I had a severe reaction to the high dose Taxol. I became almost paralyzed throughout my body, unable to walk, and barely able to urinate. I had been advised and signed an informed consent which listed all the possible, most dire side effects. The medical staff at the institution down played their possibilities because I was 'young (48 yrs.old) and healthy(aside from the bc recurrence).' Initially, I was going to be part of the arm of the trial where I would have been given five high dose drugs at three different intervals. After I had such a serious side affect, a third of my stem cells were returned, and I had no alternative but to cease being a part of the trial. What would be worse dying from a possible risk of further bc recurrence, or having neuropathy all over my body affecting my diaphram from breathing, to my chest and arm where the catheter had been placed in my chest wall having the pain of knives and glass under my skin, to having no muscle tone or strength to take a step, pick up a glass, feed myself, or ability to write, and having double vision and lacking depth perception to be able to take a step up or down? Although most of the most significant, serious pain subsided after the first eighteen months, I still suffer from neuroapthy in my toes and feet, arthritis in my knee and lower back which was exascerbated by the high

dose Taxol which was not acknowledged by the doctors(perhaps they did not know of that side effect at the time), the beginnings of osteopenia in my left hip, and rising cholesterol numbers due to being thrown into chemopause - early menopause from the adriamycin, having taken Tamoxifin for two years, and currently taking Arimidex.

Despite my difficult time with the trial I do accept the responsibility for entering it. I am grateful for the advancements in modern medicine and for the care of all of my doctors. I believe that they believe in their treatment protocols. Yet, what has become very clear through my experience, is that doctors are human, and that they administer drugs that they do not know how to reverse the side effects once they are given. They can not predict who will suffer the consequences or side effects,in addition to reaping the benefits.

What I find quite ironic is we do not seem to be addressing these concerns in the US through the Food and Drug Administration, National Institute of Health, or the National Cancer Institute, but here your proposal cites this as an initial recommendation in International Research, yet no where in the draft are these questions actually tackled.

It would seem to me that NBAC needs to consider these points as part of their draft and actually enforce and regulate them so patients do not get treated like guinea pigs. When they need to leave trials like I had to do, they should feel supported by the doctors and the medical institution, instead of never being followed by them again and having no followup Aftercare. It would seem vital and patient-centered to have that component of true concern not only in delivery of services but also aftercare. It would also be valuable for the Clinical Trial Oncologists to actually talk to the referring Primary Oncologist. In my experience the 'stem cell people' were so 'tapped out' getting patients into their trials, performing procedures and overseeing patients undergoing stem cell rescues and administration of high dose medicines as well as patients dealing with side effects who were discharged home, that they would rarely really listen to the Primary Oncologist who had dealt with side effects from standard doses of chemo drugs.

I realize all your research does not entail high dose chemotherapy, stem cell transplants, yet I feel certain that there is a proportion of patients enlisted in these trials who will die from the disease, as well as from the treatments. Some of the patients will actually be exascerbated by the treatments. It would appear incumbent upon NBAC to consider these

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001c. email	Sherri Margalit to Ms Gadbois, Mr Meslin (partial) (1 page)	11/13/2000	b(6)

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

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WHCCAM Town Hall Testimony, January 23, 2001

2011-0568-S
kc891

RESTRICTION CODES

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

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RR. Document will be reviewed upon request.

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

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[001C]

thoughts very carefully.

Under separate cover I am forwarding Ms. Gadbois several articles that deal with these issues very precisely. I am thanking you in advance for your attention in this matter. If I can be of any further assistance in this matter please do not hesitate to contact me: Sherri Margalit, (b)(6) (b)(6) NY, NY 10024; (b)(6) office 212-865-7086.

Very sincerely yours,
Sherri Margalit

MORE IS NOT BETTER

WHY IT TOOK SO LONG TO GIVE HIGH DOSE CHEMO THE BOOT

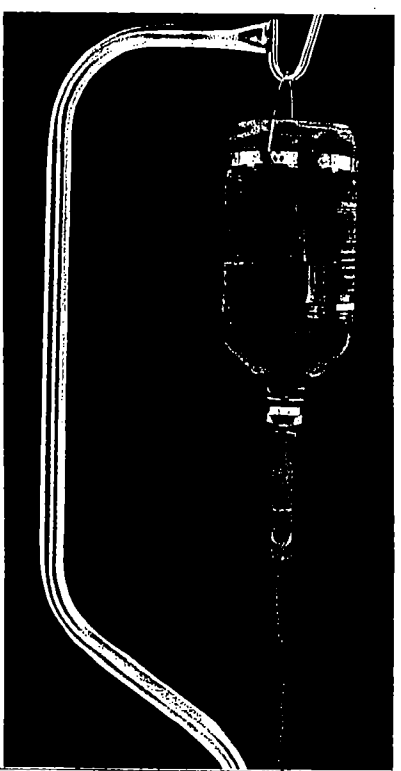
In 1979, high dose chemotherapy (HDC) was first used as a treatment for breast cancer. Incredibly, it has taken more than 20 years to discover that HDC doesn't work any better than standard chemotherapy for women with metastatic disease. Preliminary data on HDC (with bone marrow or stem cell transplant) for women with less advanced disease don't look very promising either. What can be said for sure is that HDC has failed to live up to its initial promise. Although treatment mortality has come down substantially, toxicity is still very high and quality of life very low.

An estimated 13,000 women in the United States have undergone this highly toxic, expensive and unproved therapy. But only about 1,200 of them were enrolled in Phase III randomized clinical trials. Phase III randomized trials are important because they compare a new therapy with an existing standard treatment to determine which is superior. It is the final hurdle an experimental treatment must clear before it becomes the new standard of care.

Phase I and II trials are much smaller preliminary studies that evaluate toxicity and efficacy but don't compare two different treatments. In other words, everyone gets the experimental treatment. Because so few women were enrolled in Phase III randomized trials of HDC, it has taken many more years than it should have to know if the treatment is better or worse than standard chemotherapy. How did this happen?

Much of the media coverage blamed breast cancer advocates, individual patients, and insurers who agreed to pay for HDC outside of Phase III trials for the delay. But what about physician responsibility? Focus groups conducted by the National Cancer Institute from 1995 to 1996 found that women contemplating HDC usually followed their doctor's advice. Many patients were told HDC was their "only hope." With that kind of advice, why risk entering a randomized trial with only a 50-50 chance of getting HDC? Doctors testified in court and wrote letters to elected officials and insurance companies urging coverage of HDC for breast cancer across the board.

The American Society of Clinical Oncology (ASCO), the largest organization of oncologists in the United States, also bears responsibility for prematurely promoting HDC. At its 1992 annual meeting, ASCO issued a press release headlined: "Bone Marrow Transplants Increase Survival for Breast Cancer Patients." It was exactly this kind of sound bite that made desperate women seek HDC outside of randomized clinical trials. In 1995, ASCO's official publication, the *Journal of Clinical Oncology*, published the only randomized study of women with metastatic breast cancer to ever show a benefit for HDC over standard chemotherapy, even though, as an accompanying editorial pointed out, the study was deeply flawed. Many of us know women who decided to undergo HDC based on this study. They were told about the study, but not its flaws.



Health insurers were also at fault. Initially they refused to pay for participation in clinical trials, seriously slowing enrollment for this expensive procedure. If they had agreed to cover the cost of trials from the outset, full enrollment would have occurred before there was time for such a one-sided pro-HDC campaign to gather momentum.

It's not surprising to advocates that financial incentives played a major role in HDC's widespread use outside of randomized trials. For-profit transplant centers sprang up around the country, offering HDC at a cost of $80,000 to $200,000. Many community and private hospitals, *continued on page 26*

BY HELEN SCHIFF

continued from page 25 such as Cancer Treatment Centers of America, couldn't resist milking the cash cow. Prestigious academic medical centers didn't want to lose patients to other institutions either. They ran small non-randomized trials that siphoned off patients from their own Phase III trials.

To their credit, several breast cancer advocacy groups and women's health organizations—most notably the National Breast Cancer Coalition, Breast Cancer Action, Y-Me National Breast Cancer Organization, the National Women's Health Network and the Boston Women's Health Book Collective—tried to disseminate solid information to the public. Some of these groups worked with ECRI (formerly known as Emergency Care Research Institute), a non-profit independent health research organization.

ECRI evaluated the evidence for HDC in a 1994 report and a subsequent 1996 Patient Reference Guide. ECRI pointed out that women on HDC survived longer not because the treatment was better, but because they were younger, healthier and more responsive to chemotherapy than most women with metastatic breast cancer.

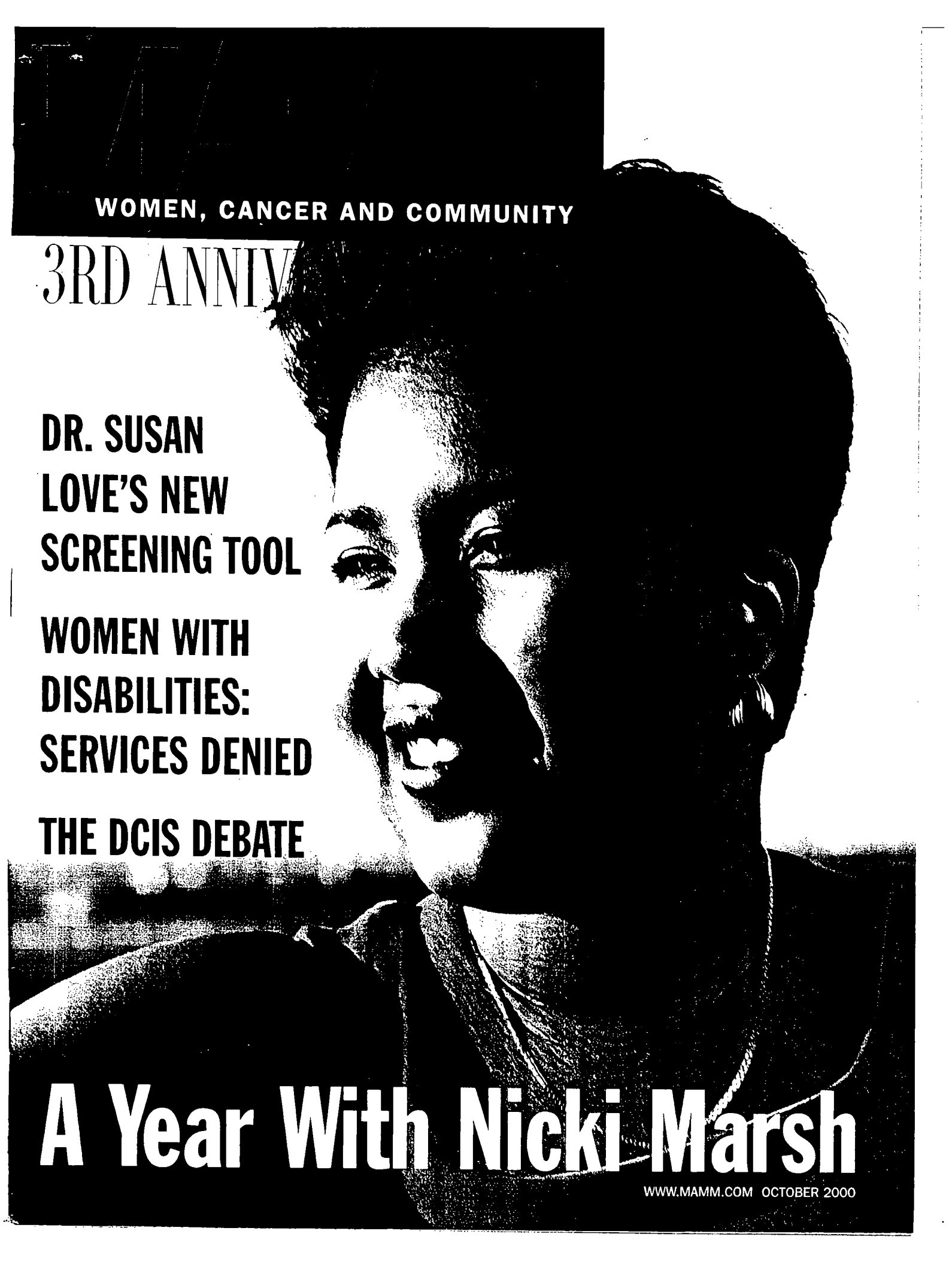
ECRI also showed that neither treatment deaths, which initially approached 25 percent, nor quality of life, was factored into the published studies. Instead, tumor shrinkage and length of time to disease recurrence, not length of survival, were used to show HDC's superiority. The guide concluded that when women on HDC were matched with comparable women on standard chemotherapy, they died sooner.

The lessons for advocates are clear. Physicians and patients need to understand research is a logical step-by-step process. This did not happen with HDC. It became "standard" based on misleading and biased Phase II data before the completion of randomized Phase III trials. A belief that "more is always better" replaced evidence-based medicine. While medical institutions made money and transplanters made careers, women suffered the consequences of undergoing an unproved and very toxic therapy.

Advocates need to encourage the cancer community to move beyond HDC, to find new therapies that are less devastating and more effective. We must make sure that kind of debacle is never repeated. ■

WOMEN, CANCER AND COMMUNITY

3RD ANNIV



DR. SUSAN LOVE'S NEW SCREENING TOOL

WOMEN WITH DISABILITIES: SERVICES DENIED

THE DCIS DEBATE

A Year With Nicki Marsh

WWW.MAMM.COM OCTOBER 2000

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001d. letter	Sherri Margalit to FLOTUS (partial) (1 page)	10/04/2000	b(6)

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[0016]

Wednesday
October 4, 2000
(b)(6)
N.Y., N.Y. 10024

Dear First Lady,

As a six year, two-time breast cancer survivor, it was really special meeting you and hearing you speak at The Roundout in Kingston, New York on August 27, 2000 and again at The Race for the Cure in NYC on September 17, 2000. I know that you meet thousands of people, and probably take an equal number of photos, but I have enclosed a great photo of you, my daughter Samantha and myself for your refrigerator. We all look so healthy and vibrant, no one would suspect that I suffer severe side effects from a Phase II Clinical Trial in which I participated two and one-half years ago.

Although pictures are great, they do not always tell the full story. While you have been in the White House these past years dealing with health care policy, I have been fighting for my life. Because of my experiences in a Clinical Trial and my breast cancer advocacy, I feel that I would be an asset on the Clinical Trials Accessibility Working Group. There is no better way for government to advance breast cancer clinical trials, research and cures, then to have survivors/advocates at policy meetings which affect breast cancer patient lives. Please feel free to contact me regarding working in this important area. I am active in NYC SHARE, a non-profit peer support organization for breast and ovarian patients and their families in the NYC metropolitan area, the National Breast Cancer Coalition, the American Cancer Society, Mt. Sinai Breast Resource Center, and the Susan Komen Foundation. I have enclosed copies of some articles and letters, which have included my case in their reports.

Thank you in advance for all your efforts in health care and for reading my words. I would like to see a world where our daughters will not have to face the threat of breast cancer.

Very sincerely yours,

Sherri Heitner-Margalit

MAMM letters

USING YOGA WISELY

The yoga article in Companion (April 2000) was excellent, especially since it provided alternative exercises through the modifications section.

However, I would like to clarify a few points. Abdominal strengthening after TRAM flap reconstruction should begin after six weeks. Women may risk hernias if they are not closely monitored. Also, the TRAM flap removes the abdominal musculature and transfers it to the breast. Thus, abdominal strengthening may not be appropriate in the first weeks after surgery. An emphasis on stretching that area is important.

Naomi Aaronson
Via e-mail

CLINICAL TRIAL TRIBULATIONS

Thank you for publishing "My First Trial" (March 2000). I work in psychooncology research at the Lombardi Cancer Center at Georgetown University Medical Center in Washington, DC. I have become particularly sensitive to the fears and concerns that many women experience when considering whether to participate in a clinical trial. Without women like Bernice Barber, researchers would be unable to gather and analyze data that could prove helpful to those participating in the study, as well as women throughout the world. I would like to encourage women who are considering taking part to find out as much information as possible about the study and to speak with researchers to determine whether participation is right for them.

I also want to thank you *MAMM* for such a wonderful resource for women whose lives have been touched by cancer. I appreciate your dedication to this special community.

Holly LaSalle
Washington, DC

I was a patient in a high dose chemotherapy clinical trial at New York's Columbia-Presbyterian Medical Center in May 1998. Ms. Milano's description of my ordeal ("Are Clinical Trials for You?" January 2000) failed to convey important lessons to be learned from it.

First, trials using toxic substances with potentially life-threatening side effects can leave participants with permanent damage, irrespective of whether the tested substances ultimately prove effective. I was left with nerve and muscle damage that manifests itself as constant pain and stiffness, making it incredibly difficult to engage in such simple activities as getting up from a sitting position to bending over.

Second, although one can always drop out of a trial, as I did when I found myself virtually paralyzed and not improving between treatments, the permanent damage inflicted cannot be undone by stopping the treatment. Worse, when I dropped out in order to save my life, I felt the people running the trial abandoned me and did not help me get over the side effects caused by their treatment. My insurance company refused to reimburse me for the treatments needed to help alleviate these side effects.

Finally, one must carefully examine the claims of doctors recruiting for trials, because an incentive exists to gloss over or exaggerate benefits in order to enroll participants. Additional opinions from doctors at other hospitals are a must to help sort fact from fiction, although they can further add to the dilemma of treatment options.

