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Clinton Budget Provides 4.7% Increase For NIH; $118 Million Raise For NCI

President Clinton proposed a fiscal 1995 budget of $11.5 billion for NIH this week. The amount represents a 4.7 percent increase, or $517 million, over the current year.

NCI would receive $2.190 billion, an increase of $118 million over the current year's appropriation of $2.082 billion.

The Institute would spend $1.967 billion on cancer-related activities,

(Continued to page 2)

In Brief

Peck Joins GenPharm Board; Dallas Hospital Selects Director For New BMT Program

CARL PECK, former director of FDA's Center for Drug Evaluation & Research, has been elected to the board of directors of GenPharm International Inc., Mountain View, CA. Peck was CDER director for six years, until last November. He is the Boerhaave Professor of Clinical Drug Research at Leiden Univ. GenPharm's European operations are based in Leiden, The Netherlands. . . . **CRAIG ROSENFELD** was named director of the bone marrow transplant program under development at Medical City Dallas Hospital. He was director of the BMT program at Western Pennsylvania Cancer Institute. The BMT program at Dallas is expected to be operational in July. Initially, it will consist of a 10-bed unit and separate outpatient center, treating both adults and children. **John Nemunaitis**, director of clinical research, Texas Oncology, will work with Rosenfeld to develop the program. . . . **SEN. DANIEL PATRICK MOYNIHAN**, chairman of the Senate Finance Committee, met with administrators of Roswell Park Cancer Institute last month to discuss the role of comprehensive cancer centers under the Clinton Health Security Act. According to institute director **Thomas Tomasi**, cancer patients must be guaranteed access to speciality services and treatment available at NCI designated cancer center, qualified clinical trials must be included in the basic benefits package, there should be a percentage add-on payment to cover cost at cancer centers, and cancer treatment specialities should not be de-emphasized in favor of primary care. Moynihan agreed to speak before cancer center directors at the annual meeting of the Association of American Cancer Institutes, on March 9. . . . **NATIONAL ACADEMY** of Sciences awarded its $25,000 prize for the medical sciences to **Donald Metcalf**, Royal Melbourne Hospital, Victoria, Australia, "for his discovery of the hematopoietic growth factors and their introduction into clinical medicine for the control of blood cell formation and resistance to infection."

Breast Cancer Research Woulde Increase 24% At NCI

(Continued from page 1)
a $99 million increase over the fiscal 1994 amount of $1.86 billion.

Funding for NCI breast cancer research would increase by 24 percent, from $262 million in FY94 to $323 million in FY95.

Funding for AIDS research—a total of $1.379 billion—would be concentrated in the NIH Office of AIDS Research. The funds would be distributed for intramural and extramural AIDS research among the institutes.

NCI's portion of the AIDS funding is estimated to be $222 million, but that amount could change depending on a NIH-wide AIDS research plan that must be developed under the NIH Revitalization Act passed last year. NCI estimates it will spend $213.4 million on AIDS research in FY94.

To avoid exceeding spending limits, the Administration set aside $100 million of the NIH budget under a "delayed availability" schedule. The money would not be spent until Sept. 19, 1995. NCI would not be able to spend $23 million until that time.

"It's a pretty bland budget for medical research," Terry Lierman, executive director of the National Coalition for Cancer Research, said to **The Cancer Letter**. "I think what it points to is that unless individuals and groups get serious about large increases for medical research, we will continue to be playing with the crumbs."

NCCR is among the advocates of the proposal by Sens. Tom Harkin (D-IA) and Mark Hatfield (R-OR) to fund an increase in medical research through surcharges on medical insurance payments. The bill is expected to be introduced later this month.

Under the President's call for restraint in discretionary spending, universities and institutions receiving federal grants and contracts will be asked not to seek additional payments for overhead costs (indirect costs) charged to awards. The proposed one-year pause in overhead payments will allow the Administration to review the system government-wide, the budget document states.

