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Health Care Reform: Fundamental Changes Ahead For Cancer Research And Care

The Administration's reform of the health care system is certain to force fundamental changes in cancer care and cancer research.

However, based on conversations with cancer professionals around the U.S., **The Cancer Letter** found that at this point the number of questions about the plan far exceeds the number of answers:

● How will the plan, which is purported to incorporate outcomes research, affect cancer care, a field where outcomes assessment is any-

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In Brief

Ozols Promoted At Fox Chase; Greenberger Moves To Pittsburgh; ACR Names New Officers

ROBERT OZOLS has been named senior vice president for medical science at Fox Chase Cancer Center. Formerly chairman of medical oncology at Fox Chase, Ozols is known for his expertise in ovarian cancer. His research focuses on anti-cancer drug resistance. His new responsibilities include overseeing patient care, clinical research and medical-science laboratory research. Before joining Fox Chase in 1988, Ozols was chief of the Experimental Therapeutics Section of NCI's Medicine Branch. . . . **JOEL GREENBERGER** has been appointed chairman of the radiation oncology department at Univ. of Pittsburgh Medical Center, co-director of the Lung Cancer Center at Pittsburgh Cancer Institute, and professor of radiation oncology, Univ. of Pittsburgh School of Medicine. He was chairman of radiation oncology, Univ. of Massachusetts Medical School. . . . **NEW OFFICERS** of the American College of Radiology were named at the ACR annual meeting last month in Orlando, FL. They are: **Karl Wallace**, Univ. of Virginia, elected to a second term as chairman of the Board of Chancellors; **Emmett Templeton**, Baptist Medical Center, Birmingham, AL, vice-chairman; **Mark Mishkin**, Jefferson Medical College, president; **Joseph Ferrucci**, Boston Univ., vice-president; **Ronald Givens**, Washington Univ., secretary-treasurer. **Kay Vydareny**, Emory Univ., was named council speaker. . . . **HERBERT PINEDO**, a leader in the establishment of the European Cancer Center in Amsterdam, The Netherlands, has decided to give up his position as clinical scientific director of the Netherlands Cancer Institute and return to full-time patient care and clinical research as head of the medical oncology department, Free Univ. Hospital. Pinedo held both posts during the last three years, but the workload made it necessary for him to continue with one job full-time, he told **The Cancer Letter**. He will remain a staff member and advisor to the Netherlands Cancer Institute.

Cancer Professionals Question Aspects Of Health Reform Plan

(Continued from page 1)

is anything but straightforward?

- Will community hospitals and academic centers sacrifice quality management (as well as quality patient care) in the cost-cutting frenzy brought about by health care reform?
- Will the gigantic new HMOs place a gate-keeper between the cancer patient and the oncologist? Will these HMO's continue to refer patients to dedicated cancer centers? Will treatment decisions in the new system be driven by science or by economic considerations?
- Will off-label indications for cancer drugs continue to be covered under the Clinton plan, as they are under the newly-enacted Medicaid regulations? Will the patients' treatment options be limited by the formularies?
- What will be the real role of the proposed seven-member National Health Board? One committee of the board, the "breakthrough drugs committee," will be given the authority to make public declarations regarding the reasonableness of the price of new products. Also, the group would have the authority to obtain information from the companies to back their pricing decisions. Could this group evolve into a price-setting board?
- How likely is Congress to force the Administration to include an added charge for biomedical research to the insurance premiums that will be paid by all Americans? The amendment to the Administration's plan is expected to be introduced by Sens. Tom Harkin (D-IA) and Mark Hatfield (R-OR).

Here is how the Administration's reform proposals are viewed by physicians, business executives, lawyers, lobbyists and administrators involved in the many aspects of cancer research and cancer care:

Bernard Salick, chairman and CEO, Salick Health Care Inc. of Los Angeles, operator of outpatient and inpatient cancer centers:

"The system that they've come up with will turn out to increase the total cost of health care and increase the level of mediocrity in the system. You can't possibly add in 40 million people and give them universal coverage and expect the health care costs not to skyrocket.