Sherri Margalit
New York, New York

FITTING INSPIRATION

Thank you for the profile of Elena Comendador, the Alvin Ailey dance instructor ("Leaps and Boundaries," March 2000)

I am 50 years old and was diagnosed with breast cancer last August. I have been through chemo, surgery and reconstruction. I was very fit when I started chemotherapy. I have made adjustments but have managed to stay in very good physical condition throughout this whole ordeal. This is the first fitness-related article I have read that gave me encouragement. Others have always indicated that the featured person was never able to regain the same level of fitness. Elena has done that. Fabulous!

Thank you again for "Leaps and Boundaries." I feel so free and liberated as a result of it!

Lainie Weade
Via e-mail

DITCH THE DISCOURAGEMENT

I am a mammographer who happens to be a colon cancer survivor. I was paging through your March issue and happened upon the article titled "My Visit to the Tush Man." I was appalled that you would publish this. I can believe that this woman had a bad experience and that is tragic, but it puts such a bad slant on getting screened for colon cancer that many women who need to may now be afraid to get the test done. Getting screened for colon cancer is just as important to women's health as having a mammogram. Also, a diagnosis of breast cancer puts us at greater risk for developing colon cancer. I would think you'd want to encourage the women who read your magazine to be screened for colon cancer instead of scaring them away.

Gail Estes
Via E-mail

I have to admit that I have not read the entire "My Visit To The Tush Man." I wish I had access to it.

I am disappointed in what I did read on your website of sigmoidoscopy as "a modern torture device." (*Editor's note: MAMM*'s website picks certain stories in the magazine to highlight each month.)

For many *continued on page 11*

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001e. letter	Sherri Margalit to Karen Antman (partial) (1 page)	02/12/2000	b(6)

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[001e]

Tuesday, September 12,2000
(b)(6)
NY, NY 10024

Dr. Karen Antman
Columbia Presbyterian Medical Center
177 Ft. Washington Ave.
NY, NY 10032

Dear Dr. Antman,

Your letter arrived in our summer mail. It was thoughtful of you to follow up with the citation from a medical textbook. Although I would not want to minimize any recurrence, I found the data cited from 1978 and 1981 quite old. I would be very interested in reading more recent statistics about local recurrences, which include more effective protocol treatments.

I took the liberty of photocopying and including the consent, which I had signed. As you can see sensory and motor neurotoxicity are not separately identified on this form. A statistic of three out of ten women affected by any neuropathy was cited. If I had been advised prior to the administration of the high dose Taxol that the statistic was nine out of ten women, I would have been much more suspect of taking Taxol in high doses, and probably would have changed my mind about participating in the clinical trial. Dr. Vahdat and the nursing staff who explained the protocol really minimized the dangers stating, 'I was young and healthy and should be fine.'

In reference to your statement about the causes of neuropathy, the only reason I have neuropathy is because of the Taxol induction. There might be other reasons why some people have neuropathy, but mine was solely caused by the high dose chemotherapy administration. I had no feet, knee, leg or back problems prior to that time.

To address your remark about contacting Dr. Vahdat, my whole hospital experience at Columbia was really awful. I believe she is aware of this, which is possibly partially why she did not even see me during my final visit when my chest wall catheter was removed. She is a good doctor who is under a great deal of pressure to enroll successful patients in her clinical trials. The following points will address the problems:

1) My chest wall catheter was inserted poorly by an inexperienced doctor and it seems like it leaked Taxol. Even after the catheter had been removed two weeks following treatment, I was unable to lift or move my right shoulder and arm for two months.
2) During my 24 hour Taxol infusion I was moved from one hospital room to another. In between I was left alone in the hall waiting for a neurologist to perform an EMG on my hands, after the infusion had already begun. My wheelchair tipped over probably from the weight

of things hung on the back of the wheelchair, I fell out of it, and the Taxol bottle fell on the floor which was connected to my IV.

3) Dr. Thomas discharged me without my filled prescriptions and no emergency supply of medications. When we attempted to fill them at our local pharmacy they were unable to be filled, because narcotic medications are only dispensed at Columbia or Sloan Kettering Hospitals. It would have been better for the hospital to fill those prescriptions or at least inform us of this information.
4) I was discharged too early. It would have been better to be under medical care in the hospital, instead of at home when reactions started escalating. It was very frustrating trying to contact Dr. Vahdat to describe fevers and symptoms, change medicines and treatments. Visiting nurse care did not begin immediately and there was an enormous problem with the blood agency that was not trained to draw bloods from the catheter, instead insisting on puncturing my vein!
5) When I was in the hospital from Thursday to Monday, the Saturday night 'nurse from hell' who was instructed to give me pain medicines would not. He was vindictive stating I needed to tell him which medicines I wanted, when I was delirious from the Taxol?!. He was of danger to patients. The next week I advised Dr. Vahdat about him, she shrugged stating she had no control over hospital nursing. I found that quite remarkable considering that this is a federally funded program with guidelines about fragile, cancer patients. In addition, I was not in isolation, but placed in a room with a young, noisy woman with stomach problems who had an enormous amount of dysfunctional family visitations. Why was I not in isolation if I was so open to ~~disease~~? infection ?
6) After discharge I had to return to the hospital four days later due to Taxol gas blockage in my intestinal area. Although I had barely eaten in two weeks, I appeared five months pregnant. When a barium enema and CAT scan ruled out obstructions, I again was sent home with no advice except, 'It will take time to heal.'
7) When the terrible side effects from Taxol continued to persist over the summer of '98, Dr. Vahdat offered no solutions. Not till I spoke with Dr. Kornfeld, from the Institutional Review Board, did she suggest I see Dr. Balmaceda, whom I saw three times – each time waiting inordinate amounts of time without any solutions.
8) Lastly, I received a copy of a letter during the summer of '99 stating my MRI and CAT scans were being returned to my radiologist's office. As you can see from my notes on the enclosed copy, they were never received by Dr. Jacob's office. Is it not unusual that those films were never received or returned?

I realize that you believe high dose chemotherapy saves women lives that have Breast cancer, but so far it is not proven. I certainly hope it has extended my life, especially considering the Taxol side effects of pain in my feet, knees, legs, and back

which continue to be with me all the time. I hate to think that I went through such a trial for naught. I felt your sincerity at the SHARE meeting in June 2000 with your attempt to help me gain some emotional closure on this HDC treatment, but the bottom line is that I am left with severe neuropathy pain from medical treatment which the doctors do not know how to heal.

My initial reason for contacting Dr. Kornfeld of the Institutional Review Board was to see if there was anything anyone could do to help heal my medical problems. I also desired to improve relations between hospital, doctors, and patients, so other women would not need to suffer and experience what I had. I still feel that it would be valuable to have a cancer patient/advocate working with the IRB and hospital administration on protocols involving delivery of services and patient relations. I would be available to help that occur.

I have included two articles, as well as my response, which have cited my medical case. Thank you for reading these words. I pray each day for breast cancer cures, so my daughter and her generation will not have to face this disease. Thank you.

Sincerely,

Sherri Heitner-Margalit

cclindavahdat

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001f. letter	Columbia University to Sherri Margalit (partial) (1 page)	07/12/1999	b(6)

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[001F]

7/15/99 Rec'd Letter
8/3/99 Called Radiol - DN Receive
8/4/99 Called Radiol - DN Receive
8/5/99 Called Columbia - Spk Joanne was not rec'd
8/6/99 Called Radiol - DN Receive
" " " "
9/17/99 " " " "
9/23/99

Columbia University | New York, NY 10032

177 Fort Washington Avenue

305-2486 will call when receive 8/6 fr:

7/15/99 July 12, 1999 - Sent Stand. mail - 2-3 wks

no! - OK mail service

Xeloda (capecitabine)

Ms. Sherri Margalit
(b)(6)
NY, NY 10024

Dear Ms. Margalit,

We have returned your films: the Bone Scan from April of 1998, the CT of the Chest, Pelvis, and the Abdomen also from April of 1998. and the MRI taken in March of 1998 to:

Beranbaum, Khilnani, Neistadt, Jacobs, Hertz, & Sherman, M.D.
121 East 60th Street
New York, New York 10022.

121 E60 838-4243

✓ Spk Karen will 8/3/99

Sincerely,

Linda T. Valdat

Linda T. Valdat, M.D.

305-2486 Tracy/Joanne 8/ Sent 3rd req films Kept unsuccessful

203 E60 486-5510 - MRI Marie fr Mitra

✓ Anna Th 8/4/99

✓ Spk Karen 9/17/99 will

✓ Spk Karen 9/23 NO FILMS

9/23 Spk Joanne will CL

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[004]

HERBERT IRVING COMPREHENSIVE CANCER CENTER

Columbia-Presbyterian Medical Center

Karen Antman, M.D.
Wu Professor of Medicine
Chief, Division of Medical Oncology
Director, Herbert Irving Comprehensive Cancer Center

Sherri Margalit
(b)(6)
NY, NY 10024

July 2, 2000

Dear Ms. Margalit:

As you specifically requested, enclosed is the section from the textbook breast diseases on local recurrences.

You had a number of questions regarding your case that cannot be answered publicly. One I remember was the incidence of toxicity with taxol in our study. I believe you have a copy of the consent form. Note that sensory and motor neurotoxicity are different and the risks of each are separated. Almost everybody gets the sensory toxicity ("severe numbness and tingling"). If Dr. Balmeceda said that 9 of ten get toxicity, she was probably referring to sensory toxicity. Motor toxicity (actual muscle weakness) is much less common.

Some people with neurotoxicity also have other reasons, painful but not related to taxol, for having neuropathy. Most common would be a disk problem leading to pain running down the leg or even muscle weakness.

You might consider calling Dr. Vahdat to ask your questions directly. She cannot answer your questions in public, but certainly can answer them to you directly in person or by phone.

Sincerely,

Karen Antman, M.D.

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Other series usually support,[6,53,63,64] but occasionally refute,[42] these findings. Thus, even patients with only small amounts of clinically evident disease may have fairly widespread subclinical deposits in the chest wall and regional lymph nodes.

PROGNOSIS AFTER DEVELOPMENT OF LOCAL RECURRENCE

Despite aggressive local treatment, almost all patients with an isolated local recurrence will eventually develop distant metastases. The 5-year overall survival rate is zero to 50%, with 10-year survival from zero to 33% (Table 20-2). The more recent series have higher survival rates, possibly because of better staging (excluding patients with occult distant metastases) and perhaps because of more effective systemic treatment after the development of metastases. The median survival time for patients with isolated local recurrence is 2 to 3 years. However, only a fraction of these survivors will be free from further disease altogether. In a series of patients treated from 1968 to 1978 at the Joint Center for Radiation Therapy (JCRT), 5- and 10-year actuarial survival rates were 50% and 26%, but freedom from distant metastases after local recurrence was 30% at 5 years, and only 7% at 10 years (Fig. 20-1).[65] Occasional patients have enjoyed extraordinarily long disease-free intervals after treatment of local recurrence. Patients surviving without disease 15 years and 21 years[39] after treatment with radiation therapy have been described, and two patients are reported alive and without disease at 13 years[66] and 24 years[48] after radical surgical procedures following recurrence. Even these patients may ultimately succumb to breast cancer. Morton[51] described a patient who had a local recurrence 16 years after treatment (and apparent cure) of a chest wall recurrence.

Several factors have been proposed as influencing the disease-free interval and length of survival time after the discovery and treatment of an isolated local recurrence. These prognostic factors seem similar to those determining survival of patients presenting with distant metastases. Among these are the interval between mastectomy and local

Table 20–1
Sites of Further Local Recurrence

Site	No Radiotherapy	Elective Radiotherapy
Chest wall*	43% (17/40)	8% (1/13)
Supraclavicular nodes†	28% (17/60)	7% (2/28)
Axillary nodes	6% (5/78)	6% (2/31)
Internal mammary nodes	4% (3/82)	0% (0/36)

*$p<0.02$ (X^2 test).
†$p<0.025$.
(Adapted from Bedwinek JM, Fineberg B, Lee J, et al: Analysis of failures following local treatment of isolated local–regional recurrence of breast cancer. Int J Radiat Oncol Biol Phys 7:581–585, 1981)

SECOND EDITION

BREAST DISEASES

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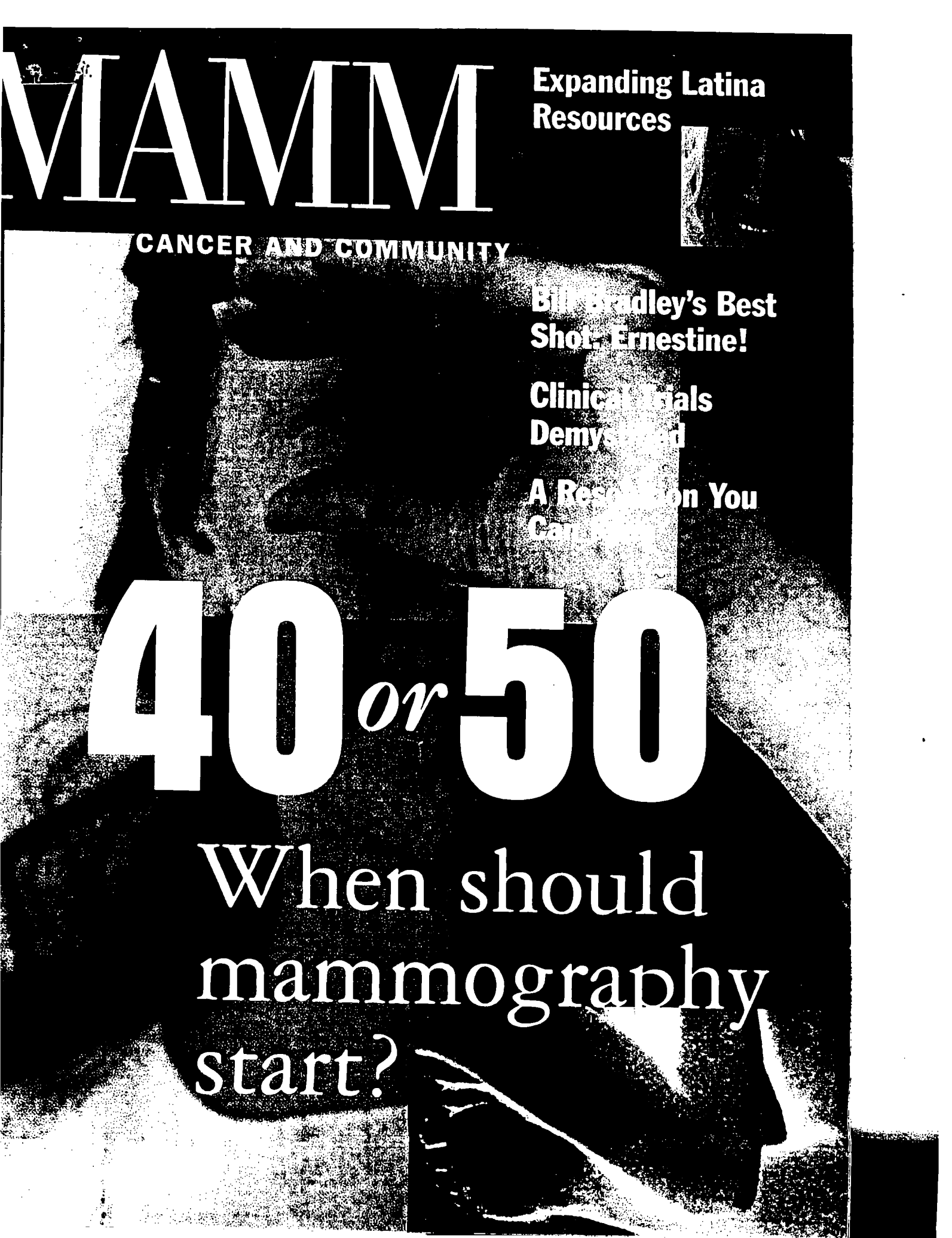
MAMM
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Clinical Trials Demystified
A Reason You Can
40 or 50
When should mammography start?

MAMM JAN 2000

ARE CLINICAL TRIALS FOR YOU?

BY CAROL MILANO

When Pat Barr was first treated for breast cancer in 1987, a member of a medical research team made a special request: Would she consider participating in a clinical trial on tumor recurrence located at Beth Israel Hospital in Boston? Clinical investigators were conducting the trial in an effort to find a blood marker that would indicate recurrence. Barr would be required to give blood for several years. "I said, 'Thank God people are studying this disease,' "

s Barr, a lawyer and member of the board of the National Breast Cancer Coalition. Since then, Barr has participated in three nondrug-related clinical trials—on stress reduction, genetics and mother-daughter linkages. "I don't want the next generation of women to have only the choices now available, which everyone agrees are inadequate," she says.

Although Barr believes her clinical trial experiences have been positive, not all participation in clinical trials is that way. Valid concerns may arise. If you join a trial, are you advancing the cause of science? Or are you merely a guinea pig caught in a laboratory maze?

For a serious understanding of the benefits and uses of clinical trials in cancer treatment, you may need to answer many more questions: What are the goals of the research? How does it relate to your health and stage of cancer? What are the potential benefits, risks and costs?

ONLY THREE PERCENT OF U.S. CANCER PATIENTS PARTICIPATE IN CL

THE ABCs OF CLINICAL TRIALS

Clinical trials, sometimes called research protocols or investigational trials, are the means by which new medical drugs, treatments and theories are analyzed scientifically.

Most cancer-related clinical trials test drugs. Others may research surgical techniques, epidemiology, behavioral patterns, environmental influences, clinical outcomes or the effects of nutrition, exercise and other factors on cancer prevention, recovery or recurrence.

Cancer treatments are tested on groups of people before they are recommended for general usage. Through carefully structured and controlled clinical experiments, the research provides evidence to determine whether a new treatment is valuable for patient care. For example, a 1985 clinical trial sponsored by the National Surgical Adjuvant Breast and Bowel Project (NSABP) showed lumpectomy in combination with radiation had the same five-year survival rates for Stage I and Stage II breast cancer patients as mastectomy. Now lumpectomy is an important option for most of these women.