NCI Spending Under President's Request

Subject to Congressional approval, here is how NCI would spend the President's proposed budget:

	FY94	FY95
Total (cancer only)	$1.866 bil	$1.967 bil
Research Project Grants	906 mil	936 mil
Competing grants (No.)	847	1,052
Centers/SPORES	151	162
Coop. Groups	77	79
Training	37	38
Contracts	125	125
Intramural Research	281	286
Research Management	89	89
Ca. Prevention & Control	146	197
Construction	18	12

The NIH Revitalization Act requires that NCI spend 9 percent of its total FY95 appropriations on cancer prevention and control. Funding for prevention and control would increase by $51 million under the President's budget request.

NCI would spend $7.5 million of the $12 million extramural construction budget on support of proton beam therapy centers, an earmark that has been included in the NCI budget for the past several years.

Institutes Budgets

For the NIH Office of the Director, the President's budget proposes $233.5 million. The NIH director would be able to direct up to 1 percent of the total NIH budget to "emergency activities the director may so designate."

The Administration's proposed budget for other Instititutes follows, with numbers in brackets representing the current year's appropriation. The FY95 figures do not include AIDS research:

■National Heart, Lung & Blood Institute: $1.267 billion [$1.277 billion].

■National Institute of Dental Research: $163.7 million

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[$169.5 million].

■National Institute of Diabetes & Digestive & Kidney Diseases: $731.5 million [$716 million].

■National Institute of Neurological Disorders & Stroke: $630.4 million [$630.6 million].

■National Institute of Allergy & Infectious Diseases: $542.8 million [$1.065 billion].

■National Institute of General Medical Sciences: $882.1 million [$875.5 million].

■ National Institue of Child Health & Human Development: $516.7 million [$555.2 million].

■National Eye Institute: $292 million [$290.2 million].

■National Institute of Environmental Health Sciences: $267.9 million [$264.2 million].

■National Institute on Aging: $433.7 million [$420.3 million].

■National Institute of Arthritis & Musculoskeletal & Skin Diseases: $228.4 million [$223.2 million].

■ National Institute on Deafness & Other Communication Disorders: $167.1 million [$162.8 million].

■National Center for Research Resources: $286.3 million [$331.9 million].

■National Institute for Nursing Research: $48.3 million [$51 million].

■National Institute of Mental Health: $545.2 million [$613.4 million].

■National Institute on Drug Abuse: $291.9 million [425.2 million].

■National Institute on Alcohol Abuse & Alcoholism: $291.9 million [$185.6 million].

■National Center for Human Genome Research: $152 million [$128.7 million].

■Fogarty International Center: $13.7 million [$21.6 million].

■National Library of Medicine: $135.3 million [$119.9 million].

■Buildings and facilities: $113.5 million [$111 million].

The Centers for Disease Control would receive appropriations of $1.983 billion, of which $3.6 million is to remain available until spent for equipment, construction, and rennovation of facilities.

The Clinton budget proposed the deletion of $2 million in Dept. of Defense appropriations for the Center for Prostate Disease Research at the Walter Reed Army Institute of Research. The DOD budget also would eliminate $5 million for the Center of Excellence in Breast Cancer Research and Training at the National Naval Medical Center in Bethesda.

Capitol Notes

NCCR Calls For 15% Increase In NIH Budget, As Investment

NIH should receive a 14 to 15 percent increase in funds, a boost the President's budget proposal reserves for the programs identified as top priorities, the **National Coalition for Cancer Research** said last week at a hearing of the House appropriations subcommittee on Labor, HHS, Education and related agencies.

"We are dismayed to learn that the Administration does not consider NIH to be an investment priority," said Margaret Foti, president elect of NCCR and executive director of the American Assn. for Cancer Research. NIH is slated for a 4.8 percent increase.

"The investment priorities of this country should produce significant benefit by improving our economic base, increasing our technological capabilities and protecting precious resources," Foti said. "There is no better example of these principles than NIH."