"To make the system work, you have to make it air-tight. That means everyone has to get the same insurance the same way. Here, you have escape hatches for companies with over 5,000 employees, the unions, the military. Once you've opened all these hatches, you effectively have no control.

"The biggest threat to cancer care is the concept of a low cost provider. The government is more focused on who is the lowest cost provider than on who is the highest quality provider.

"Big third party payers are organizing in such a way that they will become the leading providers in the community and freeze out the academic centers that have notoriously been unwilling to combine in an effective form to negotiate for managed care contracts. It's easier for a little hospital that doesn't have research or teaching programs to provide lower cost care than, say, Memorial Sloan-Kettering.

"They are going to be severely undercut since the teaching component kicker is going to be ratcheted down, so research hospitals will be at the same level as community hospitals.

"I think that spells disaster for teaching hospitals."

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Bruce Ross, senior vice president, Bristol-Myers Squibb Co.:

"I applaud the broad goals of the plan, such as universal coverage and health security. However, we have to see the details, particularly the cost details.

"I am concerned about the provisions that afford de facto cost controls. For example, the HHS Secretary has the authority to deny Medicare coverage if in her infinite wisdom she decides that she does not like the price of a pharmaceutical product.

"I am particularly concerned about the 'breakthrough drug committee.' Is this committee going to

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decide whether the price of a new drug is reasonable? How are they going to make that determination?"

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Sen. Tom Harkin (D-IA), chairman, Labor, HHS, Education Appropriations Subcommittee:

"What the Administration's health plan provides for in terms of medical research is minimal--and their proposal lacks any funding source. They just don't get it--funding medical research makes sense--through medical breakthroughs we can save lives and billions in health care costs. Besides providing access for all Americans, what other health reform goals are more important than that?

"The Republicans' draft health plan includes a medical research trust fund proposal, but without a dedicated source of revenue which will assure consistent funding for medical research. I plan to keep working with Sen. Hatfield and the over 100 national organizations that have endorsed our plan to win enactment of our trust fund proposal in the final health plan that passes Congress.

" The cancer research community can play a key role in winning this fight by contacting individual members of Congress to urge support for our efforts."

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Jerome Yates, medical director, Roswell Park Cancer Institute in Buffalo, NY:

"The biggest concern is what are the new health alliances going to be like and whether these gatekeepers are going to be put in a position where it is financially to their benefit not to refer patients to dedicated cancer centers.

"The HMOs are going to be competitive in terms of saving dollars. The pressures are going to be such that there may have to be financially driven treatment decisions rather than scientifically driven treatment decisions."

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Karen Gilden, oncology program administrator, Cobb Hospital and Medical Center, Austell, GA, and editor of "The Journal of Oncology Management":

"What I see happening is the tendency to fire or not hire experienced managers, including oncology administrators, and hiring less experienced people, presumably because they command a lesser salary.

"The down side is, can these people get the job done quickly and effectively, or will they be spending so much time on the learning curve that the hospitals that hire them would lose the opportunity for rapid action in the emerging climate of health care reform."

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Mace Rothenberg, assistant professor, the Univ. of Texas Health Science Center, San Antonio:

"I think this has been the first Administration to stick its neck out and say, 'This is a starting point.' At this point, the details of the plan will start emerging, and people will have to come up with alternatives.

"One concern from an oncologist's point of view is that under the plan the patient's access to an oncologist may be more difficult than in the past, both in initial visits and continuation of care.

"A key issue is going to be whether an oncologist is considered a primary care physician for a cancer patient. The system will be untenable if we are considered consultants."

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Michael Goldberg, president and CEO, Axion Pharmaceuticals Inc. of South San Francisco, a pharmaceutical service company:

"I am concerned that the Administration plan doesn't contemplate how cancer care is delivered. It's a 265-page plan in which the proposals affecting cancer aren't organized in one chapter. They are scattered throughout the report, and, as, President Clinton said, 'The Devil is in the details...'

