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HEALING NEWSLETTER

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Eating Wisely Gets Harder All the Time

EPA Can't Afford to Ban Carcinogenic Pesticides

BY JANET S. HATHEWAY, *Senior Project Attorney, Natural Resources Defense Council, Washington, D.C.*

This article first appeared in *The Los Angeles Times,* Thursday October 8, 1987 and is reprinted here with permission of the author.

The good news is that federal agencies are finally amassing basic data on the health effects of some widely used pesticides. The bad news is that the current federal pesticide law virtually guarantees that even the most dangerous pesticides will remain on the market.

According to a recent grocery retailers' survey, 96% of Americans believe that pesticide residues in foods are a hazard. Such suspicions were confirmed this spring by the prestigious National Academy of Sciences, which reported that cancer-causing pesticides are used extensively on even basic foods like tomatoes, apples and potatoes.

The NAS study shows that lifetime cancer risks from dietary exposure to only 28 pesticides could be as high as 5.8 cancer cases in 1,000 exposed people. The academy noted that for many of the carcinogenic pesticides, substitutes are available that do not cause cancer.

One might have expected a swift response from the federal agency charged with regulating pesticides, the Environmental Protection Agency. But that has not happened. Not one of the 28 carcinogenic pesticides has been eliminated from the American food supply. The culprit is the Federal Insecticide, Fungicide and Rodenticide Act, which perversely hinders the immediate removal of any pesticide—no matter how dangerous—that is now on the market and in your groceries.

Included in the pesticide law are two obscure provisions that exist for no reason other than to compensate producers of the most hazardous pesticides for regulatory action. These provisions, which are slowly gaining notoriety on Capitol Hill, are referred to as "indemnification" and

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The current federal pesticide law virtually guarantees that even the most dangerous pesticides will remain on the market.

No other law promises federal funds to companies that manufacture extraordinarily dangerous products. Even such politically weighty industries as automobile and pharmaceutical manufacturers must absorb the costs of their mistakes and recall defective products with no governmental assistance.

Pesticide indemnification and disposal obligations pervert incentives for companies to develop safer pesticides or to withdraw agricultural chemicals as soon as hazards are identified. Indeed, the provisions might motivate unscrupulous pesticide makers to step up production when incriminating health data emerge in order to further discourage EPA suspension of their product. Even worse, these requirements effectively eviscerate EPA's power to halt the use and sale of pesticides that are found to pose grave risks.

Both of these provisions mean big money to pesticide manufacturers. At the request of a Senate appropriations subcommittee, EPA recently estimated costs of indemnities for seven widely used, high-risk pesticides. If EPA immediately removed only these seven from the market, the action would cost more than $400 million. These funds would have to be diverted out of EPA's a Office of Pesticide Program annual budget of only $40 million.

The EPA estimated indemnity costs of $161.5 million for alachlor, a widely used corn and soybean herbicide that the NAS report identified as posing a significant carcinogenic risk; for benomyl, a carcinogenic fungicide used extensively on fruit, the cost could run to $78 million. EPA expects disposal of banned pesticides to be at least as expensive as indemnification.

Unless the federal pesticide law is reformed, EPA's pesticide budget will be strained beyond the breaking point, and objective judgements concerning regulatory matters will be jeopardized. With hundreds of old pesticides in desperate need of assessment for their potential to cause cancer, birth defects, neurological disorders and other disastrous effects, EPA simply cannot afford an insurance program for pesticide makers.

If the skimpy pesticide budget is handed over to pesticide companies that make bad products instead of being spent to improve the regulation of pesticides, Americans will continue to consume pesticides in their food and water.

There are some solutions, but they are not of the glamorous variety that appeal to most politicians. Congress needs to eliminate the pesticide law's indemnification and disposal

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requirements. Congress should provide EPA with an effective pesticide-recall authority and sufficient resources to carry out its other charges under the law. No congressional action deserves to be called pesticide reform without these crucial amendments.

Janet S. Hathaway is a senior project attorney with the Natural Resources Defense Council in Washington, a research and advocacy organization devoted to protecting public health and the environment.

These requirements effectively eviscerate EPA's power to halt the use and sale of pesticides that are found to pose grave risks.

While we're on the subject

The last time we asked you to speak out, sulfites were being added to salad materials by nearly all restaurants across the nation. The same week you received our sulfite appeal, the Centers for Disease Control in Atlanta announced the sulfite-caused death of a young girl in the Northwest who had been exposed to high concentrations in a single serving of guacamole.

This time, we're asking you to write your senators and representatives demanding that they share in your outrage at the "indemnification" and "disposal" clauses of the Federal Insecticide, Fungicide, and Rodenticide Act. Please, dear reader, cry bloody murder in the House of Representatives, the halls of the U.S. Senate, and to the White House itself.