Foti said research on gender-specific cancers should be accompanied by new funds.

"We understand that the entire increase provided to NCI in fiscal 1994 will be devoted to breast cancer," she said. "As a result, increases in other areas, such as prevention, will need to be cut from existing programs in the base. This is a difficult situation as it means reducing critical research programs in one, albeit important, area of cancer to address priorities in another cancer."

Foti urged Congress and the Administration to avoid earmarks, to support a balanced cancer research program and to address the needs of the underserved populations. "It is of critical importance that we do not repeat the mistakes AIDS research efforts have taught us," Foti said. "After a decade of input from the public in defining the direction of HIV research, and pressing for clinical treatments and prevention options, we now have public advocates coming back to researchers asking why we do not know more about the immunology and the developmental biology of HIV—questions that only a well funded basic research program could have answered."

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Rep. Ron Wyden (D-OR) urged NIH to conduct a conference on the technology transfer program.

In a letter to NIH Director Harold Varmus, Wyden said the goal of the conference would be to draft

contractual language that would lower the prices of drugs developed through cooperative research and development agreements.

"With the emergence of broad scale health care reform now squarely on the front burner, the time is ripe for careful scrutiny of this question and efforts by your agency and other appropriate departments to more fully protect a valuable public investment," Wyden wrote in a letter dated Feb. 8.

Wyden said the conference would explore the following aspects of the CRADA program:

—"The effects and success of initial NIH attempts to mitigate pricing of commercial products through model CRADAs, such as the agreement between NCI and Bristol-Myers Squibb Co. for the development of Taxol.

—"Patenting issues involving collaborative agreements as they may effect NIH influence on the pricing of products which could be commercialized.

—"Exclusivity arrangements in CRADAs which could limit the scope and kind of collaborative research NIH scientists, or NIH-sponsored scientists, may undertake with business or institutional entities which are not part of the particular CRADA.

—"Patent ownership issues which may limit the ability of NIH to encourage or demand lower prices on drugs and devices developed in part through taxpayer-financed research."

FDA's Henney To Take Post At Univ. Of New Mexico

The Univ. of New Mexico last week appointed Jane Henney as vice president for health sciences under a reorganization of the university's health programs.

Henney, deputy commissioner for operations at the Food & Drug Administration since January 1992, will begin the new job on a half-time basis on May 1, and full-time on July 1, according to the university.

Henney, a medical oncologist, was vice chancellor for Health Programs and Policy at the Univ. of Kansas before taking the FDA position. From 1980-85, Henney was deputy director of the National Cancer Institute.

"We wanted a strong leader, someone with vision and experience to meet the challenge of implementing the Health Sciences Center reorganization," said UNM President Richard Peck. "Dr. Henney meets all of these criteria. We look forward to her leadership."

FDA Commissioner David Kessler, in a speech to the National Cancer Advisory Board two years ago, said he was looking for "the best physician manager around" when he recruited Henney from Kansas (**The Cancer Letter**, Jan. 31, 1992).

Henney said taking the UNM position was a career move, and did not reflect any discontent with FDA. "Clearly, academic administration was the line I was tracking on when David Kessler came to me [two years ago]," Henney said to **The Cancer Letter**. "I felt very strongly the [FDA] chief operating officer needs to be a career officer. I did not intend to spend my career here. I couldn't have had a better experience."

In a speech to the President's Cancer Panel last week, Henney described FDA's interaction with NCI on cancer related issues.

"It is amazing to me the number of points of intersection we have with NCI," Henney said to **The Cancer Letter**. "There is a strong spirit of collaboration between the agencies. It's not just at the top levels, it's all over."

There are currently no New Drug Applications for oncology products awaiting approval by FDA, and the agency is proud of this "clean-desk operation," Henney said. There are many investigational new drugs under study, as well as new biologics. With the institution of user fees for product sponsors, Henney said, FDA will be able to hire more reviewers to speed the approval process.