"If, in an effort to contain costs, we limit clinical research, we won't be able to get the outcomes data to establish the pharmacoeconomic basis of relative treatment plans."

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C.D. "Dunk" Pruett, President and CEO, Advanced Cancer Technologies Inc., an Atlanta firm that specializes in bringing clinical trials to community hospitals:

"I am concerned by the fact that the plan, if carried out to the letter, calls for changing the health care culture overnight. I find it difficult to see how that could be accomplished without testing on a smaller scale prior to implementation on a national basis."

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Samuel Turner, Washington counsel to American Society of Clinical Oncology and partner in the firm of Fox, Bennett & Turner.

"There are some very positive things in the plan, notably the reference to coverage of patient care costs in peer reviewed trials. But there is a lot of uncertainty in the manner in which academic cancer centers would be able to have ready access to reimburse-

ment of those costs and how they would be able to accrue adequate numbers of people into clinical trials.

"The drug benefit is left unclear as to what the coverage of unlabelled indications. There is a general concern about the manner in which they may be dealing with pharmaceuticals. I don't think cancer patients want to be dealing with the formulary because a formulary may restrict their choices of treatment."

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Terry Lierman, executive director of the National Coalition for Cancer Research and president of Capitol Associates, a lobbying firm:

"It's good news, bad news. The good news is portability and comprehensive coverage, and, for medical research, the inclusion of coverage for clinical trials. The bad news is, it will probably have a very negative impact on the medical R&D industries and NIH.

"There is also some good news and recognition on the horizon: the Harkin-Hatfield Medical Research Trust Fund proposals has been accepted as part of the Republican health care reform package.

"Now, it's up to all the groups to join together to ensure that the Harkin-Hatfield amendment is incorporated into whatever Democratic plan is put forward."

Capitol Notes

Brinker Lobbies Administration To Ensure Attention To Report

How's this for a thankless job?

After hearing 150 witnesses at 11 meetings held over 18 months, Nancy Brinker finds herself having to lobby the Clinton Administration to pay serious attention to the upcoming report of her Special Commission on Breast Cancer.

The report, which will be presented to the Administration late this month, appears to have a couple of strikes against it:

First, Brinker's group, a special commission of the President's Cancer Panel, was formed by former vice president Dan Quayle, a potential liability in Bill Clinton's Washington.

More importantly, the National Breast Cancer Coalition, without overtly criticizing the Brinker's report, is calling for declaring breast cancer a No. 1 national priority and lauching an effort that would involve high funding levels, a number of federal agencies, and joint initiatives with the private sector.

"A national strategy is more than research, it's more than access [to health care]," said Fran Visco, the coalition's founding president. "It's an all-out effort from every single direction to eradicate this epidemic."

Speaking at a hearing of the newly founded Senate Cancer Coalition earlier this week, Visco described the work of [Brinker's] commission as a "very important tool in designing and implementing this national strategy."

Brinker, also a witness at the Senate hearing, came prepared to defend her report as the basis of a strategic plan, not just as an "important tool" in an effort spearheaded by another group.

"Our Commission--each of its members--and every expert who spoke with us--worked in an arena beyond politics," said Brinker, founder of the Susan G. Komen Foundation.

"Sometimes it's hard to believe that such a place exists. But it does. It exists where there is unity of purpose--and we had that, even when we disagreed about specific recommendations," Brinker said.

"I am told we will be given a hearing with the current Administration, and I trust that hearing will take place. Because if we are not heard, if this report is not accepted with the same commitment to finding a cure with which this commission was formed, you will have a very serious example of enormous governmental waste.

"In the year when health care makes headlines every day, this breast cancer agenda deserves this nation's attention, commitment and resources," she said.

In recent months, Brinker made similar pleas in letters to Hillary Rodham Clinton and HHS Secretary Donna Shalala.