The "indemnification" and "disposal" clauses of the FIFRA are bad law and should be struck down for the benefit of the American people. Any Senator or Representative who would dare to remain silent on this issue, or to uphold FIFRA as it stands, should be opposed for re-election. FIFRA's "indemnification" and "disposal" clauses are vile and corrupt, and prevent the Environmental Protection Agency from regulating carcinogenic pesticides.

The NAS study shows that lifetime cancer risks from dietary exposure to only 28 pesticides could be as high as 5.8 cancer cases in 1,000 exposed people.

Convention Reminder

Remember the Pasadena, CA, Jan. 15-17 National Health Federation Convention. For info please call the NHF National Headquarters office in Monrovia, CA, tel.(818) 357-2181.

With hundreds of old pesticides in desperate need of assessment for their potential to cause cancer, birth defects, neurological disorders and other disastrous effects, EPA simply cannot afford an insurance program for pesticide makers.

Sample text:

All Senators
Senate House Building
Washington, D.C. 20510

All Representatives
House Office Building
Washington, D.C. 20515

Dear Senator.....: or Dear Representative.....:

Please share my outrage and please represent me and all our fellow Americans in acting resolutely and immediately to quash the "indemnification" and "disposal" clauses of the Federal Insecticide, Fungicide, and Rodenticide Act.

No industry should be so protected that it can manufacture and market carcinogenic materials. But makers of insecticides, fungicides, and rodenticides *are* so protected.

The Environmental Protection Agency cannot stop the use of carcinogenic materials because under the law, under FIFRA, to ban a pesticide, fungicide, or rodenticide, the EPA must *purchase at retail rates with tax dollars* all of the remaining stockpiled chemical and, *again with tax dollars, pay for its disposal.*

The EPA has nowhere near the budget necessary to protect Americans against even a single one of these cancer causing chemicals. Please, Senator, as a person of conscience, as an American, do something to quash the "indemnification" and "disposal" clauses of FIFRA now.

For further information, please contact Janet S. Hathaway, senior project attorney for the Natural Resources Defense Council in Washington, D.C. tel. (202) 783-7800.

Sincerely,

Researcher Ties Pesticide to Town's Cancer Cluster

The *United Press International Wire Service* reported Tuesday, December 1, 1987 from McFarland, California, that a public health researcher there resigned rather than issue McFarland a clean bill of health after a cancer study. Thomas Lazar, who resigned his post as coordinator of the Kern County childhood cancer study in McFarland, believes that pesticides may have caused a cluster of cancer cases in the Kern County farming community. "I believe there is something there that is causing the cancer and I think it eventually will be linked to pesticides," said Lazar on Monday, November 30th.

Stamp of Approval

Lazar reported that although his study had revealed pesticide contamination of the Kern County water supply, the county health office issued a report giving McFarland a stamp of approval.

"The residue was just at trace levels in the water in some areas of the town but in others, cancer-causing elements were quite high," Lazar said in a telephone interview from his office at the United Farm Workers union headquarters in Kene, where he now works.

"I believe there is something there that is causing the cancer and I think it eventually will be linked to pesticides,"
—Thomas Lazar

The UFW which has been active in pesticide issues for some time now, has joined McFarland parents in contending that excessive pesticide use is the cause of the cancer cluster. There has been no response from the county health department.

Lazar's announcement followed the death November 26th of 14 year old Mario Bravo, who died in a Delano hospital of liver cancer, the fifth child cancer victim in a two-city-block area of McFarland. No less than 11 confirmed cases of fatal childhood cancer have been documented in the McFarland city limits in the recent decade. Lazar himself said there may now be as many as 30 childhood cancer cases in the McFarland area.

Expanded Probe

A study of the McFarland childhood cancer cluster which has been underway since 1985 has failed to identify the cause or causes, officials say. State Senator Art Torres (D-Los Angeles) has already held two hearings on the McFarland cancer epidemic. At the conclusion of the second hearing, held in October, Senator Torres stated that he will call for an expanded probe of the McFarland cluster, emphasizing that the county health department be relieved of its involvement in the study and that it be conducted instead by state officials.

There has been no response from the county health department.

Membership Reminder

Remember to "re-member" yourself. When did you last renew your membership? Please keep yourself current, informed, and in-the-know. Suggested minimum annual donation $25.00 *in the U.S.*

OTA Studies Cancer Alternatives

Editor Hildenbrand on Panel

Gar Hildenbrand, writer and editor of the Gerson Institute's Healing Newsletter, has been appointed to an 18 member advisory panel of the United States Congressional Office of Technology Assessment (OTA). Hildenbrand is serving as an advisor for an OTA study tentatively called "Unorthodox Cancer Treatments".

This timely study, an unforeseen event in both conventional and unconventional cancer treatment circles, was the result of a direct request from John D. Dingell, Chairman of the Full House Committee on Energy and Commerce, and member of the Technology Assessment Board. Mr. Dingell has been characterized by National Health Federation legislative advocate Clinton Miller as one of the most influential men in world medicine. The Committee on Energy and Commerce controls funding for the National Institutes of Health and therefore the National Cancer Institute.

