THE CANCER LETTER FAX

Vol. 22 No. 4
Jan. 26, 1996

Price $265 Per Year US
$285 Per Year Elsewhere

The First BRCA1 Test Hits The Market; Are Oncologists, Patients Ready?

A Maryland biotechnology firm has begun marketing a commercial product that has been eagerly awaited by some and dreaded by others: a test for mutations in the BRCA1 gene.

According to marketing documents, the firm, OncorMed Inc. of Gaithersburg, seeks to limit the use of the test to women at high risk of developing breast or ovarian cancer and women who have the disease.

Also, the research protocol compiled by the company suggests counseling before and after the test and warns that patients may encounter

(Continued to page 2)

In Brief

Simone Moves To Huntsman Foundation, Golde Named MSK Physician-In-Chief

JOSEPH SIMONE has resigned his position as physician-in-chief at Memorial Sloan-Kettering Cancer Center to take a job at the newly established Huntsman Cancer Foundation in Salt Lake City. Simone will be responsible for developing clinical programs that would complement the basic science endeavor established by philanthropist Jon Huntsman (**The Cancer Letter**, Oct. 6, 1995). **David Golde**, head of the Division of Hematology/Oncology at the MSK Department of Medicine, was named physician-in-chief effective Feb. 12, sources said. . . . **EDWARD LUSTBADER**, 49, a Fox Chase Cancer Center scientist who helped identify the hepatitis B virus and its role in liver cancer, died Jan. 11 of cancer. Lustbader, who gained international stature in biostatistics and epidemiology, worked with Nobel laureate Baruch Blumberg to identify people at risk of developing hepatitis B virus infection and liver cancer. He also made seminal contributions to understanding the relationship between diet and cancer, hereditary cancer, and familial pediatric brain tumors. “Ed had a very unusual and original mind and was never satisfied with routine solutions,” Blumberg said. “He was constantly searching and finding individualized approaches to problems.” Funeral services were held Jan. 14. The cancer center is planning a memorial service. . . . . **CLINICAL TRIAL** on the safety of estrogens for women with systemic lupus erythematosus has begun, sponsored by the National Instiute of Arthritis and Musculoskeletal and Skin Diseases, the NIH Office of Research on Women’s Health, and the NIH Office of Research on Minority Health. The SELENA trial is directed by Jill Buyon, Hospital for Joint Diseases, New York, and Michelle Petri, Johns Hopkins Hospital.

Maryland Firm First To Market Commercial BRCA1 Test

(Continued from page 1)
discrimination from insurers. The price of the test ranges between $150 and $1,650.

Observers in the explosively controversial field of genetic testing have been warning for many months that biotechnology companies would inevitably take genetic testing outside the environment of the major cancer centers and make it available to community physicians (**The Cancer Letter**, Oct. 6, 1995).

Now that the first such test has become commercially available, the issues that remain to be resolved have suddenly become more urgent, many observers said.

As at least one other company—Myriad Genetics Inc. of Salt Lake City—is preparing to launch a commercially available test, time is running out for oncologists, geneticists, business executives, government regulators and patient advocates to resolve the questions of who is to be tested, where, how, and why.

"It's still premature to perform BRCA1 testing on a wide-spread basis outside of controlled research settings," said Caryn Lerman, associate professor of medicine and psychiatry at the Georgetown University Lombardi Cancer Center.

"The scientific community needs to gather the data necessary to interpret the significance of mutations that are identified in the BRCA1 gene and determine the efficacy of available options for prevention and surveillance," Lerman said to **The Cancer Letter**.

Henry Lynch, director of the Hereditary Cancer Institute at Creighton University, disagrees.

"I feel very strongly that this is something that needs to be done because of the powerful cancer control potential that can be gleaned from that information," said Lynch, who consults for OncorMed. "My proviso is that testing be performed on individuals where the family history and risk profile merit the test.

"OncorMed adheres to this principle," Lynch said.

Meanwhile, OncorMed is not taking part in the debates. The company is in the midst of a public offering, and is therefore precluded from discussing its plans and its products.

"Because the company has a registration statement on file with the Securities and Exchange Commission for a public offering, we are in a quiet period and cannot comment on our BRCA1 program," Leslie Alexandre, the company's vice president, corporate affairs, said to **The Cancer Letter**.

The Right To Test And Be Tested?

Clearly, the debates over genetic testing are proving to be a feast for bioethicists. For oncologists, too, the issues at stake are of immediate significance.