Clinical trials on drugs begin with patients only after laboratory tests on animals have shown benefits. The trials are divided into phases that involve a widening pyramid of participants. As the research successfully passes through one phase, it moves into the next.

Phase I trials of drugs are toxicology studies. Two or three dozen patients in specialized centers receive the new treatment to determine a tolerable dosage level. Risks may be greater than in later phases, and participation generally is appropriate only for those in advanced stages of cancer who are not responding to other treatments. A Phase I participant might experience no benefit from the drug because the dose is so small, or might suffer harm—sometimes severe—because the dose is too high.

Phase II drug trials determine efficacy: They are designed to find out if there is any beneficial effect from the drug. For example, do tumors shrink? These trials expand the patient group to a larger number of individuals at several cancer centers to better establish a well-tolerated and useful dosage.

With proof of effectiveness, the research process moves on to Phase III, or comparison studies, to determine whether the treatment is equal to or better than existing treatments. Phase III trials may include thousands of patients at hundreds of sites. Patients are divided into two groups. One group of patients receives the best available treatment, sometimes called the "gold standard." The other group or "arm" receives the new treatment that is the subject of the clinical test. The two groups are then compared and the efficacy of the new treatment measured.

Clinical investigators screen participants and apply strict eligibility rules, customized to each trial. To remove any possibility that the researchers might skew the results, even unconsciously, the assignment of patients to the two groups or "arms" is done at random. In addition, the majority of Phase III experiments are double blind—neither researchers nor patients know who is receiving which treatment.

Because cancer is often a life-threatening illness, clinical trial participants rarely receive a placebo—a sugar pill, for example, masquerading as a real drug—though placebos are used frequently in other drug trials. "It would be unconscionable to withhold treatment if there were some method that might be of benefit," says Harold Moses, MD, director of the Vanderbilt-Ingram Cancer Center at the Vanderbilt University Medical Center in Nashville, Tennessee.

When the treatment is non-invasive, involving neither drugs or surgery, the research may go directly into Phase III clinical trials. These tests might seek to measure the role of exercise, nutrition or stress on recovery or recurrence.

Many studies are lengthy and track participants for five years or more. In the United States, some 400 cancer-related trials are under way through about a dozen major cooperative groups of researchers primarily funded by the National Cancer Institute (NCI), with another 600 studies organized

QUESTIONS TO ASK WHEN CONSIDERING A CLINICAL TRIAL

1. What is the purpose of the study? 2. Who has reviewed and approved it? 3. Who is sponsoring it? 4. What does the study involve? What kinds of tests and treatments? 5. What is likely to happen with or without treatment? 6. What are other choices and their advantages and disadvantages? (What are the standard treatments for this type of cancer and how do they compare with the treatment used in the study?) 7. How could the treatment affect daily life? 8. What side effects are expected? 9. How long will the study last? 10. Is hospitalization required? If so, for how long? How often? 11. What are the costs? Will any of the treatments be provided for free? 12. If the treatment proves harmful, what treatment will then be done? 13. What type of follow-up care is part of the study? *From The Cancer Dictionary (1999) by Roberta Altman and Michael J. Sarg, MD. Checkmark Books, an imprint of Facts On File, Inc.*

by other groups, according to an article in the September 1999 *Oncology Times*. As the world's largest sponsor of clinical trials, NCI enrolls about 20,000 people each year. Other trials are funded by biotechnology or pharmaceutical companies, and by private foundations.

REASONS TO PARTICIPATE

IMPROVING FUTURE TREATMENT. Most cancer advocates and medical experts see clinical trials as vital to secure better care in the future. Right now, fewer than 5 percent of breast cancer patients participate in them in the United States, compared to 70 percent enrollment in Scandinavia. Vincent DeVita Jr., MD, former director of NCI, says that if even 10 percent of cancer patients joined in clinical trials, the enrollment process could be completed within one year, instead of three to five years. Thus, the effectiveness of a new therapy could be learned fairly quickly.

Specific populations are generally underrepresented in clinical trials, especially older women and people of color (See related story, page 14). Research reported in 1999 by Kathy Albain, MD, chair of the Committee on Women and Special Populations at the Southwest Oncology Group (SWOG), one of the cooperative research groups that works with NCI, found only 25 percent of clinical trial patients in the mid-1990s were people over 65, despite the fact that 63 percent of people with cancer at that time were in that age category. There are conflicting analyses on the participation of people of color. A recent trial on the use of tamoxifen for risk reduction had too few African American participants to provide sufficient information on benefits to that population group, according to Lisa Newman, MD, assistant professor of surgery in the department of surgical oncology at the University of Texas MD Anderson Cancer Center. But Dr. Albain's research for SWOG did not find significant underrepresentation of African Americans or women in clinical trials.

SECURING HIGHER QUALITY CARE. Doctors involved in clinical trials often work at top medical centers. Participating patients are monitored carefully and frequently. "Women in clinical trials—even if they don't get the new treatment—receive better care than other women," says Cindy Pearson, executive director of the National Women's Health Network (NWHN).

For breast cancer survivor Sandra Zook-Fischler, enrolling in a trial brought an immediate benefit. In 1998, Zook-Fischler participated in one that tested nine women with three different vaccines designed to prevent recurrence. "During careful pretrial screening, a recurrence was found," says Zook-Fischler, an education specialist. "It might not have been found without the clinical trial." She was treated with radiation and was then included in the study.

DETERMINING THAT THE RISKS ARE MINIMAL. When the trials are non-invasive, such as the ones in which Barr participated, there may be no attendant health risks.

The vaccine trial in which Zook-Fischler took part "had no downside risk, just some minor tolerable side effects," she says. Measured against the possibility of helping other women, she was willing to take the chance.

In some cases, women who have cancer in an advanced stage believe their participation in clinical trials will be useful to researchers. For patients diagnosed as terminal, clinical trials may offer a chance to do something meaningful at the end of their lives.

PAYING TRIBUTE TO THOSE WHO HAVE HELPED IN THE PAST. NWHN's Pearson says that the lumpectomy trial that has saved many women from mastectomy involved "unbeliev-

TRIALS IN THE U.S., COMPARED TO 70 PERCENT IN SCANDINAVIA

If you are interested in participating in a clinical trial, start by asking your oncologist about trials that might be appropriate for you. Check nearby medical centers. Contact breast and ovarian advocacy groups. Visit *MAMM*'s website at *www.mamm.com*.

ably brave women" who volunteered in a clinical trial that called for their surgery decisions to be made by random assignment.

Likewise, Barr knows that breast cancer patients now have treatments, no matter how imperfect, only because other women have participated in clinical trials. "The protocols we choose are available to us because thousands of individuals have taken part in clinical trials," she says.

A SURVEY BY THE AMERICAN

SUFFERING FROM SIDE EFFECTS. Clinical trials may involve serious side effects, and although participants can drop out at any time, they need to carefully weigh information provided by the researchers. A consent form advises participants of the risks, but some advocates complain that the documents are excessively long, written in technical language, and downplay side effects. Even for the same trial, the forms can vary from hospital to hospital.

Sherri Margalit, a New York City resident, says although she was advised that participating in a high-dose chemotherapy trial might leave her ill, she didn't think she'd suffer permanent damage. Margalit, the mother of a 12-year-old daughter, decided to participate in the trial after her breast cancer recurred; she says one doctor told her she had Stage IV cancer. "I thought I'd be aggressive," she says. But the trial left Margalit unable to eat for a few days, and her arms and legs atrophied. She withdrew from the study, but says that a year and a half later, she still has difficulty walking.

MAKING A LONG-TERM COMMITMENT. Participation in clinical trials involves follow-up tests, sometimes for five or more years, according to NWHN's Pearson. In some cases, long-term participation is made easier when the studies are conducted by the NCI, which has a nationwide network of cooperative cancer centers.

DETERMINING THAT THE TRIAL IS NOT VITAL. Some critics suggest that not all trials are of equal value to patients. They argue that some clinical trials may primarily benefit drug companies bringing their products to the market, including new versions of older drugs. "The drug companies have built-in incentives to do controlled trials on medications that will cost a lot more," says Sharon Batt, author of *Patient No More: The Politics of Breast Cancer* (Gynergy Books, 1994). "Meanwhile, the inexpensive remedies are not studied much."

Pharmaceutical companies disagree. Steven Benner, MD, executive director of clinical oncology at the Pharmaceutical Research Institute of Bristol Myers Squibb, the manufacturer of Taxol (paclitaxel), claims that profit motives do not drive clinical testing. "Our focus is on finding new treatment," he says. Bristol Myers Squibb conducted 1,000 clinical trials on Taxol, including many after its initial approval, in order to refine its effectiveness, according to Benner. "Patients' participation in clinical trials is critical for establishing that a drug is effective, and learning its patient profile," he says.

Activists raise two important questions about research priorities. Some would like to see more trials of treatment options other than drugs; others are concerned about how outcomes are measured.

Trials on alternatives to drugs, such as diet or exercise for risk reduction, are far less common than drug trials. Advocates would like to see these kinds of largely nontoxic trials pursued.

They would also like researchers to rethink the way outcomes are measured in clinical trials. The results are usually described in increased survival time or time-to-progression—the amount of time that elapses before the continued progression of the cancer. When the survival time increases or the time-to-progression is extended, the treatment is considered successful.

But these measures do not take into account the patient's quality of life during the extended period of treatment—comfort, pain, mobility or ability to eat, read, work. Activists want to know whether drugs improve survival rates and how drugs make people feel. Says Maryann Napoli, associate director of the Center for Medical Consumers, "In some cases, a drug would make your life miserable, although you may gain a couple of weeks on it."

POTENTIAL BENEFITS OUTWEIGHED BY COSTS. Even in Phase III clinical drug trials, there are no guarantees that the drug will be better than, or even as good as the conventional treatments.

Bette Crigger, an editor at The Hastings Center, a bioethics think tank in Garrison, New York, cautions that women must realize the experimental nature of clinical trials. "Researchers hope their work will benefit people some-

day, but being in a clinical trial is research, not treatment."

In addition, clinical trials may involve costs for participants. NCI pays travel expenses for trials held at its Bethesda, Maryland headquarters, but in other situations, participants may be required to pay for travel. Usually the funder of the trial pays for any drugs used. Participants should have their doctors consult the insurance companies about costs related to clinical trials, including treatment for side effects. Older women who rely upon Medicare are not currently covered for experimental techniques (which is how clinical trials are categorized).

But getting coverage may be easier than you think. A survey of American Society of Clinical Oncologists members found that insurance companies denied less than 10 percent of the claims for clinical trials (other than bone marrow transplants). And two bills pending in Congress at press time aim to expand clinical trial coverage for Medicare patients and for those enrolled in HMOs.

Unfortunately, some physicians never even broach the idea of clinical trials with their patients. Another ASCO survey found that only half of the eligible patients are advised about potential participation in clinical trials. Ann E. Fonfa, founder of the Annie Appleseed Project, which educates cancer patients about treatment options, says that some doctors don't think to contact patients when they receive news of available clinical trials. Others, she says, are loathe to see a patient go elsewhere by enrolling in a clinical trial at another facility.

That's why patient advocates are increasingly active in the world of clinical research. In 1994, Deborah Collyar, founder and president of the California-based national organization PAIR: Patient Advocates in Research, made a presentation on why so few patients enrolled in clinical trials before a committee on breast cancer of Cancer and Leukemia Group B (CALGB), one of the large cooperative research groups. "They focus on the science questions," I said. "No one thinks about the patients until after the trials are designed." Collyar was asked to be the group's first patient representative. Now CALBG has 15. Patient representatives have been able to raise questions about the number of trips required to get to the trial site and about onerous testing requirements. Patients, she says, want exact information, feedback and access to care. Two trials planned with patient input showed substantially faster enrollment rates, Collyar says.

Breast cancer acuvist Sharon Batt had concerns about consent documents provided to patients and became the first patient advocate to join an Insututional Review Board (IRB) at McGill University in Montreal. (Institutional Review Boards are designed to protect patients from harm, interpret regulations and review the protocol and consent forms for a clinical trial. Facilities conducting clinical trials they hope to present to the Food & Drug Administration must have them.)

Some of them were queasy about including me," she says. "Six months later, one doctor told me he'd opposed my joining but now felt I made an important contribution."

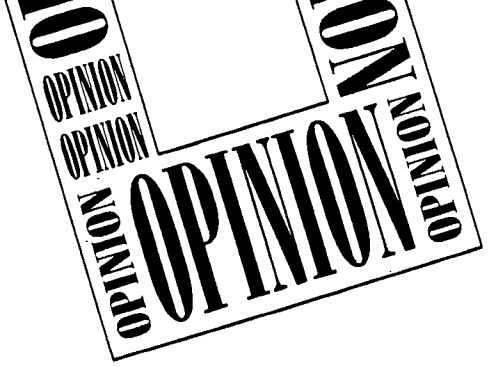
The best current source of information on clinical trials is on the NCI website (see related story). However, many pharmaceutical manufacturers fail to list their clinical trials there, and activists are working to establish a complete, centralized listing. (*MAMM* publishes a column each month listing clinical trials that are seeking participants.)

Organizations are also building stronger networks to support those who are considering clinical trial participation. New York City's SHARE provides information about clinical trials when women call with questions. An online chat recently sponsored by the medical website WebMD featured a session with an expert sharing information on ovarian cancer clinical trials.

One researcher is even studying a buddy program for participants in breast cancer trials. Allison C. Morrill, PhD, at the New England Research Institutes in Watertown, Massachusetts, will evaluate the effectiveness of a program that enlists women who have participated in clinical trials to act as trained talk-buddies for women who are considering clinical trial participation.

Batt, who is continuing her breast cancer advocacy, has a simple reason for involvement. "It would be really nice if we had a cure for this disease," she says. "But scientists can't work alone. Clinical trials are essential." ☐

BECAUSE CANCER IS A LIFE-THREATENING ILLNESS, CANCER TRIAL PARTICIPANTS RARELY RECEIVE A F



HORRIFIC HIGH DOSE

QUALITY OF LIFE CONCERNS IGNORED

Earlier this year, preliminary results from five studies on High Dose Chemotherapy (HDC) were reported at the American Society of Clinical Oncology (ASCO) conference. Four studies found HDC had no significant benefit over conventional chemotherapy. The fifth study showed considerable benefit, but only 154 women were enrolled in it. Before these results came in, more is better seemed a sensible approach. But from my perspective more is much worse.

What these reports didn't tell us is that HDC is the hands-down champ for most horrific treatment in cancer care today. In 1995, at age 45, I underwent HDC as a "very high risk" patient. My pathology report noted a 2.5 centimeter invasive carcinoma tumor with five positive nodes; oncologists told my family and me that I had a very aggressive cancer. A substantial number of us who get this type of breast cancer die of it, as my mother did at age 40. Many doctors recommended a new cutting-edge treatment using HDC. Little was published about it, but we learned there was a six- to 12-month recovery. The death rate for the procedure was supposed to be less than 3 percent and HDC would increase my chance for survival by 25 percent, doctors said then. (New reports put the death rate at about 5 percent.) I decided to undergo HDC because the standard treatments were not showing improved survival rates.

I had a tough time with the four rounds of induction chemo: Apart from their usual side effects, the drugs caused muscle atrophy, and bone and joint pain. I could barely walk and fell often. By the time I underwent HDC, I felt extremely frail. The 21 days in the hospital were spent sleepless and in unrelenting pain and misery. Friends and family have told me that my appearance was frightening. For the next two years, nothing felt good and nothing worked quite right. I suffered a clinical depression caused by the chemotherapy drugs and was unable to read, make decisions or handle simple problems. One morning, several months after HDC, my husband told me to get dressed so he could take me for a walk. Twenty minutes later he found me sitting on the bed trying to figure out which one of 12 pairs of identical white crew socks to put on.

It's four years since HDC, and I'm still struggling with long-term, possibly permanent side effects. Pain, balance, memory, neuropathy (nerve pain), cognition (ability to read, comprehend and remember it), stamina and fatigue loom large in my ability to get through the day. One foot has neuropathic damage that requires orthotics, sneakers and limited walking. I plan my activities by how long I'll have to be on my feet and how far I have to walk. Climbing stairs leaves me breathless and my heart pounding. I've talked to several survivors treated with HDC; many of their experiences mirror mine.

There's clear evidence of HDC's benefit in treating lymphomas and leukemias. While still unproven by clinical trials, HDC was accepted by the oncology world and most insurance companies as a treatment for metastatic breast cancer and for women at very high risk of recurrence. A wise approach to the reports on HDC would be to consider the overall survival rates of the women in the studies for a longer time period than is currently available before making a definitive decision. I don't believe women should continue to undergo HDC until there's longer follow-up time on the five studies. I would suggest that anyone undergoing HDC do it as part of a clinical trial. Insurance companies should be required by law to pay for medical costs in clinical trials and should stop paying for other unproven/experimental treatments. Ultimately, both patients and insurance companies would benefit.

I'm at peace with my decision in 1995 to be treated with HDC, but after reading the reports from the ASCO conference, I wouldn't make the same choice today. If HDC doesn't give us a significant increase in overall survival, the terrible deterioration in quality of life simply isn't worth it. People living with cancer aren't very interested in tumor reduction and disease-free states. We care about quality of life and overall survival. We live with a chronic disease and need less toxic treatments that allow us to lead relatively normal lives. This is the crucial lesson breast cancer advocates must continue to teach to clinicians, researchers and those who determine what types of research are funded.