At the Senate hearing, Brinker handed a draft of her forthcoming report to Harold Freeman, chairman of the President's Cancer Panel, asking Freeman to "find a home" for the report in a future strategic plan.

Last spring, President Clinton appointed Visco to replace Brinker on the President's Cancer Panel. Visco also served on Brinker's special commission.

Speaking for her coalition of 250 grassroots groups, Visco said, "I don't believe this country needs to prioritize. When we needed to build the Star Wars defense system, we didn't prioritize. When we wanted to put man on the moon, we didn't prioritize. We have the resources to do it all. We need to commit those resources to that."

At the hearing, Sen. Connie Mack (R-FL), pledged that he would see to it that Brinker's report

gets a hearing from the Administration and the Senate Cancer Coalition he cofounded with Sen. Dianne Feinstein (D-CA).

Others in the cancer field were not enthusiastic about the prospect of another, competing, strategic plan on breast cancer. "Enough studying and planning has been done; it's time to work on some cures," Terry Lierman, executive director of National Coalition for Cancer Research, said to **The Cancer Letter**.

"After talking to over 150 witnesses from around the nation and having many days of hearings, and having a stellar panel working on it, we are excited to see the final task force report on breast cancer. It's about time that we take this plan and implement it," Lierman said.

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Senate-House conferees late Tuesday were expected to reconcile the differences between the House and Senate versions of the Labor, HHS and Education Appropriations bills. Both the House and Senate bills have identical appropriations levels for NCI. The Senate bill was passed last week.

NCAB Urges Clinton To Seek $2-A-Pack Tax On Cigarettes

The National Cancer Advisory Board last month unanimously urged the Clinton Administration to seek a $2 per pack federal excise tax on cigarettes.

The NCAB, at its September meeting, said it was concerned that the Administration, in its health care reform measures, is considering a tax of only 75 cents per pack.

In a resolution, the board said the purpose of a higher tax "is not only that of raising revenues but is also that of producing a significant deterrent to this significant cause of cancer."

The new resolution also reaffirmed the board's resolution passed last February urging a tax of "at least" $2 per pack of 20 cigarettes and similar high taxes on the cost of individual cigarettes, cigars, and smokeless tobacco; and linkage of the tax to the Consumer Price Index.

The use of tobacco products causes over 300,000 cancer deaths annually in the U.S., costing about $50 billion, the board said in its earlier resolution. "Public education alone appears to be inadequate by itself to correct this serious health problem," the board said. The board recommended that the proceeds of the tax support deficit reduction and NCI research programs, including the American Stop Smoking Intervention Study (ASSIST).

"An increase in the cost of tobacco products would be the most effective way to reduce tobacco use by children and adolescents, by economically disadvantaged groups in our society, and by minority or underserved populations which have proved so difficult to reach or engage in educational endeavors," the board said. "The poor, as well as members of ethnic and racial minorities, at present suffer from a higher incidence of tobacco-related cancers (such as lung cancer, head and neck, and oral cancers) than the general population, and therefore disproportionately suffer from the tragic personal consequences of these usually fatal forms of cancer.

"We recognize that this recommendation goes far beyond the National Cancer Advisory Board's prior recommendations with respect to the dangers of tobacco, and is made with the recognition that such strong action is essential if the wastage of our nation's people due to tobacco-related illness is to be reduced and eventually eliminated."

The National Coalition for Cancer Research endorsed the NCAB's action in a statement last month. "Smoking is the single most important preventable cause of illness and premature death in this country," said NCCR President Robert Day, a member of the NCAB. "It is a well-known cause of cancer mortality, accounting for more than 30 percent of all cancer deaths."

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The National Cancer Advisory Board has formed a subcommittee to evaluate the National Cancer Program's progress against cancer over the past decade and define future directions.

The evaluation was mandated by Congress in the FY92 appropriations process.

NCAB Chairman Paul Calabresi said the subcommittee will review reports prepared by several expert panels established last year by NCI, and may hold additional hearings. The "Measures of Progress" panels presented their reports to the President's Cancer Panel last month. The subcommittee plans to complete its review in six to eight months, Calabresi said.