The American Society of Clinical Oncology is in the process of formulating a policy statement on genetic testing. ASCO officials declined to comment on the statement.

However, sources said a draft statement that has been circulated outside the society indicates that ASCO would advocate making genetic testing available outside research settings. The statement would also offer explicit guidelines on who is to be tested.

Several observers said ASCO and other professional societies are severely limited in the choices they have. The technology for testing is relatively straightforward, and its introduction and promulgation are outside the society's control.

Hence, many observers say, the technology is on the verge of entering a field ill-equipped to use it wisely.

"Available data suggest that many primary care providers lack the knowledge about genetics that's necessary to educate their patients and ensure informed consent for genetic testing," said Lerman.

THE CANCER LETTER

Founded 1974
Member, Newsletter Publishers Assoc.

Editors: **Kirsten Boyd Goldberg, Paul Goldberg**
Founder: **Jerry D. Boyd**

P.O. Box 15189, Washington, D.C. 20003
Tel. (202) 543-7665 Fax: (202) 543-6879
Editorial e-mail: kirsten@www.cancerletter.com
Subscriptions: subscrib@www.cancerletter.com
World Wide Web URL: http://www.cancerletter.com

Subscription $265 per year US, $285 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter.

In genetic testing, informed consent is likely to require follow-up that cannot be predicted at the time the initial consent documents are signed, said Patricia Ganz, professor of medicine and public health at the University of California, Los Angeles.

"An informed consent shouldn't be limited to a legal document," Ganz said to **The Cancer Letter**. "It should be a process."

This broader role of informed consent has been tested out during the controversy surrounding the Breast Cancer Prevention Trial, Ganz said.

"In the Breast Cancer Prevention Trial, we had to continue to inform women about information that was becoming available," Ganz said.

"Similarly, with this, you don't just perform a blood test. You have to fulfill the obligation to continuously inform someone about what that means. I am not sure that most practitioners are going to be able to do that.

"Even oncologists are not necessarily adequately trained for that," Ganz said.

Health care providers have had many an opportunity to demonstrate their ability to learn new technologies and use them effectively, Lynch said.

"We know that when Pap smear came out, there was little interest in it," Lynch said. "It was new, and it takes time for physicians to catch up."

The value to patients could be enormous, Lynch said. "We have to treat patients as mature, responsible people, and we have to share our findings with them," Lynch said.

Counseling, too, can be effective, Lynch said. "Many women who thought that they were at high risk would be told that their risk reverts to the general population," he said.

And, in many cases, screening could be intensified for women who test positive for a mutation in the gene.

More Political Than Pap Smear

Patient activists, however, are not lining up to be tested. In fact, the National Breast Cancer Coalition, has consistently called for a cautious introduction of genetic testing.

"We strongly believe that genetic testing should always be done within research protocols," said Fran Visco, president of the coalition and a member of the President's Cancer Panel.

"We do not believe that the medical community should begin testing women for the presence of the gene, nor should they be testing outside research studies.

"We don't have legislation in place to protect them against discrimination in insurance. We don't know what to do with the women who test positive. There is so much we don't know, and we are never going to find out unless we do the studies.

"There should be a widely available national study of genetic testing," Visco said. "However, even if we have a study that answered these questions, if we don't have legislation in place to protect against genetic discrimination, we don't think the tests should be commercially available.

"All of these pieces hinge on one another," Visco said to **The Cancer Letter**.

One approach to studying the importance of the gene was proposed recently by Francis Collins, director of the National Center for Human Genome Research. In an editorial in the Jan. 18 issue of The New England Journal of Medicine, Collins suggested that NIH sponsor a nationwide cooperative trial for BRCA1 mutations.

"This would allow a careful review of issues concerning human subjects, the standardization of the informed consent process, the education of participating physicians, the education and counseling of prospective patients, and the careful and rigorous collection of data on who sought testing, what the results were, and what outcomes followed," Collins wrote.

Also, the trial could provide a registry of women who would become candidates for intervention trials.

While it may be difficult to find two people who agree on all aspects of what is to be done, virtually all the opponents of immediate commercialization of genetic testing agree that counseling patients before and after they are tested is anything but a straightforward matter.

"The biggest issue is that we don't know how to advise people on what to do with a positive or a negative test," said bioethicist Jeremy Sugarman, assistant professor in the Department of Medicine at Duke University. "Women's information needs are huge, and they vary."

Sugarman is developing informed consent strategies for genetic testing under Duke's Specialized Programs of Research Excellence in breast cancer grant from NCI.