Henney was selected from a list of five finalists identified by a search committee headed by Philip Eaton, director of the UNM School of Medicine's Clinical Research Center.

The university last year decided to create a comprehensive Health Sciences Center. The center will consolidate UNM's School of Medicine and patient care facilities, the Colleges of Nursing and Pharmacy, and other related units. The medical school and the colleges will be headed by deans reporting to Henney.

Henney's appointment comes as Leonard Napolitano retires as dean of the School of Medicine and director of the UNM Medical Center.

In conjunction with Henney's appointment, the university appointed Paul Roth as interim dean of the School of Medicine and interim director of the medical center. Roth has served since 1992 as chief medical officer of the medical center and associate dean for clinical affairs for the medical school.

Henney is married to Robert Graham, executive vice president of the American Academy of Family Physicians.

Coffin, McIntosh Win ACS Research Professorships

The American Cancer Society Board of Directors has named two scientists ACS Research Professors.

John Coffin, professor in the Dept. of Molecular Biology and Microbiology, Tufts Univ., and J. Richard McIntosh, professor in the Dept. of Molecular, Cellular and Developmental Biology, Univ. of Colorado, were named ACS Research Professors. The appointments bring the number of Research Professors to 23.

Coffin is recognized as an international leader in the field of retroviruses. McIntosh has specialized in the study of the mechanisms of chromosome motion during cell division.

Assuming the Research Professor awards remain in effect until the professors retire, the total awarded is $1 million for Coffin and $575,000 for McIntosh. The awards are subject to scientific review every five years.

The ACS Research Professor awards, of which there can only be 25 in effect at one time, free the recipients from academic tasks and allow them to concentrate solely on research.

The ACS board, at its November meeting, also approved 190 new research grants and renewed 141 for a total of 331 grants for $40.377 million.

In fiscal year 1993, the society spent about $95 million on extramural research. Administration of the program accounts for less than 5 percent of the budget, according to the society.

Komen Foundation Offers Fellowships, Project Grants

The Susan G. Komen Breast Cancer Foundation offers postdoctoral fellowship grants to qualified applicants with MD or PhD degrees.

The three-year program offers an experienced breast cancer investigator the opportunity to select a fellow to train in his/her laboratory. The stipend will be $35,000 per year. No indirect costs are allowed.

The foundation also offers grants for innovative projects in: breast cancer education, screening and early detection, education concerning treatment of breast cancer, support programs, increased access to diagnostic and treatment services.

Applications are due March 15. Contact Elda Railey, Susan Komen Breast Cancer Foundation, 5005 LBJ Freeway Suite 370, Dallas, TX 75244, Tel. 214/450-1789.

Avon, NABCO Seek Proposals For Second Round Of Grants

Avon Products Inc. and the National Alliance of Breast Cancer Organizations will award a second round of grants through the Avon Breast Health Access Fund to support new and established community-based cancer programs that improve women's access to breast cancer education and early detection services.

At least $250,000 will be awarded in September. The funding levels will vary, with most grants to be made in the $5,000 to $20,000 range. Some "supergrants" will be made at the $25,000 to $75,000 level.

Deadline Is June 30

The application deadline for the second round of grants is June 30, and application forms will be available in mid-April.

The fund earlier this year accepted applications for the first round of grants. About $250,000 will be awarded for that round in March (**The Cancer Letter**, Jan. 7).

NABCO will offer technical advice and assistance to grant recipients, and NABCO and Avon will conduct annual evaluations of programs funded.

Applications forms may be obtained by writing to: NABCO and the Avon Breast Health Access Fund, 9 West 57th St., New York, NY 10019.

Equipment For Existing And Developing Cancer Centers

NCI has issued a "letter" Request for Applications (RFA) to institutions that have been awarded Cancer Center Support Grants (CCSGs or P30s) or Cancer Center Planning Grants (P20s) to provide equipment and instrumentation needs in cancer research.

