DKS 8/12/88

THE CANCER LETTER

Vol. 14 No. 33

August 12, 1988

Subscription: $175 year North America, $190 year elsewhere

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Progress Measures "Adequate," Committee Says; Suggestions Include New Death Rate Measure

The Extramural Committee to Assess Measures of Progress Against Cancer, established at the request of the Senate Appropriations Committee following charges over the last couple of years that the National Cancer Program has not been making much progress, has concluded that "existing

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In Brief

Griesemer Returns To NIEHS To Head Toxicology Research & Testing; Robert Burnight Dies At 69

RICHARD GRIESEMER, who headed NCI's Bioassay Program at the time it was moved to the National Institute of Environmental Health Sciences as part of the new National Toxicology Program, has returned to NIEHS as director of the Div. of Toxicology Research & Testing. Griesemer's appointment was annouonced this week by David Rall, director of both NIEHS and NTP. Griesemer left as NTP deputy director in 1980 to join Oak Ridge National Laboratory as senior scientist and director of the Biology Div. . . . **ROBERT BURNIGHT**, former executive secretary of the Div. of Cancer Prevention & Control Board of Scientific Counselors, died Aug. 1 at the NIH Clinical Center following a long fight against pancreatic cancer. He was 69. He joined NCI in 1979 after a career as a sociologist and teacher. Burnight's major contribution to the Cancer Control Program was his work in development of the successful Cancer Control Science Associates Program. He retired in 1984 after his illness was diagnosed. . . **LEE BENNETT** has been selected as the first scientist promoted to the rank of Distinguished Scientist at Southern Research Institute. The new rank, highest at the Institute, is part of a new program to allow scientists to advanced to high positions without necessarily having administrative responsibilities. Bennett played a major role in developing the Institute's cancer research program, working with Howard Skipper, John Montgomery, Frank Schabel and other Institute scientists. He retired in 1985 as director of the Biochemistry Research Dept. but continues as a key member of the Institute's cancer research team. . . . **SEYMOUR LEVITT**, Univ. of Minnesota professor and head of therapeutic radiology, has received the Univ. of Colorado Distinguished Service Award. He received both his bachelor's and medical degrees from the Univ. of Colorado, and is known for his work in lymphoma and breast cancer treatment.

"Profile Of Progress" Suggested For Every Three To Five Years

(Continued from page 1)
measures are generally adequate for assessing progress, but because of the limitations inherent in the available measures, careful interpretation is mandatory."

The committee offered a number of recommendations for improving the present methods: Reporting on incidence and survival should be coupled with an evaluation of risk factors, screening and treatment practices and advances in basic and clinical research, providing a "profile of progress against cancer" every three to five years; NCI's SEER Program should be strengthened, primarily by including with its collection of data from specific registries around the U.S. data from other federal agencies; patterns of care studies should be carried out regularly; translation of research results into practice should be tracked and reported; a review of spinoffs from cancer research should be made and reported; research should be carried out on the accuracy of incidence and mortality rates and on their relation to survival; research is needed on how cancer statistics are affected by changes in other causes of death.

Omitted from the body of the report but included in the appendix is an intruiging suggestion for a new death rate measure: Instead of using the general population as the denominator, use instead the number of diagnosed cancers in a base year.

"The principal utility of the new measure is to detect changes in the mortality rate that may be under way due to a cancer control activity sooner than is possible with the conventional death rate," the report appendix says. "Analysis of the impact of cancer control based on the new measure will require comparisons among time series for earlier periods and a time series that starts with or just before the year in which the cancer control activity is initiated. To make comparison of the measures easier, the trend series should not overlap."

Although this suggestion was not included in the main report's recommendations, the appendix stated that it and related measures should be investigated "to assess their responsiveness to changes in cancer control."

The committee was chaired by Lester Breslow, director of health services research in the Div. of Cancer Control at UCLA's Jonsson Comprehensive Cancer Center.

One of the committee members was John Bailar, now professor of epidemiology and statistics at McGill Univ. in Montreal. Bailor, who as an NCI staff member was the first director of the Cancer Control Program after it was created by the National Cancer Act of 1971, has been the principal critic of progress in the National Cancer Program. His article two years ago in the "New England Journal of Medicine" challenged NCI statistics which have shown significant improvement in cancer survival.

The reaction to Bailar's article and to other criticism led the General Accounting Office to investigate progress in cancer survival. Looking at 12 cancer sites, GAO concluded that advances in detection and treatment of cancer from 1950 to 1982 have extended survival in all but one, due to improvements in surgical and radiation procedures, earlier detection and the advent of chemotherapy.

However, GAO concluded that true improvements often are less than reported because of earlier detection.

NCI criticized the GAO report because of its focus on survival rates as the principal indicator of progress.

Last year, the Senate Appropriations Committee asked that an extramural panel be convened to recommend what measures are most appropriate to assess progress in cancer. Panel members should be drawn from outside NCI and NIH and should included recognized experts in appropriate areas such as biostatistics, epidemiology and cancer research.