At Duke, counseling involves a multidisciplinary group that includes genetic counselors, hereditary

malignancy specialists, social workers and physicians.

Regulatory Gray Area

Since FDA does not regulate genetic tests, OncorMed and the companies that will follow it encounter few regulatory barriers. However, by the same token, their products do not receive the certification of safety and efficacy that accompanies regulatory approval.

"There is a lack of regulations about whether a genetic test actually means something," said Mildred Cho, research assistant professor at the Center for Bioethics at the University of Pennsylvania. "This is not what happens in the case of prescription drugs."

However, ready or not, genetic tests are on the threshold of entering everyday practice of medicine.

"A lot of people in the medical profession don't realize that these tests are going to explode into their practices," Cho said. "And in the medical profession, the culture that surrounds diagnostic tests suggests that you just check them off on the chart and order them."

The patent issue, too, is a gray area. OncorMed's competitor Myriad has pending patent applications for diagnostic and therapeutic uses of the BRCA1 and BRCA2 genes.

Myriad said it plans to launch its BRCA1 test in the second half of 1996 and, ultimately, introduce a combined tests for mutations in both BRCA1 and BRCA2.

The OncorMed Protocol

OncorMed said it intends to limit the types of individuals it tests.

"It is OncorMed's policy to offer testing only to individuals being followed under a testing protocol to ensure appropriate patient education and informed consent," the company said in a research protocol it has compiled.

The protocol was developed by the company's Institutional Review Board to allow participation of physicians whose practices are not reviewed by IRBs. The company IRB was comprised of outside experts, who were paid consulting fees, sources said.

The company declined a request by **The Cancer Letter** to release the names of the IRB members and to disclose other information about the board.

According to company documents, the OncorMed test is available to:

—Breast or ovarian cancer patients who have two or more first or second-degree blood relatives (related through a single lineage) with either breast or ovarian cancer.

—Breast or ovarian cancer patients who have one blood relative under age 45 with either breast or ovarian cancer.

—Breast or ovarian cancer patients who developed the disease under the age of 45.

—Breast and ovarian cancer patients with multiple primary cancers or bilateral disease.

—Relatives of persons with documented mutations in the BRCA1 gene.

According to company materials, the test could cost as little as $150, if the company is trying to locate a specific mutation, to as much as $1,650 for sequencing the gene.

The following is the unedited text of the company's step-by-step instructions for physicians:

1. Obtain a detailed family history with pathological verification on the affected individual to be tested through medical records and/or pathology reports. Pathological verification should also be obtained on as many other affected family members as possible. The family history should be collected in the form of a pedigree. A pedigree outline and sample pedigree are provided for you. The pedigree is to be mailed or faxed to OncorMed for review prior to acceptance of the patient for testing. This information can then be discussed by phone with the genetic counselor.

2. Identify a geneticist or genetic counselor in the area who has agreed to provide counseling services to the patient. The patient should be given the name and number of the genetic counselor and encouraged to seek genetic counseling before the BRCA1 test is performed and again after testing. OncorMed can help identify a qualified counselor if one is not known. The cost of this counseling may or may not be covered by the patient's insurance.

3. Identify medical and surgical oncologists in your area to provide consultation to patients about the relative risks and merits of medical and surgical management options.

4. Identify a mental health professional who can provide an evaluation if there is concern that the patient may have a psychological condition precluding testing. If you suspect that the patient may have a psychological condition precluding testing, refer for evaluation prior to offering the test.

5. The patient should be informed of the

availability of counseling to help in the decision to test, to provide support through the testing process, or to help adjust to positive or negative results. This cost may or may not be covered by the patient's insurance.

6. All of the medical and counseling specialists to whom the patient is referred should be provided copies of the physician and patient Question & Answer pamphlets.

7. Conduct pre-test education and counseling as outlined on the Pre-Test Counseling Checklist. A booklet called BRCA1 and Breast Cancer: Questions and Answers for Physicians, contains the information necessary to conduct the pre-test counseling, and is provided for you.

8. Review the Pre-Test Counseling Checklist for BRCA1 Testing to confirm that all items have been discussed. The physician and the patient sign the checklist. The physician should keep a copy of the checklist for his or her records, and give a copy to the patient.

9. Give the patient the information booklet "BRCA1" and "Breast Cancer: Questions & Answers for Patients" and the consent document. There is a separate consent for individuals with breast or ovarian cancer, and at-risk relatives once a mutation has been found. The patient should be encouraged to take these materials home to review prior to agreeing to be tested.