Subcommittee members are: Chairman, Paul Calabresi; Karen Antman, Erwin Bettinghaus, Norman Coleman, Pelayo Correa, former Rep. Joseph Early, Margaret Kripke, LaSalle Lefall, Deborah Mayer, John Niederhuber, Ellen Siegal, Ellen Stovall, Charles Sanders, and Harold Freeman, President's Cancer Panel chairman.

Breast Cancer Coalition Seeks National Trials Of Screening

The National Breast Cancer Coalition has called for a "system of national trials" to gather data on the efficacy of screening methods, inlcuding mammography, to reduce mortality from breast cancer.

The coalition's board recently approved the following statement:

"Realizing that mammography does not prevent breast cancer and that much of the available data are inconclusive, we support breast cancer screening guidelines based on data from randomized clinical trials. In order to gather data on the efficacy and appropriate timing of screening over the spectrum of age groups, we demand that all screening be done through a system of randomized national trials. Because it has been shown that screening mammography is efficacious for women between the ages of 50 to 70, we believe that national trials shall include but not be limited to randomizing women in this age group into screening programs that screen at least with mammography at different intervals. As the current screening data are inconclusive for women under 50, national trials must examine the efficacy and timing of different screening techniques. There are no data on screening for women over 70 and therefore a variety of screening methods and their timing should be studied. Until such time that a trial is available to her, every woman should be eligible for screening under the current (Sept. 20, 1993) national consensus guidelines."

NCI, Komen Launch Regional Breast Cancer Summits

NCI and the Susan G. Komen Breast Cancer Foundation have awarded grants to 26 medical centers to host regional Breast Cancer Education Summits to enlist business, community, and volunteer leaders in the effort to reduce deaths from breast cancer.

The summits are intended to educate community leaders about breast cancer and the importance of detecting it early when it is most treatable.

Grants from NCI and the Komen Foundation support the summits with combined funding of up to $30,000 for each large-scale summit and up to $11,500 for each mini-summit. The General Mills Foundation donated $355,000 to the Komen Foundation over the past three years to support the summit program. The American Cancer Society also will provide funding for each of the summits.

Sixteen large-scale and 10 mini-summits will be held in 22 states and the District of Columbia. Grantee institutions, principal investigators and summit dates are as follows:

Univ. of Alabama at Birmingham Comprehensive Cancer Center, Merle Salter, Feb. 18; Arkansas Cancer Research Center, Deborah Erwin, Oct. 15; Kenneth Norris Jr. Comprehensive Cancer Center, Ronald Ross, April 20; Northern California Cancer Center, Dee West, April 19; Univ. of Colorado Cancer Center, Paul Bunn, spring 1994; Yale Comprehensive Cancer Center, Marion Morra, Oct. 20; Washington Hospital Center, Sharada Shankar, April 20; Univ. of Hawaii Cancer Research Center, Brian Issell, spring 1994; Univ. of Chicago Cancer Research Center, Marcy List, April 8; Univ. of Kansas Cancer Center, Analee Beisecker, April 15; Lucille Parker Markey Cancer Center, Gilbert Friedell, May 1994; Dana-Farber Cancer Institute, Glorian Sorensen, spring 1994 (two awards, summits in MA and ME); Univ. of Nebraska Medical Center, Warren Narducci, April 23; Hollings Cancer Center, Pamela Cipriano, Feb. 18-19; Mary Babb Randolph Cancer Center, Pamela Brown, June 1994; Univ. of Wisconsin Cancer Center, Paul Carbone, spring 1994; Arizona Cancer Center, David Alberts, April 1994; Charles R. Drew Univ. of Medicine and Science, Donna Davis, spring 1994; Medical Center of Delaware Cancer Center, Emily Penman, April 19; Meyer L. Prentis Comprehensive Cancer Center, Gwen MacKenzie, summer 1994; Kaplan Comprehensive Cancer Center, Ronald Blum, spring 1994; Comprehensive Cancer Center of Wake Forest Univ., Electra Paskett, April 29; Fox Chase Cancer Center, Robert Young, February 1994; Pittsburgh Cancer Institute, Joyce Yasko, April 1994; Utah Cancer Center, Saundra Buys, Oct. 27.