Mr. Dingell's letter to OTA director Dr. John Gibbons has been circulated widely. The complete text follows:

The health-care and economic implications of today's unorthodox therapies are vast.

Dr. John H. Gibbons, Director
Office of Technology Assessment
U.S. Congress
Washington, D.C. 20510
August 12, 1986

Dear Jack:

More than 900,000 Americans will be diagnosed with cancer this year, and each year about 470,000 Americans die of cancer. Despite improvements in treatment for some forms of cancer, progress, as measured in terms of long-term survival, has been slow at best. The overwhelming majority of patients are treated in U.S. cancer centers, teaching hospitals, or the community. Some proportion, however, opt for treatments that are out of the mainstream, including many patients who have tried conventional approaches but have not been helped. Such "alternative" treatments exist both within the United States and outside the country. Some are offered by respected members of the medical community, and others by what many would term charlatans. Many of these treatments may be without benefit, some may actually be harmful, and some, probably a small number, may have value. However, there is a general lack of objective information about them, thus making rational decisions about such alternative therapies extremely difficult.

It would be valuable to the Congress for OTA to describe the general nature of alternative cancer therapies and the theoretical bases underlying these therapies, to estimate how many Americans seek these therapies, and to the extent possible, develop guidelines for evaluating their medical value. There may be particular policy implications associated with some new approaches in this country, for instance involving FDA approval of products, or questions of differential access to treatments. It would be useful if OTA could address such implications as well.

I understand that OTA has been asked to examine existing data about the efficacy of a special treatment, immunoaugmentative therapy, and to design a formal evaluation plan for that therapy. It might be useful to use that specific therapy as a case study of the general issues involved. OTA might consider one or two other specific therapies that are of a different nature for additional case studies.

Should you have any questions in this regard, please do not hesitate to contact Dr. Lesley Russell of my staff.

Sincerely,

(signed) John D. Dingell

OTA's proposal

By September of 1986, OTA responded with a proposal for a full assessment of alternative cancer

Most patients find the internal logic and global mind body emphasis of this perspective intuitively correct and fundamentally appealing.

managements. Following is OTA's description of the study:

NONTRADITIONAL METHODS OF CANCER MANAGEMENT: SCIENCE AND POLICY ISSUES

PROJECT DESCRIPTION: In 1986, it is estimated, more than 900,000 Americans will be diagnosed with cancer, and about half of those people will die from their cancer within five years. Conventional cancer treatments, even when successful, can be painful and disfiguring, and of long duration. Each year, thousands of American cancer patients turn to methods of diagnosis and treatment which have not been assessed through the standard scientific process, and for which there is inadequate information on which to judge their safety and effectiveness. Many health people use nontraditional methods, also unproven, which are claimed to prevent the development of cancer.

The Federal Government has not taken a direct role in evaluating or controlling most nontraditional cancer treatment, although both the Food and Drug Administration (FDA) and the National Cancer Institute (NCI) have acted in certain instances. State legislatures have passed laws legalizing the use of treatments that have not been approved by FDA. For instance, by the mid-1970's, laetrile had been legalized in more than 25 states. More recently, in 1981, Immuno-Augmentative Therapy (IAT) was made legal by the Oklahoma legislature, and the Florida legislature passed a law (repealed in 1984) allowing the use of IAT and other unconventional therapies.

In the private sector, the American Cancer Society has been most active in gathering information about nontraditional therapies and disseminating it to the public. Professional societies and patient advocacy groups have also participated in critically informing medical professionals and the public about these treatments. Proponents of unconventional treatments also have information networks through which they disseminate information.

SCHEDULE: The assessment will begin in January 1987, and the final report delivered to the Technology Assessment Board in June 1988. A case study on IAT will be delivered in December 1987. Other case studies, if decided upon, will be scheduled sometime during the assessment.

The assessment will 1) examine the role of public and private sector bodies in evaluating and providing information about nontraditional treatments; 2) critically review the existing literature, both from mainstream science and from the proponents of nontraditional treatments; 3) estimate, if possible, the number of Americans who avail themselves of these treatments and the financial impact on individuals and on health insurers; 4) examine the potential for conducting evaluations of nontraditional treatments that would meet the same standards of evidence required of mainstream treatments; and 5) develop objective guidelines for planning such evaluations. IAT will be used as a case study for the development of guidelines. There may or may not be other specific case studies.

CONGRESSIONAL INTEREST: Many citizens contact their Congressmen about the availability or the lack thereof of nontraditional cancer treatments, and members of Congress need adequate information about this issue. In addition, the question of whether the current Federal role in this issue is appropriate concerns committees with jurisdiction in health and in the regulation of drugs and biologics.