10. If the patient agrees to be tested, review the consent form with the patient and give him or her a copy of the signed consent. A copy of the signed consent should remain in the physician's records.

11. Fill out a clinical history form.

12. Send the signed consent form, checklist, and clinical history form with the blood sample to OncorMed.

13. Give the test results to the patient in person and cover the appropriate information from the Post-Test Counseling Checklist. The physician and the patient sign the Post-Test Counseling (Disclosure) Checklist for BRCA1 Testing which is returned to OncorMed. The physician should keep a copy and provide a copy to the patient.

14. Refer for genetic counseling to discuss the implications of the result and/or additional testing needs.

15. Develop a surveillance and management plan with the patient. OncorMed has a clinical consultant (clinical oncologist who specializes in following these types of patients) who can help you at no cost, should this be necessary. You can contact OncorMed for the name and number.

16. Refer the patient to the specialists you have identified, if appropriate. The cost for these consultations may or may not be covered by the patient's insurance. Refer patients to support groups, as appropriate including the National Alliance for Breast Cancer Organizations at 1-800-719-9154. the National Coalition for Cancer Survivorship at 301-6568868, the Y-ME Hotline at 1-800-221-2141, the National Breast Cancer Coalition at 202-2967477, the American Cancer Society at 1-800-ACS-2345, or the National Cancer Institute at 1-800-4-CANCER.

17. Encourage the patient to inform close family members of the results if a mutation is identified. Additional copies of BRCA1 and Breast Cancer: Questions & Answers for Patients are available, or copies may be made of the one provided. Informing relatives can be facilitated by the genetic counselor.

18. Give the Consent to Contact (if it has been included with the result) to the patient at the time the results are disclosed.

19. Provide a referral for psychological counseling if the patient is having difficulty in dealing with the results. This cost may or may not be covered by the patient's insurance.

20. Contact the patient in three months to ascertain if the participant has questions, has followed the surveillance recommendations, and has notified relatives. You will be sent a card reminding you that the follow-up contact should be initiated.

The document suggests that physicians inform patients about possible discrimination in obtaining insurance.

"You will also want to discuss with your patient how the results of the testing will be kept in your records," the document states. "It is possible that a positive BRCA1 test, or even the fact that the patient is being tested, could compromise the patient's insurability (health, life, or disability)."

NCI Contract Awards

Title: Resources for procurement of human tissues from donors with an epidemiology profile. Contractor: Georgetown Univ., $400,151.

Title: Mechanisms of chemical carcinogenesis in Old World monkeys. Contractor: Bioqual Inc., Rockville, MD, $3,266,150.

FDA Proposal To Ease Rules Not Enough, Cancer Groups Say

An FDA proposal to relax its limitations on dissemination of peer-reviewed textbooks and journal articles on off-label uses of drugs and devices is insufficient to ensure that cancer patients and their physicians have unhindered access to state-of-the-art knowledge, major cancer organizations said last week.

In a response to the FDA proposal, 82 professional oncology societies, cancer centers and patient advocacy groups said the agency's regulations, though eased, would continue to hinder "academic discussion and dissemination of data about advances in cancer therapy," the societies said.

The response, submitted to FDA Jan. 19, acknowledged that the policy change would for the first time allow drug sponsors to distribute textbooks that reflect off-label uses. However, the cancer groups criticized FDA for reserving the right to stop the distribution if the textbook has "a significant focus on unapproved uses of the drug, device or biologic marketed or under investigation by the firm supporting the dissemination of the text."

According to the cancer groups, it may be difficult for a sponsor to determine in advance whether FDA would find "a significant focus" in a textbook. "Therefore, the seeming relaxation of the enforcement policy may be relatively meaningless if sponsors still do not have firm assurance that they may distribute textbooks without fear of FDA enforcement action," the cancer groups said.

Similarly, the FDA proposal would permit dissemination of peer-reviewed journal articles supporting off-label uses, but only if the articles report the original studies accepted by the agency as providing evidence of effectiveness.

"In practice, this proposal would provide little or no relief from the restrictions that are of concern to the cancer community," the cancer groups said. "The number of journal articles meeting the requirements set forth by FDA is likely to be extremely small. Moreover, ... the information obtained from the original study may have become outdated by virtue of subsequent studies."

The proposed FDA regulations were published in the Federal Register Dec. 8, 1995.

"More Information Better Than Less"

In the letter, the cancer groups called for the free flow of scientific and medical information. "Physicians and other health care professionals should be able to receive reliable information like textbooks, peer-reviewed journal articles and compendia summaries from sponsors and should be permitted to speak about the products without restraint by FDA, even in seminars and meetings funded by sponsors," the letter said.