NCI Contract Awards

Title: Geographic differences in breast cancer mortality
Contractor: Schulman, Ronca and Bucuvalas Inc., New York; $227,571.

Title: Tracing of mothers and offspring
Contractor: Equifax, McLean, VA; $7,008.

Title: A case control study of brain tumors
Contractor: Research Triangle Institute, $973,494.

Letter to the Editor

NCI Director Broder Responds To Kopans On Mammography

To the Editor:

Your article on NCI's proposed new guidelines included a statement by Dr. David Bragg "But is now the time to take a dramatic change in course and say mammography is dangerous in women under age 50?" Our draft guidelines state that experts have not reached agreement on the value of breast cancer screening with mammography or clinical breast examination for asymptomatic women in the age group 40-49. We have certainly not concluded that mammography is dangerous. None of the discussion on mammography should be based on a fear that it is dangerous.

Your article was accompanied by a Letter to the Editor from Dr. Daniel B. Kopans which included a number of charges that I would like to answer for the benefit of your readers. A similar response has been sent to Dr. Kopans.

We share Dr. Kopans' concern about breast cancer--that American women be afforded the best chances of reducing the morbidity and mortality from this disease. It was in this spirit, and with the conviction that the public and health professionals are best served when they are fully informed about health care technology, that we held the International Workshop on Screening for Breast Cancer. Much research has been published since we developed our current guidelines in 1987, and we believe that we must periodically reassess the state of science.

Until this workshop the primary support of our current guidelines had been the Health Insurance Plan of Greater New York Breast Cancer Screening Study (HIP). HIP proved that screening with mammography can save lives, achieving a statistically significant reduction in mortality for the full trial (ages 40-64), although analysis of the subset ages 40-49 did not show a statistically significant reduction in mortality.

To assess the new information, we asked investigators representing all eight trials to present the results of their research before their peers as well as members of the public and the press. We specifically did not charge the workshop with developing recommendations at the time, believing that it is the responsibility of the appropriate government agency to gather the scientific information and draft preliminary guidelines. In turn, these guidelines must then be reviewed by both health professionals and the lay public, and above all, the guidelines must be consistent with current science as well as medical judgment.

The conclusions drawn by the Workshop Writing Committee are valid. The importance of screening women 50-69 was given even greater emphasis by their review which reported statistically significant reductions in mortality in all but one trial. The one exception is the Canadian trial in women aged 50-59, evaluating mammography plus clinical breast examination against a well-performed clinical breast examination. For women 40-49, the trials showed no reduction in mortality in the first 5 to 7 years after the initiation of screening that can be attributed to screening. To quote the report, there is "an uncertain and, if present, marginal reduction of mortality at about 10 to 12 years."

This conclusion raises concern that our current recommendation for women age 40-49, namely screening with mammography and clinical breast examination every one to two years, may not result in mortality reduction.

Data from HIP and the succeeding trials indicate that breast cancer mortality among women age 50-69 could be reduced by (at least) 30 percent if all such women were to be screened. The trials for women 40-49, both singly and combined in meta-analysis do not demonstrate a reduction in mortality (Elwood JM, Cox B, Richardson, AK. The effectiveness of breast cancer screening by mammography in younger women. Online J Curr Clin Trials. 25 Feb 1993; 1993 [Doc No 32]). These results are in sharp contrast to those in women ages 50 to 69 which so clearly demonstrate the mortality reduction potential of mammography.