"People with cancer care about overall survival. ... We live with a chronic disease and need less toxic treatments that allow us to lead relatively normal lives."

—BY ANNE GRANT—

Al Gore on What It Will Take to Win

U.S.News & WORLD REPORT

OCTOBER 11, 1999

www.usnews.com

INVESTIGATIVE REPORT

Dying for a Cure

Cancer patients often fall prey to risky research. Some even lose their lives

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Dying for a

BY SHEILA KAPLAN AND SHANNON BROWNLEE

No lawyer in town would touch the case. After all, Elyse MacEwen had a deadly cancer. The fact that doctors gave the 2-year-old an experimental regimen of drugs without her parents' legal consent—and that the subsequent infection stopped her heart—was certainly tragic. But as a lawsuit, it looked like a loser. After all, wouldn't Elyse have died anyway?

Bill and Christine MacEwen will never know. When Elyse was diagnosed with rhabdomyosarcoma, a rare form of childhood cancer, the family raced to the University of California–San Francisco. There, doctors offered three choices. The MacEwens could do nothing, and Elyse would die within two months. They could remove her bladder, reproductive organs, and surrounding tissue, and follow up with chemotherapy. Or they could try something new: an aggressive combination of drugs described as the most up-to-date treatment available. They chose the new drugs, which, Christine recalls, the doctors said could cut the tumor in half. It was only after Elyse's three-day therapy was finished that the MacEwens were asked to sign a consent form. The treatment, the form explained, had not been approved by the Food and Drug Administration. "It was at that time," the couple wrote federal investigators, "we came to realize that this treatment was experimental, and standard treatment was available."

TINY VICTIM. Elyse MacEwen, 2, died while enrolled in a cancer drug trial. Standard treatment was available.

The standard treatment—surgery followed by chemotherapy—was not only available, but it was nearly always successful. "It's tragic," says J. Thomas Puglisi, director of human subject protection at the federal Office for Protection from Research Risk. The OPRR, a branch of the National Institutes of Health, oversees the safety of participants in federally funded research. "It's very clear to me that the parents didn't understand the great risk of the research and the success rate of the standard treatment." The UCSF case was Puglisi's first major investigation, nine years ago. He still thinks about it. His report concluded that the UCSF doctors' consent process failed to properly inform the MacEwens about a better option that may have saved their daughter, neglected to tell them the purpose or risks of the research, and did not inform them that the drugs to be used were experimental. The doctors never even reported Elyse's death to their overseers at the university. Officials there called the failure to obtain the couple's proper consent "a regrettable lapse."

Nobody knows how often such lapses occur. No government agency tracks how many people enroll as test subjects in trials. No one knows how often patients are helped or harmed. "We don't know how many people emerge unscathed," says R. Alta Charo, a member of the National Bioethics Advisory Commission, a presidential panel appointed to study the issue.

There are clues, though. Buried in hundreds of audits by the FDA, the National Cancer Institute, and OPRR, they point to a pattern of problems. The audits, many of which have never been made public, were obtained by *U.S. News* under the Freedom of Information Act. A review of these records, plus interviews with scores of researchers, regulators, test subjects, and their families, shows that the rules developed to protect research subjects are regularly ignored. Worse, critically ill patients, desperate for any chance of survival, are sometimes led into studies that exacerbate their conditions or hasten their deaths—sometimes, as with the MacEwens, without even knowing they are test subjects.

The extent of the rule-breaking in clinical trials is vast but hard to measure. The FDA's record-keeping system does not make it possible to search for cancer trial audits. The magazine's review of approximately 1,000 FDA spot-checks of all types of trials from January 1996 through June 1999 found these citations: 213 researchers failed to obtain proper consent from subjects,

Cure

Why cancer patients often turn to risky, experimental treatments—and wind up paying with their lives

364 failed to stick to their approved research plan, and 140 did not report adverse reactions from test drugs. OPRR investigators found an additional 50 institutions violating what are known as "human subject protection laws" in cancer trials alone. The National Cancer Institute's audits of its own trials from 1995 through September 1999 found one third of the 23,455 cases reviewed had noteworthy problems. A more detailed review of recent federal investigations of cancer trials from more than 100 institutions found still more problems. Among them:

- Researchers neglected to record or report serious adverse reactions to experimental drugs—including deaths—thus jeopardizing the safety of subjects remaining in the study.
- Patients were coerced into waiving their legal rights in case of malpractice.
- Researchers placed patients in trials that were medically inappropriate, which may have reduced their chances for survival.
- Institutions allowed researchers who had financial interests in cancer studies to conduct reviews of those studies, in violation of federal regulations.
- Doctors failed to accurately inform patients of the benefits and risks of a study or to describe alternatives that might be more efficacious.

"We give better protection to dogs than to people," says C. Kristina Gunsalus, associate provost at the University of Illinois–Champaign-Urbana and a consultant to OPRR.

Some of the cases documented in the records are chilling. At Walter Reed Army Medical Center in Washington, D.C., two federal investigations found that neurologist Andres Salazar violated basic research rules in brain cancer and multiple sclerosis trials. In a report written July 17, 1996, labeled "Formal Investigation into Research Misconduct," Army auditors wrote that Salazar failed to report the deaths of numerous patients in his drug trials, enrolled more people in trials than was permitted, neglected to obtain proper consent for patients or switched treatments without telling them, exceeded his authority to conduct research, ran trials beyond their permitted time periods, and "chose to avoid peer review and command review of his research practices."

The report to Walter Reed's commander from Army investigators found that Salazar "did engage in scientific misconduct . . . exposing patients to potential harm" and concluded that "these breaches of responsible research behavior pose unacceptable risks to patients." The OPRR, which conducted its own investigation, noted many of the same problems and expressed concern that he was still doing research. Hospital spokeswoman Beverly Chidel said no patients were harmed. "The events in question were officially reviewed, and all the issues were addressed," Salazar said. The hospital suspended the trials; Salazar works on research there as a collaborator. Says one investigator who worked on the case, "Many subjects died; it wasn't reported. We don't know if it was the drug or the disease."

Clinical trials are supposed to answer such questions. The FDA requires drug manufacturers to perform clinical trials on all experimental drugs, first to test their toxicity and then to test whether they work. Doctors give some patients experimental treatments and compare the outcomes

CANCER DOC. Two women died in Lee Rosen's cancer drug trial at UCLA. Consent forms said they would be watched closely for any side effects. Rosen believes that the drug, in low doses, is safe.

HANS GUTKNECHT—LOS ANGELES *DAILY NEWS*

with those of patients on standard therapy. Currently, there are about 1,550 National Cancer Institute trials and, the FDA estimates, at least 2,000 more sponsored by drug companies.

Medical research has led to huge advances in medicine and has saved countless lives. But the culture of clinical trials is also plagued by conflicts of interest. Drug companies pay doctors handsomely—sometimes as much as $6,000 per patient—to test new drugs. Academic research centers and hospitals increasingly rely on payments from private-sector sources to augment federal funds.

Doctors who run research trials, meanwhile, may play dual roles, as researcher and caregiver. "You are trying to serve two masters," says Joan Rachlin, executive director of Public Responsibility in Medicine and Research, a trade group for institutional review board members. "The patient and the family think you're Dr. Welby, and your department chair and your colleagues think you're some giant hero who is going to bring in grant money and publish and bring glory to the field."

Shut down. Records and FDA sources suggest the biggest problems are at high-volume, high-pressure institutions where pressure to do research is intense. Last month, the FDA shut down clinical trials at the University of Colorado Health Sciences Center in Denver. In May, the OPRR halted 2,000 medical trials at the prestigious Duke University Medical Center, where auditors found dozens of violations of human subject protection laws, including failure to advise subjects of the "purpose, risks, and benefits of the research" and failure to monitor studies for side effects. After promising to fix the problems, Duke was allowed to restart its trials. In March, OPRR inspectors closed the West Los Angeles Veterans Affairs Medical Center for serious deficiencies, including failing to obtain consent from patients before heart surgery.

Failure to obtain proper consent from participants in trials is a recurring problem. At the University of Arizona, auditors of several gynecological trials wrote: "Consent [form] did not describe the [surgical] procedures involved, was altered after the signature was obtained, or had a tendency to obfuscate rather than inform. The reviewers are at [a] loss to try to convey the seriousness of these problems."

Inaccurate reporting of results is another problem area. After receiving an anonymous tip, the OPRR opened an inquiry into the deaths of three children in a leukemia trial earlier this year at St. Jude Children's Research Hospital in Memphis. In a July 16 letter to hospital director Arthur Nienhuis, the OPRR noted that St. Jude's failed to report the deaths to overseers. The hospital also permitted people involved in the research to decide whether it should continue after the first death, the OPRR said. Its inquiry prompted St. Jude to suspend the trial. Nienhuis acknowledged that the test drug contributed to the deaths and said if the trial resumes, treatments will be amended to be less toxic. He also said the hospital has developed many of the best cures for children with leukemia. Nienhuis said a follow-up report found no fault on the part of the hospital, but St. Jude's declined to release the report. The OPRR says its investigation is continuing.

When a trial goes awry, the effects on participants can be frightening—and long-lasting. When Cheryl Arens was wheeled into the operating room for brain surgery

KEVIN HORAN FOR *USN&WR*

BREAST CANCER TREATMENT

High risk, without the rewards

Since April, when researchers first leaked word that high-dose chemotherapy (HDC) appears no more likely to cure breast cancer than standard treatment, women who suffered through it—and the families of patients who died from it—have wondered: Why were at least 18,000 women subjected to this harrowing and expensive treatment to find out that it probably doesn't work?

Credit desperate patients and a few powerful figures in the field of breast cancer research who convinced their colleagues and the news media that they had found the cure. As far back as 1990, for example, William Peters, a pioneer in the field, testified that HDC "is neither experimental nor investigational" and "has over the years proven itself to be an effective cancer therapy."

Recently, Peters, who is now the director of the Barbara Ann Karmanos Cancer Institute, told *U.S. News*, "I have never used the word 'cure.'" But many patients and test subjects—and doctors—didn't seem to notice. The few cautionary voices, like Craig Henderson, a breast cancer specialist at the University of California–San Francisco, and Bruce Cheson of the National Cancer Institute, were ignored or labeled as naysayers.

High-dose chemotherapy did make intuitive sense. If a little chemotherapy could kill some cancer cells, a lot ought to do even better. The downside: Big doses of cancer-killing drugs throttle the body's immune system, leaving patients vulnerable to deadly infections, internal bleeding, and strokes. As many as 1 in 5 women died, not from their tumors but from the treatment itself.

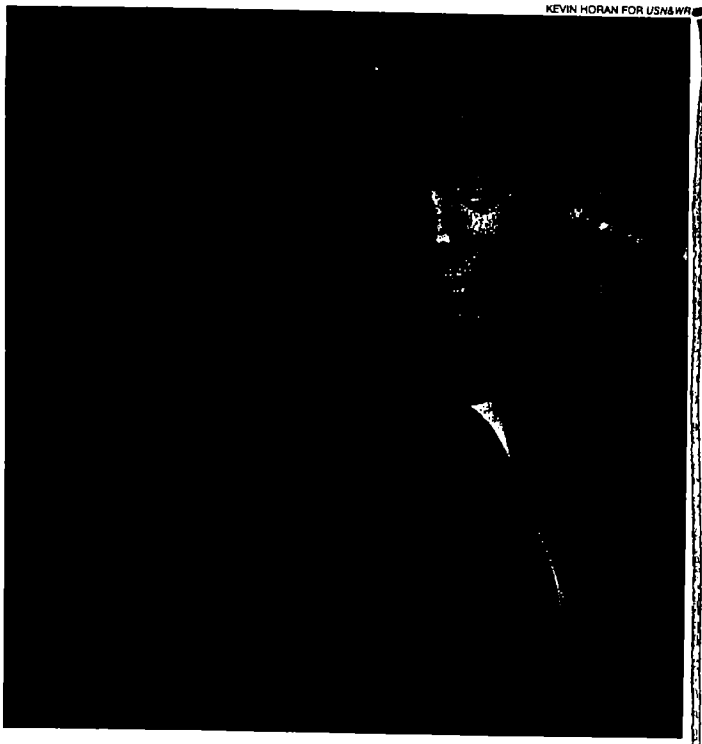
Big bucks. Still, as demand for HDC rose, hospitals were only too happy to provide it, charging anywhere from $20,000 to $200,000 per patient.

er legal consent. The doctors' goal in administering BUDR, an inspector wrote, was not to help Arens but to test the drug. She sued. The university settled for about $15,000. Nobody really knows if she was harmed by the BUDR dose. Arens says, "I would like to see the system fixed." A spokesperson for UCSF said that the university has revamped its review program to avoid future problems.

The system is better than it was in the bad old days. In the 1960s and 1970s, veterans were injected with plutonium; doctors withheld treatment from black men enrolled in the 40-year Tuskegee, Ala., syphilis study. Public outrage over such abuses spurred the federal government to adopt regulations to protect people whose willingness to participate in medical research benefits the rest of society. The government rules stipulate that participants must understand that they are research subjects and must be informed of all the benefits, alternatives, and risks.

The concept of informed consent is the heart of the patient-protection ethic. Informed consent forms, which must be approved by each institution's review board, give prospective participants details about each study. But do patients understand the forms? Do the forms say one thing while a recruiting doctor says another? "The discussion with the physician isn't taped," says Henry Friedman, an oncologist at Duke University. "The doctor says, 'I know there are other options, but there's nothing else out there that's right for you.' I am told all the time by patients that their physician didn't tell them about other options."

KEVIN HORAN FOR *USN&WR*



WATCHDOG. Marianne Elliott, a former compliance chief overseeing clinical trials, says researchers often fail to report drug side effects.

Consider Sherri Margalit. A jogger and vegetarian, she suffered a recurrence of breast cancer after nearly five years in remission. Margalit consulted several oncologists. Her chances of survival were excellent, the doctors said, with surgery, radiation, and normal doses of chemotherapy. Others weren't so sure. Margalit needed more aggressive therapy, they said. Linda Vahdat, a Columbia-Presbyterian Medical Center researcher, was among the latter. She was conducting a clinical trial of high-dose chemotherapy, an experimental therapy widely used for breast cancer despite the lack of evidence that it works (story, Page 36). Margalit says Vahdat told her that her cancer was at an advanced stage and that high-dose chemo was her best shot. "[She] scared me to death," Margalit recalls. "She said the word 'cure' . . . this was the only thing to do."

"Numbness." The procedure ended in pure agony. Soon after beginning a round of the drug Taxol, Margalit's stomach swelled with gas, a toxic byproduct of the drug. Margalit suffered searing pain all over her body, a condition known as neuropathy. It is caused by nerve damage. Columbia's consent form had warned that Taxol could cause temporary "numbness and tingling" in the hands and feet—and, rarely, difficulty walking. Margalit's condition was so severe that she was unable to walk for six weeks after dropping out of the trial. She was dismayed to discover that a bulletin circulated by manufacturer Bristol-Myers Squibb warned that the condition could be painful—a point omitted from Columbia's consent form. She believes the researchers downplayed the potential side effects while emphasizing her chances of being cured. "They never mentioned I'd be crippled," she said. "If I had been advised of this possibility, I would have taken my chances with [standard therapy]." Margalit's cancer is now in remission; she is walking, but only after physical therapy. "I'm not like I was," she says.

Columbia University officials say their patients are well informed of the risks and uncertainties inherent in research. Vahdat says she never used the word "cure." "We prefer to say, 'long-term survival,' " she said. Still, she said, for those most ill, "a clinical trial is always a patient's best shot." Donald Kornfeld, head of Columbia University's review board, says the list of side effects written on the consent form is limited to avoid overwhelming patients with technical data. But does high-dose chemotherapy offer better long-term survival? Most experts don't think so.

Review boards like Kornfeld's have one overriding objective: to protect research subjects. But sometimes their warnings go unheeded. Last January at the University of Illinois–Chicago, 10 members—nearly two thirds of the review board—resigned after administrators failed to address their concerns that competition for grant money was causing colleagues to approve risky research, among other problems. In August, the review board was vindicated after OPRR ordered

TRIAL AND ERROR. Joan Lobenfeld (left) and Ginnie Fox (with husband, Steve) both died in a trial of a potential cancer drug. The doctor running the trial called their deaths "unfortunate."

the campus to suspend virtually all 1,600 of its research trials, pending an overhaul of the university's review system.

At the same time, review boards can be part of the problem, approving trials without fully considering the risks or tracking progress. At Arlington Hospital in Arlington, Va., the review board permitted cancer researchers to show patients a consent form marked "FDA approved" for a drug that hadn't yet been cleared by the agency. At American Oncology Resources, a Texas-based managed-care cancer center, a consent form described experimental high-dose chemotherapy as "treatment" in more than 15 cases reviewed. Charo, of the presidential panel on bioethics, who served until recently on the review board at the University of Wisconsin, says that some boards rebel against what they see as burdensome regulation: "This kind of decision to engage in a kind of IRB civil disobedience is an invitation to chaos."

The boards are policed by two federal agencies: the OPRR, which governs federally funded studies, and the FDA, which oversees research by and for private pharmaceutical firms. They both have low budgets and swamped staffs. The OPRR has 15 people working full time in the unit assigned to enforce the laws designed to protect participants in trials. The office typically responds only to complaints. The FDA visits each institutional review board once every five years, checking a sample of research projects for problems. When problems turn up, they often "travel in packs," says OPRR Director Gary Ellis.