The letter suggested the following policy for dissemination of off-label information about FDA-approved products:

1. Sponsors may distribute any independent medical textbooks to physicians and other health care professionals without restriction.

2. Sponsors may distribute to physicians and other health care professionals information reflecting decisions by independent medical compendia like the US Pharmacopeia Dispensing Information.

3. Sponsors may distribute to physicians and other health care professionals peer-reviewed journal articles reporting data in support of off-label uses.

4. Sponsors may fund seminars or presentations to physicians and other health care professionals that reference off-label uses so long as the source of funding is fully disclosed; FDA will not seek to exert content control over such seminars or presentations.

"These principles reflect our belief that physicians and other health care professionals who treat people with cancer are in a position to evaluate the merits of the various data and other information that they may receive from sponsors or from activities funded by sponsors," the letter said. "We believe that more information is better than less and that these principles will facilitate enhanced access to important new data without compromising FDA's enforcement responsibilities for guarding against truly false or misleading communications."

The letter was signed by 21 NCI-designated cancer centers and 39 state oncology societies, American Cancer Society, American Society of Clinical Oncology, American Association for Cancer Research, American Society of Hematology, American Society of Pediatric Hematology/Oncology, Association of American Cancer Institutes, Association of Community Cancer Centers, Cancer Research Foundation of America, National Coalition for Cancer Survivorship, , National Alliance of Breast Cancer Organizations, Candlelighters Childhood Cancer Foundation, North American Brain Tumor Coalition, Prostate Cancer Support Group

Network, Susan G. Komen Breast Cancer Foundation, Y-Me National Breast Cancer Organization, Cancer Care Inc., Leukemia Society of America, National Childhood Cancer Foundation, Oncology Nursing Society, Radiation Research Society, Society of Gynecologic Oncologists, and Us Too International.

Pediatric Oncologists Urge Review

In a separate letter to FDA, the National Childhood Cancer Foundation said the agency's current regulations and the proposed changes are particularly detrimental in pediatric oncology, a field in which most treatments involve off-label uses of approved drugs.

The letter, signed by Denman Hammond, president of NCCF, urged FDA Commissioner David Kessler, who was trained as a pediatrician, to "undertake a comprehensive review of FDA's policy on distribution of off-label information and to issue a new policy that will permit distribution by sponsors of legitimate medical textbooks and peer-reviewed journal articles without restriction and that will merit academic symposia without FDA oversight, even when the symposia are funded by industry."

Beta Carotene Doesn't Help, May Hurt Smokers, Trials Find

Investigators conducting the Beta Carotene and Retinol Efficacy Trial, a large study of the combination of beta carotene and vitamin A as preventive agents for lung cancer in smokers and former smokers, terminated the intervention last week and told the participants to stop taking the vitamins.

Interim study results indicate that the supplements provide no benefit and may cause harm, said Gilbert Omenn, of the Fred Hutchinson Cancer Research Center and the lead investigator on the CARET study.

"These vitamins are providing no benefit and may—with the emphasis on may—have adverse effects," Omenn said.

Results of a second study released last week showed no significant evidence of benefit or harm from beta carotene on cancer or cardiovascular disease. The Physician's Health Study of 22,071 male physicians in the US ended on schedule last Dec. 31 after more than 12 years of treatment.

Both studies were funded by NCI. The Physician's Health Study also was funded by the National Heart, Lung and Blood Institute.

"Beta carotene is not a magic bullet," NCI Director Richard Klausner said.

Klausner said the research demonstrated the importance of randomized clinical trials. "Medicine and public health must be based, whenever possible, on evidence," he said. "While the results [of the trials] are disappointing, the research process is working."

In response to the findings of the two studies, the Women's Health Study, a trial of 40,000 female health professionals, removed beta carotene supplements from its intervention. The participants will continue to receive 600 IU of vitamin E and 100 mg of aspirin or placebo every other day.

Potentially Harmful To Smokers

The interim results of the CARET study, while not statistically significant evidence of harm, are similar to the results of the Alpha-Tocopherol, Beta-Carotene Lung Cancer Prevention Trial conducted in Finland and published in 1994. That study found 18 percent more lung cancers and 8 percent more deaths in male smokers who took 20 mg of beta carotene daily for five to eight years.