REQUESTERS/ENDORSERS: The overall assessment has been requested by the House Committee on Energy and Commerce. In addition, Congressman Molinari and 23 other Members of Congress signed a letter requesting that OTA examine the evidence of IAT's efficacy, and develop a protocol to evaluate IAT's efficacy, and develop a protocol to evaluate IAT. Similar requests from Senator Abdnor and Congressman Rinaldo were received. An additional 14 Members of the House and Senate subsequently endorsed the

"The emphasis of unorthodox therapy on nutrition, health as a personal responsibility, pollution, and purification has religious and moral overtones, but also represents themes of great importance not only to patient, but to science and society as well.

original letter from Congressman Molinari.

What we're looking at

Although the staff of OTA began work on the assessment in January, the advisory panel met for the first time on July 21st, 1987 in the OTA conference room at 600 Pennsylvania Avenue, Washington, D.C. An outline of the white paper to Congress has been prepared by the OTA staff and was discussed item by item.

It is not possible to predict the outcome of OTA's evaluation of the existing industry of alternative cancer care, but it is possible that the study will confirm the findings of Dr. Barrie Cassileth, Director of Psychosocial Programs of the University of Pennsylvania Cancer Center of Philadelphia, who is also a member of the advisory panel.

Dr. Cassileth authored an informative study published in 1984 ('Contemporary Unorthodox Treatments in Cancer Medicine', *Annals of Internal Medicine*, 101:105-112). We reproduce its concluding discussion below:

"This study shows that patients who use unorthodox therapies are well educated, frequently asymptomatic, and are in the early stages of disease. Only 25% initiated alternative regimens while under active conventional treatment, and 40% of patients who had used both treatment types had discontinued conventional care after adopting an alternative therapy. Major factors associated with the use of unorthodox treatments included patients' belief that their cancer could have been prevented and therefore was now reversible by the same means, dissatisfaction with conventional practitioners and health care systems, and preferences for nontoxic regimens and for an active role in treatment.

"Although the (660) patients came from 26 states across the country, it is possible that regional preferences may have skewed the relative popularity of unorthodox treatments used by the patients studied. The most commonly used alternative treatments were metabolic, diet, and megavitamin therapies. These and other unorthodox therapies were adopted with the expectation that they would control the disease. Most patients spent under $1000 for the first year of unorthodox care, and 50% spent under $500. Of 138 practitioners of unorthodox therapy studied, 60% were physicians and 18% were board certified.

"Although unorthodox therapies differ by underlying concepts and treatment mechanisms, they share a common perspective. Cancer and other chronic illnesses tend to be viewed not as disease entities, but as symptoms of underlying dysfunction, disorder, or toxicity. Thus, treatments are geared toward improving the patient's own biologic and psychic capacity to counteract illness. Most patients find the internal logic and global, mind body emphasis of this perspective intuitively correct and fundamentally appealing.

"Both the overall orientation and some of the specific practices associated with unorthodox therapies are consistent with the popular contemporary focus on physical fitness, proper nutrition, and improved mental attitude. The practices are also consistent at some level with conventional medicine's emphasis on environmental causes of cancer, with established conclusions that a number of dietary variables may contribute to the development of human cancers, and with media reports that the Federal Government is putting new emphasis on research aimed at preventing cancer through dietary means. Further, similar to the contemporary experience in England, currently popular unorthodox methods are not entirely repudiated by conventionally trained physicians: 60% of unorthodox practitioners in this sample are physicians; and 30% of patients' conventional physicians supported the use of alternative treatments.

"Intrinsic to the belief in unorthodox therapies is that conventional cancer treatments weaken the body's reserve, inhibit the capacity for cure, and misguidedly address the symptom (cancer) rather than the underlying systemic

Similar to the contemporary experience in England, currently popular unorthodox methods are not entirely repudiated by conventionally trained (U.S.) physicians: 60% of unorthodox practitioners in this sample are physicians; and 30% of patients' conventional physicians supported the use of alternative treatments.

disorder. Nevertheless, only a small group of patients studied (8%) had refused to receive any conventional treatment, and 60% of patients who added unorthodox regimens remained on conventional therapy as well. The notion of noncompliance, traditionally used to describe patients who fail to follow physicians' orders, does not accurately encompass the behavior of this patient population. Most of these patients continue treatment as prescribed, and many physicians are supportive or neutral, if not actually involved, in today's alternative therapies.

"Because most contemporary unorthodox practices seek to correct or prevent underlying systemic deficiencies, patients with cancer represent only a segment of their clientele. Patients with diabetes, arthritis, neurologic degenerative disorders, and other chronic illnesses, as well as healthy persons hoping to prevent disease, also use alternative programs. Consequently, the health-care and economic implications of today's unorthodox therapies are vast.

"This study shows that many patients receiving alternative care do not conform to the traditional stereotype of poorly educated, terminally ill patients who have exhausted conventional treatment. Similarly, although some unorthodox practitioners may well fit the characteristic portrait of quacks and charlatans, many are well-trained, few charge high fees, and most, on the basis of patients' views and our own observations, sincerely believe in the efficacy and rationality of their work.