Following is the notice of the RFA, published in last week's "NIH Guide to Grants and Contracts":

The awards are in the form of one-time supplements with no outyear commitments. Equipment requested should be for items not generally considered to be "portable" and/or generally not available through the traditional research grant mechanisms (e.g., R01s, P01s). These types of equipment normally require dedicated space, serve as a resource for several peer-reviewed, funded research projects; and are centrally managed by the cancer center.

Requests can be for a single piece of equipment, an upgrade to a piece of equipment or an existing facility, or several pieces of equipment that are components of an integrated setup. Up to $2 million in total costs will be committed to fund applications that are submitted in response to the "letter" RFA.

Institutions with P30s will be limited to one request and are required to provide matching funds of 50 percent of the costs of the equipment. Institutions with P20s will be limited to two requests and are encouraged to provide matching funds of 50 percent of the costs of the equipment.

Requests broadly related to breast cancer, prostate cancer, or other areas designated as areas of "high priority" research would be especially welcome; however, applications need not be limited to these cancers.

The receipt date for applications is March 1 and awards are anticipated before September 30. A copy of the complete "letter" RFA may be requested from: Anna Levy, Div. of Cancer Biology, Diagnosis and Centers, NCI, Executive Plaza North Rm 502, Bethesda, MD 20892, Tel. 301/496-8537.

RFA Available

RFA HG-94-001

Title: **Studies Of Genetic Testing And Counseling For Heritable Breast, Ovarian And Colon Cancer Risks**

Letter of Intent Receipt Date: March 1

Application Receipt Date: April 22

This RFA will solicit projects designed to examine the psychosocial and clinical impact of using gene-based diagnostic tests in families with heritable forms of breast, ovarian, and colon cancer to identify those individuals who have an increased risk of developing cancer and those who do not; and to gather information needed to establish clinical protocols for the optimum use of these risk assessment technologies in the future.

Up to $2.4 million (total cost) per year for up to three years will be available for 8-10 studies funded under NIH R01 and small research grant mechanisms (R03).

The goal of these studies is to identify clinical practices that best increase individual and provider understanding of genetic testing for cancer risks; the meaning and implications of test results; and strategies to promote health, prevent the development of cancer, and reduce the risk for test-related psychological harm, stigmatization and discrimination in individuals tested and their families. Multidisciplinary research teams are encouraged to respond to this RFA.

Research questions that may be appropriately addressed in applications responding to this RFA could include, but are not limited to:

1) identifying individuals who are most likely to benefit from genetic testing for heritable cancer risks;

2) determining optimum ways to educate individuals considering having genetic tests for cancer risk assessment, including public education and education through support groups;

3) establishing mechanisms to assess individual readiness for genetic testing for cancer risks (including minors and other individuals with diminished autonomy, in whom testing may be recommended) and determining factors that influence the decision to be tested;

4) defining issues that should be addressed in the informed consent process for individuals in families considering genetic testing and counseling for cancer risks, including the potential for the use of persuasion within families, changes in family dynamics, and stigmatization or discrimination;

5) examining diverse models (including a variety of settings and providers) of delivery for providing genetic testing and counseling for cancer risks;

6) identifying and evaluating strategies for providing post-test counseling and follow up for individuals who have had genetic tests for cancer risks (for both those individuals who were found to have an increased risk and those who were not);

7) determining what the psychosocial impact is on individuals who learn through genetic testing that their risk to develop cancer is either substantially increased above or no greater than that of the general population (especially as it pertains to family relationships, subsequent health behavior, reproductive intentions, and quality of life);

8) defining the impact of genetic diagnosis for cancer risk on subsequent interactions with health professionals and third party payers;

9) examining the behavior and actions of non-test-takers, including women, men and non-tested minors;

10) ascertaining attitudes, levels of understanding and interest in genetic testing to determine cancer risk in provider populations by whom testing might be offered in the future, distinguishing discipline, training, gender and ethnocultural differences;

11) ascertaining attitudes, levels of understanding and interest in genetic testing for cancer risks in individuals and families with diverse ethnocultural backgrounds to whom genetic testing for cancer risks may be offered in the future; and

12) examining the economic impact and technical accuracy of various genetic testing strategies for

determining cancer risks in families and other populations, including analysis of associated health care costs placed in the context of health outcomes related to early detection and interventions to reduce risks.