The $42 million CARET trial followed for an average of four years 18,314 male and female heavy smokers and recent quitters, as well as men exposed to asbestos at work. Half took supplements containing 30 milligrams of beta carotene plus 25,000 international units of vitamin A daily; the rest got a placebo.

No one seemed to benefit from the supplements, and there were 28 percent more lung cancers and 17 percent more deaths among smokers taking the vitamins than those who got the placebo.

Former smokers may respond more favorably to the vitamins than current smokers, but the data are too limited to draw conclusions, Omenn said.

In a letter dated Jan. 13, Omenn ordered participants to stop taking the supplements, 21 months earlier than planned. The participants will be followed for five more years to determine the long-term effects of the intervention.

The study was conducted at six sites: Fred Hutchinson Cancer Research Center, Kaiser Center for Health Research (Portland, OR), University of Maryland at Baltimore, University of California-San Francisco, University of California-Irvine and Yale University School of Medicine.

Stop Smoking, Eat Right

In the Physician's Health Study, male physicians aged 40 to 84 years took 50 mg of beta carotene or a placebo every other day for 12 years. Half the participants had smoked at some time in their life, and 11 percent were current smokers when the study began.

Beta carotene supplements had no significant effect on cancer or cardiovascular disease in the participants.

The results of both studies provide strong evidence of no benefit from beta carotene supplements and raise questions about their safety, said Peter Greenwald, director of the NCI Division of Cancer Prevention and Control.

"NCI has never had a recommendation for Americans to take supplements," Greenwald said. "The best advice for smokers who want to reduce their risk of lung cancer is to stop smoking. Results from the CARET and ATBC trial do suggest that smokers should avoid beta carotene supplements."

The studies do not affect recommendations for a low-fat diet high in fruits, vegetables, and grains, the researchers said.

"A beta carotene supplement neither substitutes for a good diet nor compensates for a bad one," said Charles Hennekens, of Harvard Medical School, who led the physicians' study.

NIH Consensus Conference On Cervical Cancer April 1-3

NCI and the NIH Office of Medical Applications of Research have scheduled a Consensus Development Conference on Cancer of the Cervix, April 1-3 at the Natcher Building on the NIH campus.

The conference is designed to address ways to screen and prevent cervical cancer, the appropriate management of low-stage cervical cancer, the management of advanced and recurrent cervical cancer, and directions for research.

Consensus panel chairmen are Patricia Braly, professor and chief, Section of Gynecologic Oncology, Deptartment of Obstetrics/Gynecology, Louisianna State University Medical Center, and Allen Lichter, chairman, Department of Radiation Oncology, University of Michigan Medical School.

To register for the conference, contact Annette Besignano, Technical Resources Inc., tel: 301/770-0610, fax: 301/468-2245.

Letters to the Editor:

It's Simply Common Sense To Abolish FDA--Isn't It?

To the Editor:

Now that NIH is more or less back in operation, it can be presumed that our elected representatives who so thoughtfully stopped life science research in its tracks will be able to return to another urgent matter: bashing FDA.

In the spirit of the fiscal year when the government stopped, we bring to your attention a modest proposal. Rather than taking potshots at FDA, Congress should take the most radical step possible and abolish the agency altogether.

Picture America without the tyranny of FDA. Young people free to experience the exhilaration of premature death from tobacco... Pharmaceutical companies liberated from the oversight of onerous regulators... Healers in turbans casting fear aside and administering time-tested remedies to desperate patients forsaken by Western medicine...

As Congress strives to get the government off our backs, surely it can liberate us from the dogma of scientific rigor and the obligation to protect the desperately ill from exploitation by the purveyors of white magic.

For the benefit of purists concerned about safety and efficacy, we point out that many of the "alternative" remedies are based on ancient wisdom of India and China. Thus, in India, traditional ayurvedists treat alcoholism, anorexia, ascites, edema, indigestion and nausea with a combination of goat feces and urine; constipation, with a mixture of milk and urine; and epilepsy and insanity, with ass urine.

Rather than engage in the mind-numbing process of clinical evaluation, the US government should fund an assessment of how many people in India are sane, sober and unconstipated.

Here in America, we know that con men don't have doctorates in naturology, naturopathy, nutrition and wellness science—all available from fine, non-accredited correspondence schools. And we know in our hearts that no God-fearing American, whether an alternativist or a drug company executive, would knowingly market dangerous or therapeutically useless products.

For this reason, the American voters no longer want government protection. Their common sense is protection enough.

Or is it?

Saul Green, President, Zol Consultants
Jack Raso, Editor, The Nutrition Forum