"Contemporary alternatives, unlike the pills and potions of the past, are long-term, lifestyle-oriented options that exist within a broad view of health and personal responsibility. Patients welcome the self-care role and the concomitant responsibility to attain health. However, it may be assumed that a burden of guilt is associated with the corollary responsibility for having caused their own disease.

"When patients move toward alternative treatments, they are simultaneously moving away from perceived deficiencies in conventional care. The quality of patients' relationships with their physicians was related inversely to their propensity to seek unorthodox care. Some of what unorthodox therapy has to offer is not available in the conventional context: simple explanations of the cause of disease based on common experience (eating, elimination, emotional and spiritual stress); remedies that are pleasant for the most part and that are usually free of physical side effects; and therapy based in the home rather than hospital.

"Other features to which patients gravitate are available, at least potentially, within the conventional treatment framework. These features include the opportunity for patients to participate actively in their own care; the inclusion of nutritional and dietary factors, which patients read about in their daily newspapers; and the opportunity for patients to develop a sustaining relationship with a primary physician whom they perceive to be caring and involved.

"The emphasis of unorthodox therapy on nutrition, health as a personal responsibility, pollution, and purification has religious and moral overtones, but also represents themes of great importance not only to patient, but to science and society as well. As such, unorthodox therapy is unlikely to be readily discarded."

No Recommendations to be Made

The Office of Technology Assessment has broad powers under the law and can essentially do and spend anything necessitated by a particular evaluation process. OTA has subpoena powers accorded by the U.S. Congress, and great latitude to move. OTA is closely scrutinized by the Congressional Technology Assessment Board which is equally represented by the House of Representatives and the Senate. Objectivity and freedom from bias are hiring prerequisites for all OTA staff. OTA has an excellent and seemingly unblemished record thus far in its evaluation of many a technologies, some of which are surrounded by raging controversies

Our sympathies are with the dedicated professionals of OTA who, while not inexperienced in controversy, have probably not encountered any other issue quite so passionately contested and involving so many activists from the general population. ***Good luck to us all.***

involving formidable adversaries.

However, OTA does not make recommendations to Congress. It simply states its findings in printed reports to Congress and, in certain instances, creates and depicts several scenarios which might possibly occur should policy be enacted to alter existing conditions.

Allegations of Bias

Recently Roger Herdman, Deputy Director in charge of OTA's medical assessments, has been criticized for allegedly having lucrative stockholdings in Oncogene, Inc., a cancer medicine manufacturer, and for his position as a director of a Florida-based mutual fund which specializes in placing investor funds in the cancer drug industry. It has been alleged that Herdman has profited considerably from his Oncogene stock holdings. Do Herdman's ties with cancer drug finances represent a substantial conflict of interest? Does Herdman's involvement with the IAT study jeopardize its outcome? Can his presence at OTA flavor the judgement of Hellen Gelband, the director of the "Unorthodox Cancer Treatments" study? At the time of this writing, national columnist Jack Anderson is considering the topic of Herdman's industrial ties. If the topic is treated by Mr. Anderson, we will request permission to reprint his article in this Newsletter.

My personal opinion, based on the assumed validity of the above allegations by Tanya Ish of Jack Anderson's staff, is that the potential influence of Roger Herdman on the work of his staff is considerable, but it is not a matter of fact. It is a matter of concern. The question is important and must, of course, be addressed by Clyde Benney and Jack Gibbons of OTA. It is my impression that Hellen Gelband is aware of potential bias. She has been deluged by numerous form letters mailed to OTA and various Congressmen as a result of newsletters circulated by Mike Evers of Project Cure, Clinton Miller of the National Health Federation, and Catherine Frompovich of the Coalition of Alternatives in Nutrition.

It is not surprising that OTA should be the battlefield for a war which has been raging since the Fishbein era of the AMA. Our sympathies are with the dedicated professionals of OTA who, while not inexperienced in controversy, have probably not encountered any other issue quite so passionately contested and involving so many activists from the general population. Good luck to us all.

"Ode to the Liver"

The Associated Press wire service picked up an item which bears repeating. Jaime Quintanilla Ulla, the mayor of Ferrol, Spain, presided at the unvieling of a $3,500 granite sculpture of a human liver as poet Laura Perez Landiera read the late Chilean poet Pablo Neruda's "Ode to the Liver".

The spirit of the event was light, but the undertone was serious. Mayor Ulla is a physician who also serves as the coroner of this northwestern port city. In his dedication address he observed that as coroner he had seen "hundreds of these organs tortured by cocktails, wine, tranquilizers and other medications. But every day, the poor little liver is at work neutralizing and purifying everything we take in."

Funding for the unique monument was provided by the Ferrol City Council and a local bank.