Such was the case at the University of Texas Medical Branch at Galveston. According to official records, only three of 17 subjects placed in an advanced cervical cancer trial had given proper consent. The others had signed a form that stated that the test drug, edatrexate, "is an attempt to give me at least as good a chance of response as is available to me by alternative treatments." In fact, the drug had not yet been tested to see if it worked for cervical cancer in people. "That leans toward being a coercive statement," acknowledges Wayne Patterson, who became the university's research director after the NCI deemed the trial "unacceptable." The form should have said, according to Patterson: "Although this drug might cure my cancer, no benefits can be guaranteed, and my cancer might worsen." The university's institutional review board had ordered researcher Edward Hannigan to revise the form in 1992—four years before auditors uncovered the problem—yet subjects continued to get the older version. The consent form also stated that subjects could not expect compensation from the university if they were injured in the trial—the kind of statement that bioethicists say misleads patients into believing that they have no legal rights.

The wording of the consent forms tipped off auditors to a more serious problem: The drug wasn't working. The auditors noted that the one positive response claimed for the test drug was in error. Hannigan concurred, and the university stopped the trial. Asked why the university needed outside reviewers to alert it to the fact that the drug was failing, Hannigan said it can be difficult to determine a drug's effectiveness in seriously ill patients. Hannigan points out that the test drug was the last hope for patients who had failed all other therapy. The government review, he says, prompted a "reassessment," in which the university decided to shut down the test because of "lack of efficacy." In a letter to the NCI, which Hannigan supplied to *U.S. News*, he called the audit "devastating" and vowed to take steps to prevent future problems.

Judgment calls. Another common violation of laws governing clinical trials is a failure to report side effects of test drugs. Once a clinical trial has begun, says Marianne Elliott, former compliance chief for the OPRR, review boards "say, 'OK, you're on autopilot.' [They] don't do the ongoing verification and monitoring."

Charles MacKay, a project officer at the National Institutes of Health and one of the early staffers at OPRR, says researchers may not report side effects if it's unclear that the problems are caused by the drug—or if they don't want to jeopardize their project. "Adverse events must be reported," says MacKay. "[But] it doesn't always happen. There are tough judgment


KEVIN HORAN FOR USN&WR

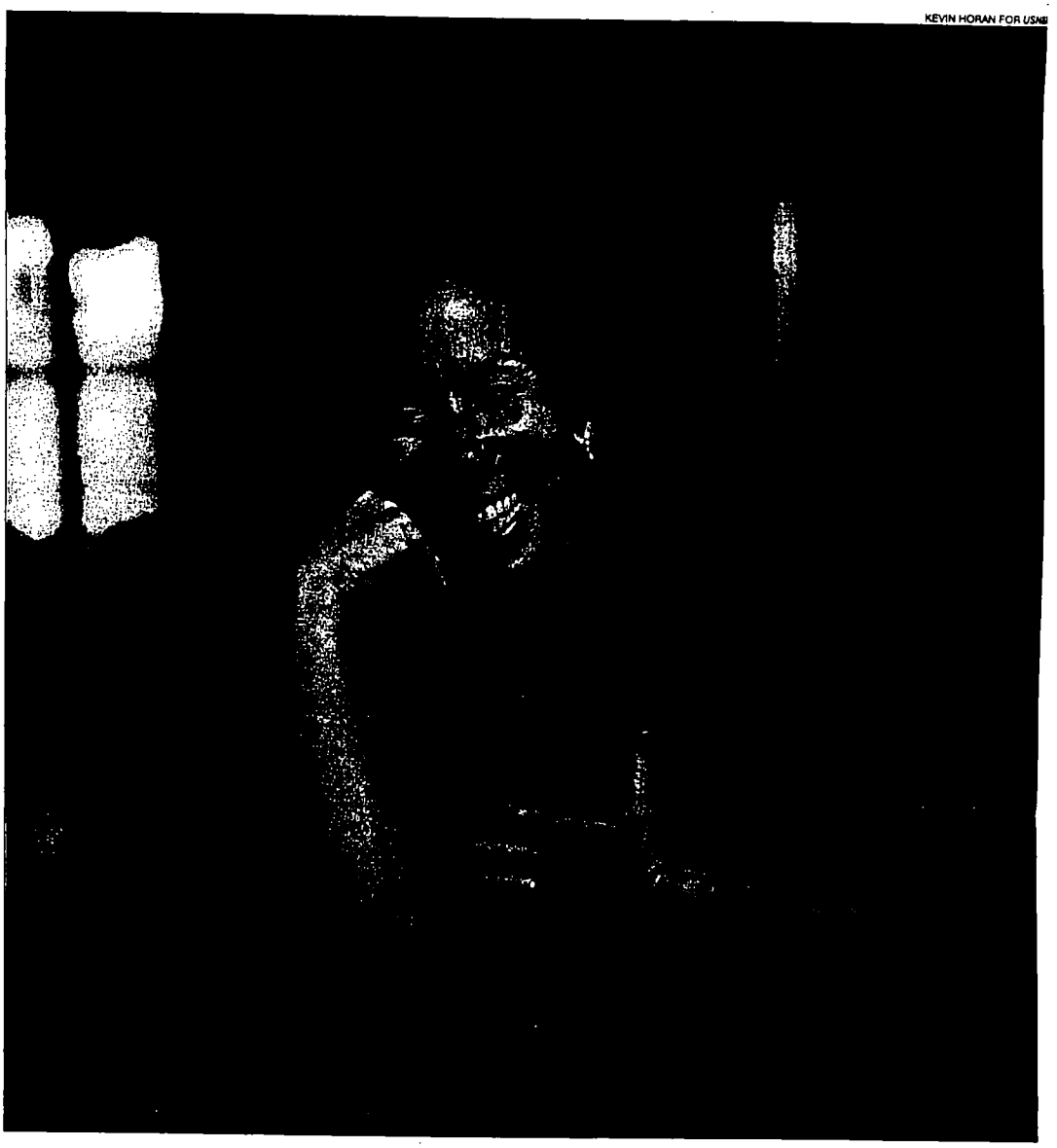
VIGILANT. David Bailey, suffering from brain cancer, rejected the recommendation of one doctor and found a cancer trial more suitable for himself on the Internet. His cancer is now in remission.

calls sometimes. Somebody might say, 'Let's wait and see what happened before we get the word out.' "

Ginnie Fox and Joan Lobenfeld would have lived longer if word had gotten out sooner. In the advanced stages of ovarian cancer, both women enrolled in a trial testing the safety of SU101, a drug being developed by Sugen, a California biotech company that recently merged with Pharmacia & Upjohn. The consent forms the women signed at the University of California–Los Angeles stated that they would be "watched closely for any side effects."

Steve Fox and his wife, Ginnie, knew there was only a slim chance that the drug would cure her, but they were hoping it might buy them a little more time. On December 12, Ginnie was given a dose of SU101. By evening, Steve Fox was alarmed at his wife's condition. "She was so out of it, I'd never seen her that way," he recalls. Fox refused to take his wife home as scheduled, insisting that the nurse contact Lee Rosen, the doctor running the UCLA trial. Rosen allowed her to stay in the hospital. At 3 a.m. Fox again expressed alarm at his wife's deteriorating condition and again asked the nurse to page the doctor. At that point, his wife was not responsive, Fox says. Rosen ordered tests but did not come to the hospital until 7 o'clock the next morning. By then, it may have been too late. Ginnie Fox was slipping into a coma. She died a week later. The cause? Cerebral edema, or swelling of the brain. Joan Lobenfeld also died, the cause of death the same as Fox's.

KEVIN HORAN FOR *USNWR*



CRIPPLED. Sherri Margalit, a breast cancer patient, says she was persuaded to enter a trial of high-dose chemotherapy instead of standard treatment. She says she suffered nerve damage, not walking for months.

What haunts Fox is that his wife was not the first patient to suffer from this side effect of SU101. Sugen had received reports from researchers conducting trials of SU101 at other sites of at least two other patients with cerebral edema. The company included this information in its protocols.

Doses. Rosen, who is director of the school's cancer therapy development program, maintains that it was not clear that the previous cases of cerebral edema were caused by the drug, rather than by the patients' underlying illness or the way the medication was given. He did, however, report to his review board and the FDA that the drug killed the two women in his study. In a December 26, 1996, letter to Donald Tierney, chairman of the UCLA review panel, Rosen wrote, "This is a phase 1 study for patients for whom there is no good alternative anticancer therapy, and [who] in all probability will die shortly of their disease. Though we would never knowingly give a treatment that we believe to be unsafe, even to dying patients, we fel[t] SU101 in lower doses is a safe drug."

Stephen Carter, senior vice president at Sugen, said that since the trial was a Phase 1 study, its purpose was to determine how much of the drug could be given safely—something that is often hard to do without eventually causing side effects. "It would become a dose we would never give again," Carter says. "When you get involved with a cancer drug, you really don't know what's going to happen." That point, he says, is conveyed to patients. Sugen is not even sure the earlier deaths were caused by the drug, one official there said. Rosen says although he conveyed to patients that he had previously seen only mild side effects, he also told them they could not know what to expect. Yet Fox feels he and his late wife were misled. "The consent form says they'll take care of you," says Fox. "You're led to believe that you're going to be watched, and this was certainly not the case." Fox sued the university but dropped the suit when Sugen settled out of court for $25,000. The low settlement fee does not surprise some legal experts. "The patient

was probably coming to an end of what life remained. It would be hard to assess damages," said Barbara Mishkin, a Washington, D.C., health lawyer.

When hospitals and drug companies do admit their mistakes, they tend to give doctors only light reprimands, and the public seldom knows what happened. In 1996, for example, when the NCI audited neurology trials at Massachusetts General Hospital, the agency noted "serious noncompliance" by neurosurgeon Fred Hochberg. The NCI said that Hochberg enrolled ineligible patients and failed to obtain proper informed consent. In addition, auditors found that in Hochberg's trial, a pump that administered the drug being tested was not giving the correct dose on "the majority of patients" in the study.

After the NCI alerted the hospital to the problems, Massachusetts General did its own audit. In two letters to OPRR, Greg Koski, director of human research affairs at the Harvard-affiliated hospital, said that "our investigation has confirmed the findings" and vowed "very stern" action against Hochberg. But although the hospital suspended him from leading any research trials for two years, he continued to participate in them. Koski says patients were not at risk. "The issues raised . . . had to do with documentation," Koski said. Marianne Elliott sees it differently: "There was no ongoing monitoring of this protocol by the institution as I can see. This goes back to the issue of investigators being physicians and everybody trusts everybody."

Clearly, patients need to know what's available to them, but that information is difficult to obtain. There is no central repository of cancer clinical trials. NCI trials are posted on the Internet, but that list does not include the research trials sponsored by drug companies. "There's no way I can look at 30 different brain tumor studies and 150 cancer studies and figure out which one is best," says Peter Eisenberg, an oncologist affiliated with the University of California–San Francisco. "People come in all the time with a list of protocols and want me to tell which one is the best treatment. But we don't know."

If even doctors don't know, a heavy burden falls on patients to find the most appropriate trial for them. David Bailey did just that. After being diagnosed with brain cancer, Bailey ignored the recommendation of his local doctor, did his own research, and found a better trial for himself on the Internet. He is now in remission, being treated by Henry Friedman at Duke. Bailey says he knew he had found the right trial and the right doctor when Friedman told him this: "You're too young to die." ■

GENE THERAPY

A promising experiment ends in tragedy

Jesse Gelsinger got to Philadelphia on September 9 in high spirits. It was the 18-year-old's first flight without his parents, and he had left Tucson, Ariz., to participate in a groundbreaking gene-therapy study at the University of Pennsylvania. Eight days later, Jesse was dead, apparently killed by the experimental treatment.

The tragedy has sparked a fierce debate over the level of acceptable risk in clinical trials. Clearly, the expert panels at the National Institutes of Health and the Food and Drug Administration that approved the trial found it both justified and promising. And by all accounts, the investigators, led by James Wilson of the university's Institute for Human Gene Therapy and Mark Batshaw of Children's National Medical Center in Washington, D.C., followed the protocol carefully. But even as the therapy was getting underway, other geneticists questioned whether the trial was unduly risky.

AP

Jesse Gelsinger, 18, died in gene research.

Gelsinger suffered from a mild form of ornithene transcarbamylase deficiency. OTC is a rare liver disease cause by a genetic defect that renders the body incapable of ridding itself of ammonia, which is produced when protein is metabolized. Most kids with the severe form of OTC die within hours of birth. But Gelsinger's symptoms could be controlled with drugs and a strict diet.

The goal of the Pennsylvania trial was to develop a way to deliver to the liver a normal version of the defective gene that causes OTC. At this stage, investigators were testing the safety of the method, not offering a cure to Gelsinger or the other 17 patients.

The trial was unprecedented. For the first time, gene therapy was being tried on relatively healthy patients, rather than those desperately ill. It also used a novel approach, injecting the vector—a modified cold virus containing the missing gene—into the artery that supplies blood to the liver. The vector they were using was toxic; at high doses it killed baboons in animal trials.

Low risk? What troubled other investigators is that a high dose of the virus might cause liver inflammation. In OTC patients, that could lead to a buildup of toxic ammonia in the brain. The Pennsylvania researchers felt the risk was low. So did the two federal panels that approved the experiment. Paul Gelsinger, Jesse's father, says he didn't accompany his son to Philadelphia because he was told that the riskiest part of the procedure was a liver biopsy to be performed seven days after the gene transfusion.

Jesse Gelsinger received his infusion on September 13, the second person to receive the highest dose in the trial. The first person did fine. But Gelsinger's ammonia levels shot way up. Four days after the therapy, the shaken doctors declared Gelsinger brain-dead and advised the family to remove life support. The researchers immediately halted the trial and began an investigation.

Paul Gelsinger grieves for his son. But he feels no ill will toward the doctors who tried to treat him. "They are good people," he says. "Their intent was pure." *–Leslie Roberts*

Michele,

FYI - New York City Ballet.

Do you have this?

Love

Whccamp (NCCAM)

From: Jordi Ros [jjros@earthlink.net]
Sent: Monday, March 05, 2001 5:12 AM
To: Whccamp (NCCAM)
Subject: SPEECH

Attached is a copy of a speech I was invited to deliver before the WHCCAMP. I did not have time to file a copy before the speech, so I am sending it to you for your records. Please acknowledge receipt thereof.

Speech Delivered by Jordi Ros Before the White House Commission on Complementary and Alternative Medicine Policy.
New York City. January 23, 2001

I want to thank the White House Commission on Complementary and Alternative Medicine Policy and Jim Navarro for inviting me to speak here today. I feel a little out of place among such a distinguished group of panelists, but I hope my perspective as a filmmaker can be of some benefit to your mission.

For the last year we have been working on a documentary about Cancer. We call it, "The War." It is the story of how Jim and Donna Navarro have fought to keep their son Thomas alive. In my fifteen years in the film business no story has moved me as much as the plight of Thomas. As a studio executive in Hollywood I was involved with three films of which I am proud.

"Kundun", the story of the Dalai Lama and his struggle for his homeland; "The Insider", the story of how tobacco executive Geoffrey Wigand's testimony helped break the Tobacco lobby; and "A Civil Action" the story of attorney Jan Schlictman's litigation against polluters in Massachusetts. I don't know if you have seen any of these films, but they share with Thomas' story the belief that the courage of one individual can have a positive effect on the lives of many.

I believe the courage shown by Thomas Navarro and his family -- their willingness to stand their ground with the Food and Drug Administration and the medical establishment -- will be seen as an important turning point in the mission that brings all of you here today.

I want to share a brief story with you. When we began filming this documentary (We hadn't met Thomas yet.) we used to do this little experiment. We would go up to random people in the street and ask them to do a word association game with me. I am sure you are familiar with the game. I would rattle off a number of words and about seven or eight words in I would drop the word "cancer." Can you guess the word I got back in response? I would say that eighty percent of the time, the word I got back was death or pain or dying or something to that effect. I think this is significant.

Now, this wasn't a controlled experiment, and it was not a random sampling. So I'm sure it's of no real value, and it will definitely not get published, right? But as a filmmaker I was intrigued. To me this meant that too many of us are walking around and when one out of two or one out of three, whatever that statistic is, when one of us is diagnosed with Cancer in the near future, a good many of us will believe we have been handed a death sentence. Now, I wouldn't say that this is a healthy state of affairs in a country in which medical expenditures dwarf the GNP of so many poorer nations.

So when we first started the documentary, we had this goal that even if we could change just one person's belief that a cancer diagnosis did not have to mean death, we would have done our job.

And then we met the Navarros. And we realized that nobody could make our case more eloquently than this family who have defied all the odds and who believe that more than money, expensive drugs, and technology the power of love, the power of a parent's love for their child, can keep a child alive.

Thank you.

NYC file
as testimony

3

Kingsbury, Doris (NCCAM)

From: NARVEEN VIRDI [institute@qconline.com]
Sent: Wednesday, January 17, 2001 2:01 PM
To: Whccamp (NCCAM)
Subject: The White House Commission report

Re: Integrative Wholistic Healing and The White House Commission report.

We would like to circulate the The White House Commission report, written by Dr. James Gordon, and published in the last issue of Alternative Therapies among our supporters and subscribers.

Enclosed is an attachment regarding our work in the Intergrative Wholistic Healing area.

We would like to address the commission and look to you for a convenient time for scheduling an address.

Please contact us at your convenience.

Regards,
Narveen Virdi.
President.
The Institute for Cultural and Healing Traditions, Ltd.
1530 5th. Ave.
Moline.
Illinois. 61265

encourages Independent Scholars and, for this purpose, provides a public forum every Thursday evening during fall and spring. Often the forum is attended by patients at both the chronic stage of their ailment as well as at recovering stages.

Integrative Wholistic Healing.

1530 5th. Ave.
Moline.
Illinois.

(309) 762-9202

email: institute@qconline.com

www.qcinstitute.org

Please review our webpages.