Inquiries: Elizabeth Thomson, Ethical, Legal, and Social Implications Branch, National Center for Human Genome Research, Building 38A Rm 617, Bethesda, MD 20892, Tel: 301/402-4997, FAX 301/480-2770.

Program Announcement

PA-94-033

Title: **Culturally Sensitive Intervention Strategies For Promoting Or Implementing Compliance With NCI Dietary Guidelines Among African Americans**

NCI invites R01 and FIRST (R29) applications for studies to develop and evaluate the effectiveness of culturally sensitive intervention strategies to assist African Americans in adopting eating patterns consistent with the NCI Dietary Guidelines.

This PA has four research objectives: 1) To identify barriers and motivators of dietary change among African Americans; 2) To develop culturally sensitive intervention strategies to increase knowledge and promote attitude and dietary/behavior change among African Americans; 3) To evaluate the effectiveness of these culturally sensitive dietary/behavior intervention strategies on achievement and adherence to the NCI dietary guidelines; and 4) To examine the effect of dietary changes on selective biochemical and anthropometric parameters, such as serum lipids, estradiol, body mass index, and waist to hip ratio.

Intervention sites may include, but are not limited to, various African American religious, professional, medical/nursing, social, public housing organizations, and community health centers as well as worksites, and businesses. Interventions may target individuals, households, groups, and/or organizations.

Two types of evaluation should take place under this PA: 1) process evaluation to identify ways of improving the program and determine how much of the program is being implemented as planned; and 2) outcome evaluation to judge how effectively the intervention strategies have worked. Investigators will be required to provide full details of how they intend to accomplish these types of evaluation, and how they will recruit and retain study subjects. A variety of culturally sensitive intervention strategies rather than a single approach should be used and should be adapted to the special needs of African Americans to provide them with the skills they need to make dietary change. Multidisciplinary teams are encouraged to apply.

Inquiries: Jacqueline Whittted, DCPC, NCI, Executive Plaza North Rm 232, Bethesda, MD 20892-4200, Tel: 301/496-8584.

Letter to the Editor

Broder Response To Waxman Is "Political Back-Pedaling"

To the Editor:

It is difficult to listen to and read the increasing number of scientifically incorrect and clinically unrealistic statements concerning breast cancer detection and diagnosis.

The most recent example of this was an exchange between NCI Director Samuel Broder's and Rep. Henry Waxman (D-CA), reported in the Feb. 4 issue of **The Cancer Letter.** It is ironic that Dr. Broder would suggest that NCI disregarded the National Cancer Advisory Board's recommendations because "we feel [the recommendation] is not consistent with the facts and realities."

The Director's response to Rep. Waxman's question as to how he would advise a 45-year-old woman raises questions as to who is out of touch with reality. Dr. Broder's original reply to a similar question was: "What I would do as an individual is recommend annual mammograms, but I can't recommend it to the public because I don't have the facts." (**The Cancer Letter**, Sept. 24, 1993)

His elusive response to Rep. Waxman can represent only political back-pedaling. Dr. Broder indicated that he did not wish to interfere with the doctor-patient relationship. Yet NCI's one-sided analysis of the screening data has done exactly that by deciding for the doctor and the patient.

Since most physicians and women do not have time to go back to the original data, it is impossible for them to make truly "informed" decisions. They look to NCI for guidance. Although Dr. Broder argued for a "full disclosure," NCI has never provided such a discussion and has ignored the arguments that suggest that screening can reduce breast cancer deaths among women ages 40-49, as it does for women ages 50-59.