A Unique Opportunity to Help

Dear Friends of Gerson:

We are set to begin a tremendously important job, and we need your help. The Gerson Institute and the Hospital de Baja Califoria have engaged the services and expertise of Dr. Ross Pelton, R.Ph., Ph.D., (pharmacy, psychology, nutrition, & wholistic health) to wrestle ten years of clinical data into a statistically viable format. The endpoint of this effort will be publication of survival data and quality of life for all diseases with sufficient numerical bases, and tentative conclusions for those which number too few for statistical significance.

I have estimated that the study will entail expenditures of no less than $250,000 in man hours and computer time. We will be flying an advisory panel from all corners of the world to assist us in designing our studies. We will be contracting objective, independent pathology and radiology teams to validate readings of original slides and films used for diagnoses and stagings. We will be transporting patients to magnetic scanner facilities and paying to have their remissions documented. We will hire a computer program specialist to build sortable data fields for the evaluation.

We need your help. Many of you have read us for years now and you know that we have never solicited funds beyond our very modest annual membership donation. We were waiting for a good reason, and now we have one.

Please, help us make it through the next year. We simply cannot accomplish the evaluation and publication without you.

We would like to have a significant portion of the data in at least readable condition before the U.S. Office of Technology Assessment report on "Unorthodox Cancer Treatment" is completed. A preliminary report for the benefit of the OTA has been made by Dr. Lechner of Graz, Austria, who is conducting a trial of a modified Gerson therapy in metastasized breast cancers and liver-metastasized colorectal cancers. It is essentially a very conservative report of four years clinical experience with 60 patients which details extended survival in advanced metastasized breast cancers and liver-metastasized colorectal cancers. We will comment more fully on that report in the next issue of Healing.

The Gerson Institute and the Hospital de Baja California have accumulated a wealth of experience with approximately 4,000 patients over the course of ten years of clinic. Statistical evaluation of this information in the form of a "best case" study and a concurrent prospective study are essential prerequisites to the acceptance by the United States of the invaluable contributions of Dr. Max Gerson.

Will you please help with the largest possible tax deductible donation you can make? Please consult your financial advisor. You will probably be told that your donation will be much more wisely made in 1987, before the next stage of the new tax law takes effect.

If you cannot contribute immediately, but will be able to help later, please send us your written pledge of support now, stating the amount you intend to donate, so that we may include it in our planning.

The time is NOW! As Californians say, the surf is up. We don't want to miss the wave.

We're counting on you!

Gar Hildenbrand

GAR HILDENBRAND

Comprehensive Government Report Challenges NCI Claims

BY GAR HILDENBRAND

The U.S. Congressional General Accounting Office (GAO) concluded in a 131-page report released in March of 1987 that the National Cancer Institute's (NCI's) analyses of its own statistics artificially inflate the amount of "true" progress in the war against cancer. GAO characterized its report as "the most comprehensive evidence to date on what actually occurred in the area of cancer patient survival from 1950 to 1982." GAO stated that "the extent of improvement in survival for specific cancers is often not as great as that reported" by NCI. The report was requested in 1985 by Massachusetts Democratic Representative Ted Weiss, Chairman of the House Subcommittee on Intergovernmental Relations and Human Relations. "GAO's findings raise serious questions about the performance over the past a several years of the $1 billion-a-year national cancer program," commented Congressman Weiss. "While it is heartening that cancer patient survival has improved for some cancer patients, we have apparently not done nearly as well treating cancer as Government officials have led us to believe. Neither the Congressional policy-makers nor the public is well served by unwarranted expectations that we have turned the corner on this group of devastating diseases."

GAO based its report only on NCI's comparative 5-year survival rates because these numbers are the figures presented at funding time to Congress by NCI officials as evidence of the effectiveness of NCI programs. By contrasting 5-year survival rates of 1982 and 1950, NCI officials were able to show Congress increases of 15%-30% in leukemias, lymphomas, and cancers of the breast, bladder, endometrium, and prostate. Increases of 5%-15% were shown for cancers of the head & neck, lung, stomach, colon, rectum, and uterine cervix.

GAO found, despite NCI claims, that only "slight improvements" were statistically evident for those cancers during the preceding 30 years of increasingly heavily funded research.

GAO said survival rates must be interpreted in the light of many of the above mentioned biases. "Using survival rates alone to reach conclusions about general progress is therefore inappropriate," GAO concluded. Strangely, NCI director Vincent T. DeVita, Jr. argued that GAO should not have been so narrow in its evaluation, saying that GAO's use of only 5-year survival statistics was the study's "fatal flaw". "Cancer statistics are very hard to grasp," he said, "because you should look at several factors but there is a tendency to simplify to make them easier to understand."

Breast-, colorectal, and lung cancers are the most commonly occurring forms of malignant neoplastic disease. GAO found, despite NCI claims, that only "slight improvements" were statistically evident for those cancers during the preceding 30 years of increasingly heavily funded research.