We would like to hear from you.

Thanking you,

Narveen Virdi.
President.
The Institute for Cultural and Healing Traditions, Ltd.

We have been observing, with great interest, the progress that is being made with the White House Commission report.

We would like to circulate the report among our supporters and would like to know if it is available on the internet, or if you could forward it to us via email.

Additionally, we would like to highlight our work in the area of Complementary methods of treatment in the form of the Integrative Wholistic Healing public forum.

We are a free standing, public educational organization and work with area hospitals and educational centers to provide access to information on Integrative Wholistic Healing. We also provide a venue for their interaction and interchange.

The Integrative Wholistic Healing center is sponsored by The Institute for Cultural and Healing Traditions, Ltd. based in Moline, Illinois as well as Genesis Health Care System, the hospital in the regional area.

This organization works with area hospitals to set up units and retreats in Integrative Wholistic Healing, as well as working with administration of hospitals and educational institutions to offer a variety of authentic complementary healing methods for the community under their care.

As the word Integrative implies, we work with physicians and hospitals, combining Wholistic methods of healing as an optional addition to the care provided.

Wholistic refers to Mind, Body and Spirit.

The Institute network includes healers and care givers providing traditional and complementary healing to their communities. The network is structured to reflect the authenticity of the traditional care provided.

The Institute reviews credentials among other aspects of its networking members.

Some aspects of our track record:
After our first retreat, the local hospitals included yoga at their facilities.
After our second retreat, acupuncture was officially provided at one of the hospitals.
After our third retreat, prayer was included in the operation room during cardiac surgery at The Genesis Health Care System, one of the local hospitals we work with. It is, thus far, the only hospital in the country to have such a service provided.

Integrative Wholistic Healing is sponsored by The Institute for Cultural and Healing Traditions, Ltd. a 501(c)3 organization. The Institute also

Joe's
advice
DO NOT
INSERT

WRCCAM Town Meeting
Presentation
and
Bibliography as
requested by
Dr. Gordon

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January 23, 2001

Statement of Martin L. Rossman, M.D.
President, Academy for Guided Imagery
PO Box 2070, Mill Valley, CA 94942

To: WHCCAMP Town Meeting, New York City:

Dr. Gordon, distinguished Commissioners and participants:

I speak today to present the results of critical research conducted by the Academy for Guided Imagery, a postgraduate training institution in Northern California. This research demonstrates a pressing need to provide education in mind/body/spirit healing interactions at all levels of the American educational system, and most importantly, for our health care providers.

While we have barely begun to probe the complex relationships between consciousness and health, we believe that mind/body/spirit effects differ in several important ways from other modalities currently considered in the CAM arena:

First, mind/body/spirit interventions are not related to specific modalities, but usually involve a combination of approaches that create a context in which therapeutic interventions are applied. They not only reflect what practitioners do, but also the ways in which they do it.

Second, mind/body/spirit interactions are an inherent component of all other therapeutic interactions and they can often determine the outcome more powerfully than the therapeutic interventions themselves. In one study, for example, when patients with nausea were given ipecac (which usually induces vomiting) and told that it would relieve their nausea, most patients reported that it did, contrary to the physiologic actions of the drug.

Third, there is already a significant body of published peer-reviewed research clearly demonstrating that mental, emotional, and spiritual factors can significantly affect a person's health and well-being, resistance to disease, the progression of their illnesses, the amount of suffering they experience, and the outcome of medical interventions:

For the past two years, the Academy has carefully reviewed and assessed the published literature in this regard and feel that existing studies firmly support the following statements:

1. **The accuracy and completeness of information patients are given, and the way they interpret it can significantly affect their medical outcomes:**

   (6,7,8,9,12,13,15,17,19,21,22,23,24,25,26,27,29,30,31,33,39,40,43,44
   45,50,51,53,55,56,59,68,69,70,71,75,76,83,86,89,91,92,94,105,113,114,11
   7,108,120,125,128,129,130,131,132,133,134,135,138,142,144,151,158,16
   2,172,175,176,177,179,180,182,183,186,187)

1. **The way a healthcare professional communicates and interacts with patients can significantly affect their medical outcomes:**

   (8,13,15,19,22,25,26,29,30,40,42,44,45,48,49,50,52,53,54,57,58,62,
   68,70,71,76,84,85,86,90,91,92,94,96,97,98,99,101,107,108,114,120,
   121,122,128,132,135,136,138,142,145,146,147,148,152,156,160,163,
   164,165,167,171,176,177,179,180,185,186,189,190,191)

2. **A person's attitudes, beliefs, expectations, and hopes about illness and healing can materially affect their medical outcomes:**

   (2,3,8,14,15,16,17,19,21,23,24,25,26,30,31,32,37,38,40,45,48,50,52,
   53,54,55,59,62,6976,83,88,91,93,96,98,102,105,107,110,117,118,119,121,
   122,128,129,133,134,135,136,137,138,139,140,142,148,149,151,
   153,154,155,157,158,159,160,163,165,168,169,174,176,177,178,179,
   180,181,184,186,189,191)

3. **A sense of connection with people, nature, and something larger than themselves can have a significant effect on a patient's health outcomes:**

   (3,13,22,27,34,36,41,42,46,47,48,50,52,54,59,69,77,78,98,102,103,
   105,118,132,133,134,135,153,155,160,165,169,174,177,178,179,192)

4. **The skills of relaxation, imagery, stress management, assertiveness and ability to manage emotions can directly influence all of the above and can be taught:**

   (1,2,4,5,6, 11,12,13,14, 16,17,18,19,20,21,23,24,27,29,30,33,38,39,40
   42,51,55,57,58,59,60,61,62,63,64,65,66,67,68,69,71,72,73,75,79,80,
   82,83,84,85,86,87,89,91,95,97,99,100,101,102,103,104,105,106,107,
   108,110,112,113,114,115,117,119,120,121,123,124,125,126,127,128,
   129,130,131,132,133,134,140,141,143,144,147,149,150,152,158,159,
   166,167,169,171,172,174,175,176,177,181,182,183,185,186,188,189,
   190)

A total of 192 references mentioned above are included in the accompanying bibliography.

Because this literature is so strong, yet unknown to the majority of health care professionals, the Academy would like to submit the following policy recommendations to the commission:

1. That this literature be collated and reviewed by an independent panel and judged as to whether or not these statements have been adequately demonstrated;

2. That if the panel agrees that these statements have already been scientifically demonstrated to be valid, that a special emphasis be placed on making information about mind/body/spirit interventions a part of the core curriculum for all health professionals treating patients at appropriate levels, so that they can;

    - ❖ Use mind/body/spirit interventions to promote healing, recovery, and optimal health in themselves and their patients

    - ❖ Share accurate information with patients with support and sensitivity to the personal information processing and decision-making style demonstrated by the patient

    - ❖ Share information in a way that inspires patient participation, evokes self-efficacy, and maximizes retention and compliance,

    - ❖ Become aware of how their own attitudes, beliefs, and expectations can influence their patients' health;

    - ❖ Enthusiastically support their patients' efforts to get well and stay well;

    - ❖ Encourage the use of family, community, and spiritual connections to support patients in their efforts toward better health;

    - ❖ Teach mind/body/spirit health skills to members of their communities at every level of educational instruction

Over the past 12 years, the Academy for Guided Imagery has developed effective educational methods to teach both professionals and public to work with consciousness in a way that honors both what is already known while respecting the underlying mystery of mind/body/spirit interactions. We would like the Commissioners to know that we stand ready to assist them in the educational efforts recommended above in whatever way we can be of service.

Thank you.

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Kingsbury, Doris (NCCAM)

From: Kent Swanson [swanson@genie.idt.net]
Sent: Saturday, January 13, 2001 5:29 PM
To: Whccamp (NCCAM)
Subject: written comments for NY Town Hall meeting

----- Genie Online Services E-Mail -----
Please accept the following editorial as commentary for the NY Town Hall Meeting of WHCCAMP. Thank you.

THE PHILOSOPHY OF HEALTH FREEDOM

by Kent Swanson

It is ironic that, in a society where "Life, liberty and the pursuit of Happiness" are considered "unalienable rights," the freedom to choose alternatives to conventional medicine is not supported by our current political or healthcare systems.

There is the illusion of health freedom in so far as one may choose from a list of doctors within a managed care system; but this will never include any practitioner outside the bounds of the conventional model--or, in other words, an alternative practitioner. This is most unfortunate, since the freedom to choose only within the confines of a restrictive health paradigm is not real freedom at all. Individuals, for example, of a more spiritual orientation, who regard the body as a "temple", most worthily honored through the use of natural, non-invasive forms of therapy, have, historically, been denied access both to natural healthcare therapies and to accurate, unbiased information regarding them.

While one is constantly bombarded through conventional media channels by press releases from standard medical journals or pharmaceutical concerns, touting the latest ostensible advances in drug or surgical therapies, there is rarely an equal forum extended to qualified advocates and practitioners of natural medicines. The reason for this is obvious: there is far more money and power backing the orthodox medical model than the natural model. Since the orthodox medical model has always perceived the natural model as a threat to its domination of the healthcare industry and has never sought a fair and open dialogue with natural healthcare providers, it has persisted in waging a tireless campaign of suppression and disinformation regarding natural healthcare alternatives. Alternative healthcare providers have been attacked mercilessly, having their reputations destroyed and their right to practice taken away, not because they were guilty of inflicting harm or injury upon people, or even of deluding them with "false hopes," as is often alleged, but because they chose to practice outside the dominant medical model.

And what is the dominant medical model? It is a materialistic, bio-mechanical model, whereby

the treatment of disease is restricted to the surgical or pharmaceutical manipulation of either structural or chemical abnormalities. Alternative treatment modalities, on the other hand, such as herbalism, naturopathy, homeopathy, acupuncture, faith healing, and different forms of body work, which often invoke the concept of a vital force, or spiritual energy that is believed responsible for the self-healing of the individual, are demonized by the dominant model. This is not because they have been proven, empirically, to be invalid, but because their concept of healing doesn't 'square' with the accepted medical model. Since the concept of spirit, or vital force, is not accepted by the dominant medical model, natural healing modalities are therefore rejected out of hand as being "unscientific," when, in fact, they simply engage a different worldview.

The point we wish to make is not whether one paradigm is the correct one or not, since arguments can be made to support the efficacy and verity of either worldview. Nor should they be regarded as necessarily mutually exclusive, since many practitioners are now able to view the two paradigms as "complementary." Each paradigm, the orthodox and the alternative, has a proven sphere of efficacy, so that the complementary healthgiver is not forced to view the abundance of healthcare options in terms of a clash of opposing and exclusionary ideologies, but rather in terms of what works best for any given situation.

Yet even if most physicians are not able to accept the legitimacy of both paradigms, it is the belief of those in the health freedom movement that the choice of individual healthcare should least of all be left to government, which was never ordained to judge in such matters. Our government has been constitutionally-mandated to protect, and not restrict, the rights of individuals to make appropriate life choices. Therefore, instead of suppressing, marginalizing and criminalizing the practice of natural healthcare, the government should be stepping aside far enough to allow legitimate and proven forms of natural healthcare, which happen not to fall within the dominant medical model, to practice according to the consent and will of the people. For in a true democracy, the choice of individual healthcare should be left to the discretion of the individual, for whom the choice is most material and most proper.

When only the upholders of the dominant model are allowed to decide the worthiness of a particular worldview or lifestyle then all dissenters necessarily fall victim to suppression and persecution, as history has clearly shown over and over again. Thus, the cause of health freedom is the cause of democracy. Just as we have in the first amendment to the Constitution a provision for separation of Church and State--so that one state-mandated religion should not be allowed to exist, and to dominate and suppress other religions--so also should we not have one dominant medical model as the sole authority in judging what healthcare is appropriate for all citizens, at all times. Healthcare should and must be a personal right, just as surely as the freedoms of speech

and worship are deemed "unalienable" personal rights.

One of the ways the dominant model tries to remove the rights of individuals to choose their own healthcare is by appealing to its own authority. Since the dominant model has been proclaimed as the correct one--the one 'true religion', as it were--it has become self-mandated to judge all other medical models simply according to its own constructs. This gives the dominant model a certain hermetic protection, such that it, alone, is ordained to judge in medical matters, while at the same time remaining immune from judgment itself. Thus, the rights of citizens to choose their own healthcare is supervened, on the grounds that the citizenry is simply not qualified (since they are not in possession of the proper initiatic training which bestows authority) to judge what is best for their own bodies. The personal experiences of individuals no longer matters. If one, for example, has overcome a long-standing complaint using a natural therapy, then that is regarded as purely anecdotal, and not scientifically credible. For, ultimately, one's personal experiences cannot overcome or disparage the fact that the natural therapy couldn't possibly work...according to the dominant medical model. Thus, the patient is disempowered, and his right to freely choose is superceded by the need of the dominant model to preserve its own dominance.

Without denying the specific expertise of medical specialists in their own field of endeavours, we must assert that this does not entitle them to be qualified judges of other modalities of which they often know little or nothing, and which exist outside of their conceptual framework. What makes, for example, a proctologist an expert in judging the value of homeopathy or herbology other than the fact that he/she has a medical degree and a medical license? A medical degree and a medical license to practice orthodox medicine are laudable, but if the practitioner has never studied a form of healthcare which he insists upon attacking, then how informed and objective will his criticisms be?

It is well-known to most people that many natural systems of medicine, such as herbalism and Chinese acupuncture, have been around for literally thousands of years. It would hardly be credible that such systems could have survived that long if they were totally without merit. So rather than denying and marginalizing such traditional forms of therapy, as the dominant model seeks to do, it would seem to better serve the public interest to explore the possible uses and benefits of such therapies--especially in the face of the vast abyss of ineffectiveness and ignorance that still challenges our current treatment of chronic diseases. The dominant medical model has not been successful enough to justify its arrogance. And thus to reject alternative points of view without first trying to understand them is simply intellectual bigotry, plain and simple; and society is the worse for having been deprived of an open dialogue of ideas.

"A free society," writes Paul Feyerabend, "is a society in which all traditions should be given equal rights no matter what other traditions think about them." In a similar vein, John Stuart Mill

writes in his essay On Liberty: "The only freedom which deserves the name, is that of pursuing our own good in our own way, so long as we do not attempt to deprive others of theirs, or impede their efforts to obtain it. Each is the proper guardian of his own health, whether bodily, or mental or spiritual."

Shouldn't we, then, as aspirants to a free democracy, and as rightful legislators of our own bodies, demand the right to equal access for non-orthodox therapies? Shouldn't those of us who believe in the spiritual sanctity of the human being be allowed to receive the kind of medical treatment which honors the body in the manner we see fit? To deny people the right to treat their own bodies, in both sickness and in health, in a manner in accordance with their spiritual beliefs, can only be regarded as a form of religious intolerance, and opposed to our Constitutional rights. But even those who choose to obtain alternative medicine without any particular spiritual convictions should be accorded the same rights, so long as one's informed consent has been freely given to the practitioner. As always, any practitioner who inflicts harm upon a patient according to the unaccepted standards of his/her own sphere of practice, should be subject to the appropriate reprimands or punishments. In that way, the patient's right to a safe and effective form of treatment will be safeguarded. If a particular practice can then be shown to be either dangerous or ineffective, then it's unworthiness will have been proven in the marketplace of ideas, not according to the self-interest of the dominant authority.

If one of the essential features of a democracy is the right to know, then the current healthcare system, which suppresses the truth about available health options, must be changed. It is time that the consuming public stood up and declared, once and for all, their intention to reclaim the power over their own health and disease which had been handed over to the medical establishment. It is

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[002]

Martha Eddy, Ed. D., CMA, R.M.T

(b)(6)

New York, NY 10027

February 13, 2001

Dear Dr. Gordon and other members of the WHCCAM:

On January 23, 2001, I had the opportunity to speak at the WHCCAM Town Hall meeting held in New York City (Panel 17). I was representing the International Somatic Movement Education and Therapy Association's (ISMETA) view that NCCAM's classification of CAM practices has not specifically and accurately classified the practices represented by ISMETA. At the meeting you requested that we inform WHCCAM how we would like to be classified. The following is our proposal.

Currently many of the practices within our profession are listed under **Category V - Manipulative and Body-based Systems – Massage and BodyWork.** While we understand the affiliation with other manual hands-on/touch methods, as movement professionals we do not feel this is an appropriate classification for us.

We strongly urge you to review the recommendations that were sent by a number of somatic practice professional associations to the US Department of Education (DOE) as public comment for their final draft of the publication Classification of Instructional Programs (CIP – 2000).

I have included this document for your review, as well as another copy of my statement made on January 23.

As mentioned at the Town Hall meeting, ISMETA has already been in active dialogue with the DOE on this project for over one year. They have struggled to make sense out of the proliferation of educational programs that prepare individuals to become CAM professionals. This past summer, in (what was supposed to be) the eleventh hour for their final draft, they decided to adopt the NCCAM's taxonomy. As you see in our letter to them, we find there to be a difference between a classification system for research purposes and a classification system for educational training.

Proposal I

The professions represented by ISMETA would rather be listed under **Category II – Mind-Body Interventions** – of the NCCAM classification, which states:

Mind-Body medicine involves behavioral, psychological, social, and spiritual approaches to health. It is divided into four subcategories: Mind-Body Systems; Mind-Body Methods; Religion and spirituality; Social and contextual areas.