The trial results do not lead us to formally conclude a negative answer, namely, that mammography is ineffective in reducing breast cancer mortality in younger women. In science, it is very difficult to prove such a negative. We do believe, however, that there is uncertainty as to whether mammography can reduce mortality in younger women and if so, on the extent of the reduction. Based on the high statistical power of meta-analysis, we are quite certain that the non-statistically significant results are not masking as much as a 20-30 percent mortality reduction.

Our views are really rather straightforward. We believe women and their physicians must be informed

of this uncertainty. We recommend, therefore, that women seek counsel with a health professional, and we will provide guidance to both the lay public and health professionals on the potential benefits and risks of screening. We certainly do not oppose the use of screening mammography in this age group. What we are saying in the draft under discussion is that this is a decision that an informed woman should make in consultation with her physician.

Dr. Kopans' letter states that there is "good evidence that screening can benefit women ages 40-49 just as for women 50 and over." He invokes the results of the Breast Cancer Detection Demonstration Project (BCDDP) to argue that survival of patients over 50 and under 50 is similar when cancers of similar size, grade, and stage are compared, pointing out that "there is nothing mystical that happens to the breast at age 50." Yet the screening trials show considerably different results for women 50 and over versus women under age 50. These results are a function of the higher incidence of the disease in older women and, we believe, a function of changes in breast tissue at menopause.

One factor is the reality that some women have palpable tumors that cannot be detected on mammography. In addition, we certainly cannot rule out that premenopausal women are more liable to exhibit micro-metastatic disease at an earlier point in their cancer.

I fervently wish that the results of the trials had shown that mammography reduces mortality in younger women. Unfortunately, we do not know that this is the case, and our change in guidelines reflects this uncertainty. At a minimum, we believe the statement that experts do not agree on the value of screening mammography in this age group is absolutely fair and true.

Dr. Kopans charges that the Workshop was "a mere formality;" that we wish to ignore "good evidence;" and that there is a "lack of science, logic, and consistency in NCI's analysis." He also charges that "good medical advice is being overshadowed by the desire to reduce the cost of health care, and that NCI is "pronouncing that screening doesn't work."

Please note that the Workshop was planned long before the current health care reform plan was formulated; that as a science-based institution we are more than open to the review of evidence through the peer review process; and that, above all, our mandate is to reduce the morbidity and mortality from cancer.

The NCI would never knowingly take any action that would lessen progress against this disease. And please note once again, that we have not concluded that screening mammography fails to work for women 40-49, only that our most recent evidence does not allow us to draw a conclusion.

To quote our draft guideline, "experts have not reached agreement on the value of breast cancer screening with mammography or clinical breast examination for asymptomatic women" ages 40-49. Certainly this latter point is not open to serious dispute.

Our draft recommendation of annual clinical breast examination (CBE) for women 40 and over, and breast-self examination, is prefaced by our statement that the value of these procedures has not been established through clinical trials. In our judgment we consider these practices prudent, and especially so for CBE, an important part of a periodic examination by a health professional. We believe there are fundamental differences between a recommendation for CBE and screening mammography, and the algorithm for making a recommendation is quite different. Dr. Kopans appears to disagree with this point, and this is his right.

We believe that these guidelines are consistent with our obligation to fully inform the American public of the benefits and risks of all cancer interventions. We believe there is no "lack of science, logic, and consistency" in this approach, but, in fact, it is based on science to the greatest degree possible.

We understand that some may choose screening, and we are simply saying that randomized clinical trials have not demonstrated a clear reduction in mortality for asymptomatic women. This stands in clear contrast to the results in women over 50, a huge subset of our at-risk population, and also a subset of women who appear to under-utilize this technology. We believe that each woman requires independent evaluation with a health professional and that symptoms or risk factors must always be assessed.

Our guidelines must reflect the results of our scientific studies, and as such, they are subject to change as new information becomes available. Moreover, it may well be that advances in imaging technology or molecular medicine will cause us to improve and revise our guidelines in the near future. We certainly hope so! But for now, we must play the hand that has been dealt.

Samuel Broder
Director
National Cancer Institute