NCI has promoted its cause before the U.S. Congress, which provides its funding, by comparing 5-year survival rates of current patients with those who were treated during the 1950's. In doing this, a statistical mirage is created, e.g.: In 1950, 53% of breast cancer patients lived 5 years. In 1982 (the last year for which complete data were available), 77% of breast cancer patients were alive at 5 years. NCI's conclusion: There has been a 15% increase in the 5-year survival rate of breast cancer patients as a result of treatment. In spite of this claim, the reality is that most patients who develop breast cancer die with gross manifestations of the a disease, usually as a direct result of malignant breast cancer tumors. The mortality rate of breast cancer patients exceeds that of age-matched normal controls for almost 20 years.

"While it is heartening that cancer patient survival has improved for some cancer patients, we have apparently not done nearly as well treating cancer as Government officials have led us to believe. Neither the Congressional policy-makers nor the public is well served by unwarranted expectations that we have turned the corner on this group of devastating diseases." —Congressman Ted Weiss

Statistical bias

Even though NCI's data were not challenged, its interpretation was considered invalid by GAO. There are statistical biases which account for the majority of the apparent 15% "improvement" in 5-year survivals of breast cancers. These are "lead time bias", "self-selection bias", "length bias", "overdiagnosis", "stage migration", and "improved reporting".

Lead time bias

Due to an increase in screening of healthy persons and definite strides in diagnostic technologies, increasing numbers of preclinical cancers are now being discovered. In the 1950's these cancers would not have been diagnosed until they became symptomatic, a point much later in the development of the disease. Because survivals are measured from the point of diagnosis, the early discovery of cancer appears to create a longer survival, but this is not the case. When compared to symptomatic cancers diagnosed in the 1950's, preclinical cases of the 1980's add statistical lead-time rather than survival time, ie: when seen correctly, these patients represent an extended early observation period and do not compare equally to 1950's patients until they develop symptoms. This is referred to as a lead-time bias.

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Self-selection

Additionally, participants in cancer screening programs do not represent the "average" cancer patient. They are usually self-motivated volunteers who are interested in health. By comparison with the "average" cancer patient, screening volunteers tend to be better educated, maintain better nutritional and hygiene habits, and possess more awareness of subtle changes in their bodies. Because they tend to have higher than average income and intelligence, they are more likely to be positively oriented, are more often capable of obtaining higher quality medical services, and are more likely to be compliant with whatever medical treatment they choose. Such advantaged patients have a better chance for survival. Adding such patients to general data creates a type of prognostic selection bias called patient self-selection bias.

Length bias

A second type of prognostic selection bias involving voluntary screening participants results from the preclinical discovery of slow growing tumors. Slow growing tumors tend to remain slow growing even once they reach the clinical stage. Such tumors would not have been found in the 1950's until they became clinical. Inclusion of slow growing tumors creates the impression that both early discovery and treatment have extended survival in these patients while neither may have done so as the patients would have enjoyed long survivals in any event. Including these tumors in overall data creates what is called "length bias".

Overdiagnosis

A third type of prognostic selection bias created by the addition of screened patients is "overdiagnosis". With screening, cancers are discovered which would never have become symptomatic. These are true cancers which either fail to

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Moving early metastasized cases from stage I leaves that stage with only less serious cases. Moving them into stage II loads its bottom end with less advanced cases. Feinstein (New England Journal of Medicine, 1985) called this the "Will Rogers Phenomenon" noting that Rogers had quipped that "when the Okies moved from Oklahoma to California they raised the average intelligence in both states".

grow or spontaneously regress without treatment. Such cancers would have never been found in the 1950's. The majority of NCI's claimed 28% gain in the 5-year survival rate for prostate cancer can be accounted for by overdiagnosis.

Stage migration

Failure to statistically account for earlier detection of metastatic disease by increasingly sophisticated technologies has also created a statistical distortion called "stage migration" to occur within each stage. Just as lead-time bias results from unrecognized loading of stage I with early preclinical cancers, stage migration bias is caused by reclassifying the earliest detectable metastasized cancers from stage I to stage II. Such early metastases would have gone unnoticed in the 1950's. Moving early metastasized cases from stage I leaves that stage with only less serious cases. Moving them into stage II loads its bottom end with less advanced cases. Feinstein (*New England Journal of Medicine*, 1985) called this the "Will Rogers Phenomenon" noting that Rogers had quipped that "when the Okies moved from Oklahoma to California they raised the average intelligence in both states". Stage migration does not affect 5-year survival rates but does affect any attempt to determine improved survival rates within each stage.

Improved reporting

A last bias is created simply by improved physician compliance in reporting non-fatal cases. Such cases were not uniformly reported in the past.

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Allegations

Bruce Chabner, director of NCI's Division of Cancer Treatment called GAO's conclusions "unfair" and their study design "unprofessional". He asserted that there was "an argument about the interpretation" of the GAO data. David Korn, Stanford Medical School Dean and National Cancer Advisory Board Chairman dismissed the report as a "shabby polemic".