In the **Mind-Body Intervention** Category the professions which ISMETA represents would like to be listed under **Mind-Body Methods** as ***Somatic Practices of Movement Education and Movement Therapy***

Rationale:
Somatic practices of movement education and movement therapy are not solely based in the body. These practices are intrinsically educational in that they consciously engage cognitive and emotional processes. Their theoretical framework includes perceptual-motor, neuro-developmental, and behavioral theory. Thus, we feel it is best that we are listed under Mind-Body Interventions as a CAM practice instead of under Massage and BodyWork as a Body Based Therapy. Furthermore, Yoga, Tai Chi, and Internal Qigong are practices listed under Mind-Body Methods that have already set a precedent for movement based practices in this category.

If it is helpful please consider the following definition of our field.

Somatic Practices of Movement Education and Movement Therapy are practices that promote somatic awareness and optimal psychophysical functioning to enhance functional and expressive integration. The scope of practice includes skilled touch, kinesthetic awareness processes, movement observation, assessment, guidance and patterning methods, verbal, touch and movement communication. These practices include but are not limited to the following: The Alexander Technique, Bartenieff Fundamentals ™, Body-Mind Centering ®, Dynamic Anatomy ®, Halprin Life Art Processes, Laban Movement Analysis, Phoenix Rising Movement Therapy, Rolf Movement Integration, Rubenfeld Synergy ®, Somatic Movement Coaching, Somatic Movement Education, Somatic Movement Therapy, The Topf Technique®, and could theoretically include Aston Patterning, Feldenkrais Method®, and the Trager® Approach, if they desired.

In summary, and for clarity, ISMETA would like to have all the above listed Somatic Movement Practices listed under **Category II Mind-Body Interventions – Mind Body Methods – CAM Practices**, as ***Somatic Practices of Movement Education and Movement Therapy.***

If it is absolutely impossible for this suggestion to be implemented please consider its alternative, **Proposal II.**

Proposal II
Re: the new/added program title and definition ***Somatic Bodywork: Under Manipulative and Body Based Systems.***

We request that you consider a re-categorization to include the following three categories

Somatic Bodywork.
Somatic Practices of Movement Education and Movement Therapy.
Energy-Based Therapies.

Rationale:
A range of individual systems, modalities and practices is included under this title. The educational providers and movement specialists of some of the systems listed do not identify their instructional programs as Somatic Bodywork.

For your information please consider these alternative definitions:

Somatic Bodywork. promotes physical and emotional balance and well being through the application of skilled touch principles and techniques. Methods include hands-on methods, anatomy and physiology, structural integration and various holistic health systems, practice management, professional standards and ethics. (Breema, Hellerwork, lymphatic drainage, Rolfing/Structural Integration, Rosen Method, and others).

Somatic Practices of Movement Education and Movement Therapy are practices that promote somatic awareness and optimal psychophysical functioning to enhance functional and expressive integration. The scope of practice includes skilled touch, kinesthetic awareness processes, movement observation, assessment, guidance and patterning methods, verbal, touch and movement communication. These practices include but are not limited to the following: The Alexander Technique, Bartenieff Fundamentals ™, Body-Mind Centering ®, Dynamic Anatomy ®, Halprin Life Art Processes, Laban Movement Analysis, Phoenix Rising Movement Therapy, Rolf Movement Integration, Rubenfeld Synergy ®, Somatic Movement Coaching, Somatic Movement Education, Somatic Movement Therapy, The Topf Technique®, and could easily include Aston Patterning, Feldenkrais Method®, and the Trager® Approach.

Energy-Based Therapies. A program that prepares individuals to promote health and well being through the application of techniques intended to affect the human energy system. Instruction may include a combination of theory and basic principles of orthodox and energetic anatomy and physiology, energetic evaluation and integration, skilled touch, communication and facilitation skills, energetic nutrition, movement, stretching postures, practice management, professional ethics, and service delivery, as appropriate to each practice. (Bioenergetics, cranio-sacral therapy, Polarity Therapy, Reiki, Therapeutic Touch, Qigong, and others).

In summary, we strongly urge you to accept **Proposal I** as detailed above. If upon giving **Proposal I** careful consideration, its adoption is simply not possible, then we ask you to accept **Proposal II**. In summary, **Proposal II** would entail a **re-categorization** to more appropriately separate several diverse modalities into three distinct sub-categories: 1) ***Somatic Bodywork***, 2) ***Somatic Practices of Movement Education and Movement Therapy***, and 3) ***Energy-Based Therapies***.

ISMETA would also like to state that it is in support of the letter from Missy Vineyard of the American Society for the Alexander Technique (AmSAT) to Dr. Kaczmarcyzk on February 10, 2001. In particular ISMETA shares her skepticism towards "creating one big CAM amalgam, complete with a single regulatory system that attempts to be appropriate for all." However, we would also like to state that whereas some somatic movement practices (most notably those Teachers of the Alexander Technique represented by AmSAT) may not want to work toward receiving third party payments, this is not a monolithic view. There are some practitioners that may seek to work as part of HMO's or in conjunction with the insurance system in order to provide greater access of this work to more diverse people, in particular those people unable to afford, 'out of pocket' services.

Again, thank you for your extraordinary efforts to consider this update of the classification of CAM practices under the NCCAM and all that you do to support a greater understanding of the wide range of holistic practices that are being used in our country.

Respectfully yours,

Martha Eddy, Ed.D.
Board of Directors
International Somatic Movement Education & Therapy Association (ISMETA)
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THE ROLE OF SOMATIC MOVEMENT EDUCATION & THERAPY IN COMPLEMENTARY AND ALTERNATIVE MEDICINE WITH AN EXPRESSION OF OPINION ABOUT LICENSURE, STANDARDS, AND ACCESS.

Hello, thank you for inviting this diversity of dialogue. I am Dr. Martha Eddy, a Professor at Columbia University - Teachers College. I am currently involved in developing research models for the qualitative analysis of movement. I am here to represent the International Somatic Movement Education & Therapy Association otherwise known as ISMETA. ISMETA is a self-regulating board that registers individual somatic practitioners of movement education and movement therapy. Somatic movement education and therapy aims to enhance movement behavior. The eleven ISMETA approved training programs that teach disciplines such as The Alexander Technique, Rubenfeld Synergy®, Laban Movement Analysis, BodyMind Centering®, and Rolf Movement Integration, among others, train our registered practitioners. Each individual and professional organization in our field shares skills in assisting people to gain greater awareness of their movement habits and movement's role in communication, vitality, and self-expression.

ISMETA wishes to assert four ideas about regulation, access, and research. Firstly, access to somatic practices is currently threatened in New York State. *The massage board is challenging in particular, somatic practices that use touch.* **This has included even those somatic movement practices that use movement**

re-patterning to support the facilitation of new awareness and proprioception. The assumption that one field can establish standards for another completely different field needs to be challenged.

Secondly, we realize that the NCCAM classification of CAM practices has been developed for research purposes. However, we are aware that it is being used by other governmental agencies, such as the Department of Education as a model for their classifications of instructional programs (which in turn influences the O*NET categories). **Even without intention the NCCAM is setting a precedent for other organizations and, in our case, our practices are not specifically or accurately classified. Thus, viable and successful Somatic Movement Practices are being omitted, or inappropriately classified with other practices affecting the legitimacy of these fields.**

This furthermore can create problems when licensing is being discussed because the requirements for one discipline may not be appropriate or applicable to every other discipline. What is the solution? A licensing board for each modality? Of course not, this would be a costly and inefficient task to accomplish, however it is also unlikely that any one set of standards will be suitable for the diverse modalities classified by WHCAM. We need to find another solution.

ISMETA has developed a Scope of Practice, Standards of Practice, a Code of Ethics, and Grievance Procedure, which are agreed upon by all of its registered members. ISMETA believes strongly that this model of self-regulation not only benefits our profession, but also enhances the possibility of any individual to have access to somatic movement disciplines of their choice.

Thirdly, the notion of "uniform standards to all CAM practices" also concerns us. ISMETA would like to see regulatory standards be developed by practitioners from specific fields or by committees inclusive of these practitioners. These standards must be true to the model they represent. The somatic paradigm is not necessarily best represented by either allopathic or traditional 'hard science' models.

Fourthly, the diversity of types of CAM also raises issues about research appropriate to somatic movement. Double blind experimental research may prove too reductionistic for the types of questions about movement choices and behavior that we are addressing.

We can glean much from the quantitative studies on biomechanical aspects of movement as well as from the studies of applied physiology. In the work of somatic movement education and therapy the client's movement experience involves an understanding of motor functioning but also reaches into the arena of human expression and communication. Improved movement comes not only from exercise but also through gaining awareness by increased proprioception, enhanced motivation, and applied

understanding of movement principles. (E.g., that there is a constant interplay between mobility and stability; function and expression...etc) The skills employed by such a practitioner are highly individualized and the benefits may vary widely from one client to the next. Thus, standards developed from double-blind placebo studies will not always accurately represent Registered Movement Educators or Registered Movement Therapists. The case study work of neurologists Oliver Sacks and Jonathan Cole may be a useful model. Inclusion of Qualitative research methods allows for holistic, rich and in-depth analysis of these processes.

Increasing the variety of research models accepted by NCCAM to include qualitative studies, (e.g. case studies, cross case analyses, ethnographic analyses, and historical reviews) **combined quantitative and qualitative approaches, and single subjects analyses as well as multivariate analyses could better inform the public about complex and overlapping aspects of human behavior. This type of research can, in turn, support the visibility of holistic therapies and thereby the process of giving the public access to a full spectrum of alternatives.**

Thank you for your consideration of the needs of the public and the specific nature of somatic disciplines concerned with human movement in meeting these needs.

U.S. Department of Education

December 8, 2000

Dear Dr. Morgan and Ms. Korb,

As authorized representatives from the organizations below, we have reviewed the second draft of the *Classification of Instructional Programs (CIP - 2000)* and respectfully submit the comments and corrections in this letter.

We can only begin to imagine the work involved in your overwhelming job of updating this document. Our professions, categorized in Series number ***51.43 Alternative, Complementary and Somatic Practice Health and Therapeutic Services*** have wrought big classification challenges. We sincerely hope you understand our firm commitment to support your efforts with accurate, current information that best represent our educational programs in the growth areas of health and wellness. This in turn will provide a truly updated document for public use.

First, we'd like to put our comments and suggestions in context. It is our understanding that it was your group's decision to apply a classification system developed at the National Institutes of Health, National Center for Complementary & Alternative Medicine (NCCAM) to our professions' educational training programs for the *CIP - 2000*.

The purpose of the NCCAM's *Classification of Complementary and Alternative Medical Practices*, now referred to as the *Major Domains of Complementary & Alternative Medicine* is to provide a reference tool in evaluating research grant applications. While it has other related purposes, all center on expanding research outcomes. This classification system was not arrived at to describe instructional programs preparing professionals to practice these modalities.

We, as representatives from instructional programs listed in the NCCAM's classification system of CAM modalities, and, therefore, the second draft version of the *CIP - 2000*, urge you to evaluate this framework's use for its intended purpose, and consider our suggested adaptations inclusive of educational purposes rather than based on research science purposes alone.

We are eager to assist you in clarifying the criteria for categorizing, entitling and defining our educational training programs, and would welcome engaging NCCAM staff and advisory council members as well. Because you have been through a number of reviews and revisions already, we hope our input can directly serve to integrate the final feedback you receive regarding Series ***51.43***.

Guided by the review instructions and request for feedback on the second draft of the *Classification of Instructional Programs (CIP - 2000)* "...comment on the appropriateness of the titles and definitions used for the new programs and provide corrections or alternative titles or definitions, where needed", we strongly urge you to consider the following two proposals and choose one in accordance with your overall review of ***51.43.***

Proposal I

Re: the new/added program title and definition ***51.4307 Somatic Bodywork:***

> A range of individual systems, modalities and treatments is included under this title. The educational providers of some of the systems listed do not identify their instructional programs as Somatic Bodywork. We request that you consider a re-categorization in ***51.43*** to include the following

Alternative category titles:

> ***Somatic Bodywork.***
> ***Movement Education and Movement Therapy.***
> ***Energy-Based Therapies.***

Alternative definitions:

> ***Somatic Bodywork***. A program that prepares individuals to promote physical and emotional balance and well-being through the application of skilled touch principles and techniques. Instruction includes hands-on methods, anatomy and physiology, structural integration and various holistic health systems, practice management, professional standards and ethics. (Breema, Hellerwork, lymphatic drainage, Rolfing/Structural Integration, Rosen Method, and others).
>
> ***Movement Education and Movement Therapy.*** A program that prepares individuals to promote somatic awareness and optimal psychophysical functioning to enhance functional and expressive integration. Instruction includes skilled touch, kinesthetic awareness processes, movement observation, assessment, guidance and patterning methods, verbal, touch and movement communication, practice management, professional standards and ethics. (Alexander Technique, Aston Patterning, Body-Mind Centering, Feldenkrais Method®, Laban Movement Analysis, Trager Approach, Yoga Teacher Training, Yoga Therapy and others).
>
> ***Energy-Based Therapies.*** A program that prepares individuals to promote health and well-being through the application of techniques intended to affect the human energy system. Instruction may include a combination of theory and basic principles of orthodox and energetic anatomy and physiology, energetic evaluation and integration, skilled touch, communication and facilitation skills, energetic nutrition, movement, stretching postures, practice management, professional ethics, and service delivery, as appropriate to each practice.

(Bioenergetics, cranio-sacral therapy, Polarity Therapy, Reiki, Therapeutic Touch, Qi Gong, and others).

Proposal II

Re: the new/added program title ***51.4307 Somatic Bodywork:***

Somatic Bodywork does not convey a broad enough title for the range of individual systems and modalities included under this title. If you do choose to retain this grouping of instructional programs under one category, then we suggest the following

Correction of title:

Somatic Bodywork, Movement Education and Movement Therapy, and Energy-Based Therapies

Re: the definition used for ***51.4307 Somatic Bodywork*** :

1) Massage Therapy and Therapeutic Massage are listed as a program in ***51.4304***.

Correction:
Delete these terms from ***51.4307***. The generic term used for entry level instruction in hands-on methods, applied educationally and/or therapeutically, is "skilled touch". Skilled touch principles and techniques are taught in all Somatic Bodywork, Movement, and Energy-Based Therapy modalities.

Replace with:
"A program that prepares individuals to promote physical and emotional balance and well-being through a combination of skilled touch principles and techniques and other somatic healing arts and modalities. Includes instruction in skilled touch;" etc.

2) The word "hypnotherapy" is listed as a program in ***51.4303***.
Correction:
Delete "hypnotherapy" from this section.

3) The word "aromatherapy" is listed as a program in ***51.4301***.
Correction:
Delete "aromatherapy" from this section.

4) Reiki is one of many methods of energy-based therapies.
Correction:
Include with list of other energy-based therapies.

5) Cranio-sacral therapy is a program area best associated with Somatic Bodywork.

Correction:
Move from ***51.4304*** to ***51.4307***

6) Yoga teaching and yoga therapy are forms of movement education and movement therapy instructional programs.
Correction:
Include with other movement education and movement therapy programs.

7) Colon Hydrotherapy is a body cleansing modality, quite distinct from any approach to somatic bodywork, movement, or energy-based therapies. If anything, it has more connection with Nutritional Counseling, although it is different from that as well.
Correction:
Delete under category ***51.43.07***. Include under the category ***51.4309 (..., Other)***.

Correction of definition used for

Somatic Bodywork, Movement Education and Movement Therapy, and Energy-Based Therapies. A program that prepares individuals to promote physical and emotional balance, health and well-being which may include a combination of principles and techniques of skilled touch, kinesthetic awareness, movement evaluation and patterning methods, techniques intended to affect the human energy system, mind-body healing methods and other somatic healing arts. Instruction may include skilled touch, anatomy and physiology; kinesthetic awareness processes; movement observation, assessment, and guidance methods and verbal, touch and movement communication; structural, functional and expressive integration; energetic evaluation and integration; practice management, professional standards and ethics. (Breema, Hellerwork, lymphatic drainage, Rolfing/Structural Integration, Rosen Method, Alexander Technique, Aston Patterning, Body-Mind Centering, Feldenkrais Method®, Laban Movement Analysis, Trager Approach, Yoga Teacher Training, Yoga Therapy, Bioenergetics, cranio-sacral therapy, Polarity Therapy, Reiki, Therapeutic Touch, Qi Gong, and others.)

In summary, we strongly urge you to accept **Proposal I** as detailed above. This would entail a **re-categorization** to more appropriately group together several diverse modalities into three distinct categories: 1) ***Somatic Bodywork***, 2) ***Movement Education and Movement Therapy***, 3) ***Energy-Based Therapies***.

If upon giving this proposal careful consideration, its adoption is simply not possible, then we ask you to accept **Proposal II**. This would involve **an expansion of the title** ***Somatic Bodywork*** to ***Somatic Bodywork, Movement Education and Movement Therapy, and Energy-Based Therapies***. This expanded category title would more accurately represent the diversity of systems and modalities included under this one category.

Again, thank you for your extraordinary efforts to update the *CIP – 2000.*

Respectfully yours,

Ellen M. Barlow
Board of Directors
International Somatic Movement Education & Therapy Association (ISMETA)
Ebarlow@gateway.net

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CC: National Center for Complementary & Alternative Medicine (NCCAM), NIH

401 North Michigan Avenue
Suite 2100
Chicago IL 60611
312 494-3030 xt 3989

FLYING COLORS

2

Fax

To: Doris Kingsbury **From:** Autumn Williams

Fax:301 480-1691 **Pages:**

Re:WHCCAMP Report Info **Date:** 1/17

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Doris -

This came in yesterday afternoon - we will register, but wanted to forward additional info.

Autumn

Jack

File in
NYC 1/23 as
~~under~~ Josepher
testimony

Xponents INC.