As a participant in the NCI Workshop on Screening last February, I proposed that the workshop summary include both analyses. This was ignored.I have written to Dr. Peter Greenwald, director of the NCI Div. of Cancer Prevention and Control, with a summary of the data that support screening women ages 40-49 and requested that this be provided to

women and their physicians. This, too, has been ignored.

Dr. Broder's statements to Rep. Waxman indicate that he feels that a mammogram is justified for a woman age 40-49 only when she or another examiner feels or senses something in the breast that may be breast cancer. Clearly, he does not understand the proper use of mammography.

By the time a woman has signs or symptoms that suggest possible cancer, the advantage of mammography has been lost. Anyone who is directly involved in caring for women with breast problems realizes that the last thing mammography should be used for is to try to exclude breast cancer when there is a clinical suspicion. A major reason for obtaining a mammogram in a symptomatic woman, therefore is to *screen* the remaining portions of the ipsilateral breast as well as the contralateral breast for clinically occult cancer.

Dr. Broder legitimately suggested that before a woman has a mammogram she should be made aware that it may detect abnormalities that are not breast cancer, which may lead to "unnecessary" anxiety, and to a breast biopsy. He failed to mention that the same holds true for breast self-examination and clinical breast examination.

By the time a woman has signs or symptoms of cancer, the advantage of mammography has been lost.

Since these are both primarily screening techniques, both lead to the discovery of abnormalities that raise concern, anxiety and "unnecessary" biopsy of benign lesions. In fact, clinical breast exam instigates most breast biopsies. Since the vast majority of these prove to be benign, more "unnecessary" biopsies are instigated by clinical breast exam than by mammography.

Another myth holds that surgery will cause permanent scarring of the breast that will compromise future mammography. This same argument would also apply to the biopsy of palpable abnormalities.

The fact is, if surgery is performed properly, there is rarely any persistent, perceptible change, let alone change that could be confusing on the mammogram. Since mammography's primary role is detecting breast cancer earlier and it is of limited use in evaluating clinically suspicious abnormalities, keeping it "in reserve" for the evaluation of the symptomatic woman is ridiculous.

Finally there is the persistent myth that the breasts of young women are dense, and that they turn to fat at age 50, permitting screening to work. Many have the mistaken belief that radiogragraphic density correlates with breast firmness. In fact, breasts with higher fat content tend to be firmer. The mythology that the breasts become more radiolucent at age 50 has been perpetuated by analyzing the data with age 50 as the break point. Any phenomenon that occurs gradually over time will suggest a point of change if the data are analyzed around that point. When a pattern of change occurs, it is gradual, and in only 1 percent of the population, each year beginning at least by age 30. The ability to detect breast cancers earlier is the same for women ages 40-49 as it is for women ages 50-59.

It is illogical and scientifically inconsistent that NCI would continue to advocate routine clinical breast examination and be completely negative with respect to routine mammography. Furthermore, if NCI does not support screening mammography for women ages 40-49, it cannot logically or scientifically support clinical breast examination or the screening of high risk women under age 50. After all, there are no randomized, controlled trials that show that either can reduce mortality for women ages 40-49.

To satisfy the statisticians, a trial involving as many as 500,000 women would be required. If such a trial is undertaken, its results would not be available for 10 to 15 years. In that time 250,000 to 400,000 women ages 40-49 will be diagnosed with breast cancer. While we wait, women and physicians should be provided with full disclosure.

NCI states that there is disagreement among experts, but has thus far chosen to provide interpretation of data from only one perspective.

Rep. Waxman's question was on target. The response was nonsense. It is unconscionable for the NCI Director, with all the analytical resources at his disposal, to suggest that he has sufficient reason to recommend that his own patients be screened, but that he not share those reasons with women and their doctors.

Clearly, the discussion of what should be provided under a National Health Plan is a complicated one. However, NCI must avoid being pressured by politics into a non-scientific, medically illusory, unrealistic and insupportable position.

Daniel Kopans
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