GAO developed its statistical methodology by extensively interviewing 24 groups of research physicians at leading U.S. cancer centers and by conducting an exhaustive review of the scientific literature. A majority of independent reviewers from prominent cancer centers found the report to be "fair and objective". However, the Department of Health and Human Services (HHS), of which NCI is part, issued a written objection which was attached to the GAO report as an appendix. HHS argued that the report is "negative", "counterproductive", and should "be considered opinion, not fact".

DeVita also stresses that therapeutic advances were not measured by the GAO report. "Fifteen years ago, radical mastectomy and postoperative radiation therapy left women with ribs showing through skin and a swollen non-functional arm, with no increase in survival. Today, lumpectomy, sophisticated radiation therapy, and easily tolerable adjuvant chemotherapy

"NCI is run by an entrenched bureaucracy which has been in place for two decades. Its contract system is no longer operational. It used to have a peer review which met in conference. Now review is conducted by mail...all fixed. People lose enthusiasm when only 1 of 5 or 7 grants are OK'd. They've got centralized control of drug testing. Cooperative groups are being wiped out in the name of efficiency and economy. The bureaucracy is controlling the system... Congress needs to look at the disability of the system to innovate. I'd be willing to go before Congress to speak about the entrenchment of bureaucracy, and someone should subpoena Dr. _____ _____ (a former division director of NCI) because he has all the information about cronyism and centralized control. The only thing that will change this is Congressional action."

leave women with a non-discernible scar, a normal breast, a totally functional arm, and a reduction in their mortality." However, NCI under DeVita did not pioneer or usher in any of the above less aggressive modifications but, on the contrary, promoted radical Halstead surgery and radiation long after the world's refereed journals published the superiority of more moderate approaches.

The real controversy here is a political one, not one of data and interpretation. Money is everything to any research organization. NCI has command of vast financial resources and has come under criticism by such noted scientists as Bailar, Smith, Cairns, Bush, Carter, Eddy, Feinstein, and Peto.

An esteemed colleague, who has served until a short time ago as director of medical oncology for a major U.S. teaching hospital, was critical of NCI in a recent telephone interview. Asking not to be named, he explained that he had been part of NCI's peer review panel for many years. He offered a blunt assessment. "NCI is run by an entrenched bureaucracy which has been in place for two decades. Its contract system is no longer operational. It used to have a peer review which met in conference. Now review is conducted by mail. A buddy of Bruce Chabner's (Director of NCI's Division of Cancer Treatment) go a $2.7 million contract on an IL2 (interleukin II) request. It was all fixed. People lose enthusiasm when only 1 of 5 or 7 grants are OK'd. They've got centralized control of drug testing. Cooperative groups are being wiped out in the name of efficiency and economy. The bureaucracy is controlling the system. OTA (Office of Technology Assessment) is asking the wrong question about alternative cancer therapies. Congress needs to look at the disability of the system to innovate. I'd be willing to go before Congress to speak about the entrenchment of bureaucracy, and someone should subpoena Dr. _____ _____ (a former division director of NCI) because he has all the information about cronyism and centralized control. The only thing that will change this is Congressional action."

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Perhaps Congressional action will be forthcoming. It is unlikely that it would take the form of an inquisition, but it might result in funding ceilings and increased accountability for NCI. It might also mean an opportunity for "high risk" research initiatives, such as nutritional therapeutics, to achieve funding.

Team learns why drugs don't cure cancer

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A joint Japan-U.S. research team has discovered *why* drugs are ineffective in curing a cancer patient with a relapse, the team announced recently.

The joint team, formed by Dr. Takashi Tsuruo and Dr. Yoshikazu Sugimoto of the Cancer Research Institute attached to the Japanese Foundation for Cancer Research and Dr. I. Roninson and Dr. I. Pastan of the National Cancer Institute of the U.S., said a substance called glycoprotein pumps anticancer drugs out of human cells and makes cancer cells drug-resistant.

Tsuruo and his fellow researchers extracted deoxyribonucleic acid (DNA), the main body of a gene, from a cell of a myelogenous leukemia patient who had become multi-drug resistant as a result of a massive administration of the anticancer drug adriamycin.

By using this DNA, they succeeded in separating the gene which controls multi-drug resistance.

On the other hand, by using a computer, the American doctors analyzed the base sequence of the gene which controls the multi-drug resistance. As a result of their joint research, the team found that glycoprotein performs the function of a pump and expels from human cells any drug that tries to infiltrate them, thus making cancerous cells multi-drug resistant.

Many new cancer drugs have been developed in the past decade, but they seldom prove effective in curing cancer patients with a relapse, because many of them are multi-drug resistant.

How to conquer the multi-drug resistance, therefore, has been a major theme of study for cancer researchers all over the world.

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