TRANSMITTAL COVER SHEET

DATE: 1/16/01

NUMBER OF PAGES INCLUDING THIS SHEET: 27

TO: Autumn

PHONE (312) 494-3030

FAX (312) 494-3015

FROM: Maria A. Josepher, Deputy Director/CFO

PHONE (212)243-3434 Ext.#105

FAX (212)243-3586

- ☐ URGENT
- ☐ FOR YOUR REVIEW
- ☐ PLEASE RESPOND
- ☐ FOR YOUR FILES
- ☒ AS PER OUR CONVERSATION

COMMENTS: I was told by Dr Gordon + Carin that I will be on a panel focusing on CAN's + high risk populations (ex-offender / substance user)

151 West 26th Street • New York, NY 10001
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Visit our Website: http://www.exponents.org
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White House Commission on Complementary and Alternative Medicine Policy Registration Form

New York City Town Hall Meeting
January 29, 2001 – 9:00am-6:00pm*
Lighthouse International Conference Center and Auditorium
111 East 59th Street
New York, NY 10022

*Times are tentative and may be adjusted.

Last/Family Name (required)	Josepher
First Name	Maria (Sam)
Middle Name	
Degree	B.S.
Organization (required)	Exponents Inc.
Address	151 West 26th St.
City	New York
State	NY
Zip Code/Postal Code	10128
Telephone (required)	212 243-3434
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Email Address	SJosepher@aol.com

Anyone wishing to present oral comment must register by end of day, January 18, 2001.

I wish to:

- (•) Provide Oral Comment
- ( ) Observe (no oral statement)

Please note that the public comment session will be throughout the day. There is a time limit of 5 minutes for all oral comments- 3 minutes of testimony and 2 minutes of questions from the commissioners.

My oral comments will focus on: (check any that apply) Provision of CAMs to minority & high risk populations, people with disabilities

1. Coordinated Research and Development to Increase Knowledge of Complementary and Alternative Medicine Practices and Interventions. [ ]

- What can be done to expand the current research environment so that practices and interventions that lie outside conventional science are adequately and appropriately addressed?
- What types of incentives are needed to stimulate the research of CAM practices and interventions by the public and private sectors?
- How can we more effectively integrate the CAM and conventional research communities to stimulate and coordinate research?

2. Guidance for Access to, Delivery of, and Reimbursement for Complementary and Alternative Medicine Practices and Interventions.

- Do you have ready access to CAM practices and interventions?
- How can access to safe and effective CAM practices and interventions be improved?
- What types of CAM practices and interventions should be reimbursable through federal programs or other health care coverage systems?

3. Training, Education, Certification, Licensure, and Accountability of Health Care Practitioners in Complementary and Alternative Medicine.

- How can uniform standards of education, training, licensure and certification be applied to all CAM practitioners?
- What training and education should be required of all health care providers to assure access to safe and effective CAM practices and interventions?
- What sources of funds exist for the education and training of CAM practitioners?
- Are performance standards or practice guidelines needed to ensure the public will have access to the full range of safe and effective CAM practices and interventions?

4. Delivery of Reliable and Useful Information on Complementary and Alternative Medicine to Health Care Professionals and the Public.

- How can useful, reliable, and updated information about CAM practices and interventions be made more accessible? How would you like to receive such information?
- As a consumer, what kinds of information about CAM practices and interventions are most needed and important to you?
- As a health care provider, what kinds of information about CAM practices and interventions are most needed and important to you?

Please provide a written summary of your 3 minute oral statement (500 characters or less):

Special Assistance Requirements:

- Sign Language Interpretation
- Wheelchair Access

How did you hear about the Town Hall Meeting:

____Web Site ____Federal Register ____Other: Dr. Gordon

PLEASE FAX FORM TO: 212 494-3015

Exponents, Inc. 2000
White House Commission on Complementary
and Alternative Medicine Policy
Maria (Sam) Josepher
Exponents Inc., Deputy Executive Director
Focus: Employee Wellness/ Minority and Incarcerated Populations

1. Summary

Exponents is a not-for-profit, community-based organization, operating in New York City since 1990. A majority of Exponents' board members are from minority communities and reflect life experiences of the agency's clients. Exponents' clients are inner city individuals and families whose lives are caught up in cycles of drugs and crime. Most have been incarcerated, or involved with the criminal justice system. Most are HIV positive, or with AIDS, and many are existing with dual and triple diagnosed conditions. The agency has a long history of successfully engaging substance abusers and the incarcerated populations because of its strong reputation among recovering addicts and outreach efforts in the correctional system.

Exponents offers substance users and their families a continuum of prevention and care services. From early intervention/harm reduction to recovery readiness; from HIV/AIDS education to health and wellness education; from drug treatment to career planning.

Exponents oldest program, ARRIVE, was initially targeted (1988) for intravenous drug users coming out of prison and was one of the first efforts in the United States to address AIDS with individuals going in and out of prison. The program is presented in a training format and is delivered primarily by peers, persons who have had personal experience with addiction or HIV/AIDS. ARRIVE holds five, 8 week, 24 class training cycles a year for 750 individuals. ARRIVE is funded through the Ryan White CARE Act and private sources. An outcome observation from independent evaluation stated, "Students appear to emerge from ARRIVE not only somewhat better educated and better prepared for employment in HIV and drug treatment services organizations, but also with a better sense of self-worth and belonging." (Hunter, College, School of Health Science, Center on AIDS, Drugs & Community)

There are now over 5,300 graduates from ARRIVE, many employed in the AIDS and substance abuse field. While attending ARRIVE, and post-graduate classes, topics covered both traditional and alternative approaches to health and recovery. Workshop topics and experiences include: risk reduction for sex and drug use; tuberculosis; the immune system; nutrition and vitamin supplements; aroma therapy; hepatitis ; diabetes; stress management and meditation; sound healing for immune boosting (crystal bowls); cognitive, psycho-education relapse prevention; infection control; mainstream HIV/AIDS medications; complementary and alternative treatments; syringe cleaning and harm reduction education; and eroticizing safer sex. A brief meditation is practiced before and after all training sessions. Soothing music is often played softly in the background during presentations in order to optimize relaxation and learning.

Services are provided in a clean physical environment and in a non-judgmental, compassionate setting. Exponents utilizes hospital quality air purifiers throughout the facility to help reduce infections and specialized hepa vacuum cleaners which trap allergens, dust and fumes to reduce irritants causing asthma and allergy attacks. Purified water and medications refrigeration is also provided.

There are 45 fulltime staff members at Exponents, more than three-quarters of are ARRIVE program graduates, persons in recovery, and ex-offenders. Twenty-five percent

are HIV positive; a number have Hepatitis C; 15% have diabetes; and 25% have asthma. (These statistics are gathered through self-disclosure.) It is an organization that has been built from within and represents the efficacy of the peer model. It is also an organization that benefits from the participation of some very fine professionals. It was, however, the **need to keep people with disabling diseases well** and working which prompted the organization to look extensively into providing the skills and information that promote wellness and prevent further deterioration and other illnesses.

2. Comparison to convention

> In many ways Exponents has broken away from conventional methods of engagement and treatment for substance using populations. Focusing on health and wellness, especially HIV/AIDS prevention and care, services are provided whether the individual chooses to be abstinent from substance use, or not. The consistent ability of ARRIVE to engage and graduate over 75% of its students, demonstrates both an eagerness and receptiveness to innovative programs of a population generally considered hard to reach. ARRIVE's training format is much less invasive than traditional treatments but draws upon many of the underlying values established in drug free treatment. The development of a sense of community among participants, a social learning approach and credible role models are intrinsic to the agency's culture.

At ARRIVE, getting off of drugs is not required for participation but overcoming addiction is a main theme of the program's overall message. Services offered include conventional and alternative modalities and we feel this is the best of both worlds. Final outcomes with regard to cost we feel are immeasurable. If a person learns something at ARRIVE that keeps them out of the hospital for one day, it would pay for the entire cost of the two month training ($1000).

Added to the conventional, life-stabilizing services, are alternative therapies to enrich and move individuals forward with increased self-awareness and mindfulness through the practice of meditation. They are encouraged and given skill training to be **partners in their own healing**: on how to select a physician; preparing for a doctor's visit; and what questions to ask regarding HIV, Hepatitis C, etc. Curriculums are written to translate difficult disease concepts into easily understood subjects. **Coping skills to reduce relapse to drugs** are provided through conventional group support along decelerated music, auricular acupuncture and aromatherapy.

Stress reduction classes which included **progressive relaxation**, conscious breathing, and methods of rage reduction were also taught in the **Rikers Island prison** for its HIV population. These were well received and reported effective by inmates in helping them to reduce stress. These classes were stopped because of the difficulty in gaining cooperation of prison escorts, and lack of private training areas needed to maintain confidentiality.

Progressive relaxation tapes with affirmations written by drug treatment clients themselves have been produced and are distributed for those entering detoxification facilities, those **having problems sleeping**, and to those who want a 'feel good' substitute to drug use.

Programs for Staff

Exponents utilizes hospital quality **air purifiers** throughout the facility to help reduce infections and specialized **hepa vacuum cleaners** which trap allergens, dust and fumes to reduce irritants causing asthma and allergy attacks. **Purified water** and medications refrigeration is also provided. Air purifiers may be borrowed for home use during times of illness for both staff and families of employees.

An extensive **wellness lending library** for staff has been accumulated with books audio and videotapes on meditation, diet, exercise, yoga, herbs, asthma, skin conditions, hepatitis, nutrition, vitamin supplements, reiki, acupressure, massage, menopause, conscious breathing and spiritual practices. Employees are encouraged to borrow books and dialogue with other members of the staff as well as support each other in dieting, exercising, and smoking cessation.

Offices are equipped with soothing sound generators and rock fountains for both staff and client benefit. Staff members are provided with audio equipment and numerous relaxation CD's including those utilizing **brain synchronization technologies** now available to the general public and developed by musicians such as Steve Halpern, physicians such as Andrew Weill, and organizations such as the Synchronicity Foundation. These CD's are also provided for employees during their hospital stays. These have also been found effective among clients and staff suffering from insomnia. Quartz crystal bowls which produce relaxing harmonics are also distributed around the 15,000 square foot space.

Organizational policy allows for sick time to be used for well visits thereby encouraging employees to use preventive measures. **Organizational policy** implemented catastrophic sick time of up to one month for hospital stays of over four days and during which other staff members are committed to fill in for the sick employee. This policy was implemented when anecdotally it was observed that ill employees only became sicker when faced with the pressure of returning to work or having to go on disability at a greatly reduced pay. This **reduces the stress** a sick employee has when using up all one's sick and vacation time and fear of losing one's job when facing prolonged illnesses. It has been noted that persons with illnesses such as pneumonia (especially in the HIV population) return to work in an appropriate time frame when truly ready to begin work again without relapse to illness.

Smoking cessation and wellness workshops which included group meditations and crystal bowl harmonics presented by the Deputy Executive Director has also prompted more than half of the smoking staff to stop. Employees have been offered individual coaching in the creation of their own wellness plan.

3. Barriers

Political correctness of prison policy which keep our system **a warehouse of human life rather than an opportunity for re-education.**

Most employers (even in the HIV field) are **shortsighted in the handling of employee benefits** which would allow people with disabilities such as HIV to function productively in the workplace.

Lack of knowledge and **acceptance of technologies and modalities** which can create environments promoting healthier brain wave patterns, reduce stress, increase creativity, and enhance whole brain function.

Lack of research and hard evidence available supporting technological modalities.

For the most part, the conventional addiction treatment field maintains a politically correct, abstinence biased, opposition to new and alternative treatments. This opposition can be seen in the refusal of the federal, and many state governments, to support alternative harm reduction modalities such as needle exchange.

Complimentary and alternative methods utilized in drug treatment are not eligible for reimbursement under the current Medicaid system. What are needed are policies that acknowledge alternatives as a viable health choice. Funding needs to be made available for programs to educate and practice these alternative methods.

4. **Target**

Access should be made to those in most desperate need. The homeless, those incarcerated the poor communities, the infirm. Complementary and alternative approaches to health are generally self-empowering and can have their greatest impact in our poorer and most marginalized communities.

Persons with **mental illness and chronic diseases** who otherwise are able to work but need a **supportive environment and enhanced coping skills** also should have access to education and services which helps to foster wellness, prevention of disease and self-empowerment.

5, **Additional policy recommendations**

Prioritizing the hiring of persons with personal experience with addiction in all drug treatment and prevention programs receiving government funding. **Funding employers** to implement **employee wellness** within their organization to support productivity and longevity among persons with disabilities.

Funding of legitimate and acceptable projects utilizing meditation, enhanced coping skills and environmentally enhancing technologies for use in the prison system.

A shift in the spending of the federal government's drug budget to represent a 50-50 division between overseas interdiction and programs for substance abusers at home. Currently, 75% of federal funds goes for interdiction.

Reform of mandatory minimum drug sentencing and reform of NY State's Rockefeller Drug Laws.

Lifting the federal ban on funding for needle exchange and increased support for harm reduction programs.

Decriminalizing the sale and possession of syringes (recently achieved in NY State).

Exponents, Inc. 2001
White House Commission on Complementary and Alternative Medicine Policy

Biography: Maria (Sam) Josepher

Ms. Josepher is the Co-founder of Exponents, Inc., a nonprofit organization dedicated to improving the lives of recovering substance users, ex-offenders and their families by providing innovative training programs and peer facilitated services. She was instrumental as co-creator of the ARRIVE Training, a model HIV prevention and skills building program for parolees and other high risk populations in New York City. Ms. Josepher has been with Exponents for twelve years where she successfully manages programs, finance, technology and development as Deputy Executive Director and Chief Financial Officer. She is also an executive mentor, coach and non-profit management consultant.

Sam has a twenty-five year professional history as an administrator, trainer, and grant writer. Her career as an educator and training developer has spanned many levels and settings including prisons, universities and schools, the military, and corporations. She has extensive experience in organizational and workforce development and grants administration.

Ms. Josepher is a long-term meditator and has a special interest in the use of modern meditative technologies for stress management in prisons, the workplace and for the disabled. She has been developing wellness strategies for organizations serving persons with a history of substance use and coaching employees in foundational skills for the last decade.

Sam is a member of the Screen Actor's Guild and has appeared in *Law and Order* and Woody Allen's recent movie release - *Small Time Crooks.*

cy given to Michelle & Steve

Albrecht, Joan (NCCAM)

From: Coalition for Natural Health [cnh@naturalhealth.org]

Sent: Wednesday, February 07, 2001 12:22 PM

To: Whccamp (NCCAM)

Subject: Fw: Testimony of Jeff Goin before WHCCAMP NY Town Hall Meeting

To whom it may concern:

Thank you for the opportunity to participate in the NY Town Hall Meeting. I was pleased and impressed with the turnout supporting natural health feedom. Attached please find my written testimony for inclusion in your record. Please acknowledge receipt of this document by replying to this email.

Best regards,

Jeff Goin
President
Coaltion for Natural Health

Mr. Chairman and members of the Commission, my name is Jeff Goin. I am president of the Coalition for Natural Health, a grassroots organization that represents over 2,500 natural healers nationwide. The majority of my testimony today deals with the advisability of this body's concerning itself with the matter of licensing natural healers at the state level.

The arguments against the White House Commission's adopting a position on this matter are simple and straightforward: Licensure and regulation are within the sole province of the states. The circumstances and needs that exist in Alaska are very different from those prevailing in Louisiana, New Mexico, or Iowa. Only the lawmakers, consumers, and practitioners can know what – *if any* – level of licensure and regulation is appropriate in the various states.

The Coalition, its members, and its stakeholders are grateful for the good and necessary work that the White House Commission is carrying out. However, I must respectfully convey to you, in the strongest possible terms, the extent to which we feel it inappropriate for a Federal agency, department, or advisory board to insert itself at the state level for purposes of mandating, or even recommending processes or guidelines for licensure. If this commission were to engage in this activity, it would be entirely unprecedented. Doing so would be akin to the Federal Government setting professional requirements and standards for dogcatchers, brain surgeons, and accountants. Again, the establishment and maintenance of professional standards and qualifications for natural healers is best left to the states.

Ultimately, though, the most effective screening of natural health practitioners will be neither the state nor federal governments. It will be consumers. As it relates to such natural healers as Ayurvedics, Reiki healers, and Naturopaths, these practitioners are, first and foremost, advocates for healthier lifestyles. The health principles they espouse are non-invasive, do not involve the prescription of drugs, and are not a danger to the consuming public. In fact, according to statistics compiled by the Natural Nutritional Foods Association Americans have a greater chance of being killed by lightening (89 deaths annually) than from consuming natural supplements (16 deaths annually). Prescription drugs, conversely, account for deaths of 106,000 American consumers each year. Providing education about living a healthy lifestyle and the application of noninvasive natural health modalities pose virtually no threat to the consumer. The same statement cannot be made about the conventional medical model or the desired goal of naturopathic physicians.

Many natural health modalities have histories that predate conventional medicine by thousands of years. The proof of their efficacy is found in the sustenance of their practice. If the services that these healers offer weren't effective, they wouldn't be flourishing as they are now. Simply stated, the most important litmus test for these service providers will be the one administered by consumers and the competition of the free market.

The objective of the White House Commission should be to enable and expedite the flourishing of natural health in this country, not to restrict it. Growth and availability of these treasured services will not come about by giving consumers fewer choices through restrictive licensing procedures that have proven to be a dismal failure. This is evidenced by the legislatures of 17 states that have soundly rejected this type of restrictive legislation over the last four years. In this regard, if the Commission is to look to any developments at the state level, it should be to encourage the advancement of natural health freedom bills such as the innovative and progressive legislation passed in the state of Minnesota last year.

Thank you for your time and attention.