All Experts

The Senate also said that "one or more panel members should be nonexpert public representatives." That apparently was overlooked because all of the members are experts in cancer or other health related areas. In addition to Breslow and Bailar they are:

--Byron Brown, head of the Div. of Biostatistics at Stanford Univ. Medical Center.

--Helene Brown, director for community applications in the Div. of Cancer Control at UCLA's Jonsson Comprehensive Cancer Center. Brown is also a member of the National Cancer Advisory Board and member of the American Cancer Society Board of Directors.

--William Darity, dean of the Univ. of Massachusetts School of Health Sciences. He is also a member of the Board of Scientific Counselors of NCI's Div. of Cancer Prevention & Control.

--Vittorio Defendi, chairman of the Dept.

of Pathology at New York Univ. School of Medicine.

--Bernard Fisher, professor of surgery at the Univ. of Pittsburgh, chairman of the National Surgical Adjuvant Breast & Bowel Project, present member of the National Cancer Advisory Board and former member of the President's Cancer Panel.

--Robert Goodman, chairman of the Dept. of Radiation Therapy at the Hospital of the Univ. of Pennsylvania and former member of the Board of Scientific Counselors of NCI's Div. of Cancer Treatment.

--Frederick Mosteller, director of the Technology Assessment Program of the Harvard School of Public Health.

--Sam Shapiro, professor emeritus of the Dept. of Health Policy & Management at Johns Hopkins Univ. School of Hygiene & Public Health. He is a former member of the Board of Scientific Counselors of NCI's Div. of Cancer Etiology.

The 60 page report has been submitted to the Senate Appropriations Committee. The exeucutive summary of the report follows:

Introduction

This report responds to the request by the Senate Appropriations Committee "to recommend what measures or series of measures are most appropriate to assess progress in cancer."

Interest in the question arises from many circumstances:

1. Cancer is the second leading cause of death in the U.S. and five million living Americans have been diagnosed at some time to have the disease.

2. It is almost 20 years since the national declaration of "war against cancer," during which time large sums of money have been allocated to the fight; a myriad of scientists, health professionals, and other people have enlisted in the effort; and many claims have been publicized.

3. Recent attempts to assess progress against cancer have not achieved consensus in the medical science community.

4. Appropriate measure(s) of progress against cancer are needed not only to evaluate what has happened in the past, but more significantly, to help determine the nature and extent of further efforts to reduce its burden on people and society.

This report deals with the measures now used and suggests additional measures that might be used to assess progress against cancer. The assessment of cancer progress itself was not part of the charge to the committee.

Summary

The final measure of progress against cancer must be its effect on people. Reducing the extent to which people develop cancer, suffer from it, and die from it is the aim of efforts by physicians, research investigators, patients, family members, legislators, and others concerned about the disease. Thus, examining the occurrence of cancer (incidence), resulting deaths (mortality), and the duration and quality of life after diagnosis (survival and quality of survival) constitute major methods of measuring progress against cancer.

Complexities immediately arise, however, in using these measures. The first is that cancer is not a single disease; it is a group of at least 100 diseases affecting various tissues in various parts of the body. Progress may be made against certain kinds of cancer while other forms of the disease remain undiminished or even increase. Furthermore, cancer strikes various segments of the population (defined by age, sex, racial-ethnic group, and socioeconomic status) with different force; and the relative impacts in these groups may change over time. Thus, summary measures may conceal important variations with regard to the cancer burden and trends in change over time.

Secondly, while cancer measures seem straightforward, their interpretation requires much care. For example, data on patients diagnosed as having a particular type of cancer may show a marked improvement in the length of survival following diagnosis. This progress could be due to improved therapy, to earlier detection, to detection of cancers of a more indolent type through a change in screening or detection methods, or to some other factor in the chain of events that brings the patient to timely diagnosis and therapy.

In assessing progress it is also essential to consider how the past and present efforts of physicians and research investigators could influence the way and extent to which cancer will affect people in the future. For example, current change in tobacco use in the population is a surrogate or indirect measure for predicting cancer mortality attributable to that risk factor. Whether women get Pap smears or screening mammography of good quality indicates what future benefit they will obtain from present use of those screening services. How closely physicians seek state of the art

diagnosis and therapy for their cancer patients, or adhere to it, will determine the amount of benefit their patients will derive from available technology. Scientific research yields ever increasing knowledge that may be pertinent to the prevention and treatment of cancer.

In guaging progress against cancer, it is tempting to count increments in knowledge of biological mechanisms related to cancer, advances in diagnosis and therapy (e.g., promising new therapeutic innovations), changes in health habits (e.g., decreases in smoking), and changes in routine medical practice (e.g., increases in cancer screening). Such indicators are all encouraging, and many will reduce the cancer burden; but it is important to be realistic in projecting the potential impact of these advances, and to be aware of past failures in translating the possible into the achieved. Projections should be data based and experience linked, where possible, with indications of the certainty or uncertainty associated with the projections.

Two sets of measures are therefore appropriate: (1) direct measures such as mortality, incidence and survival; and (2) indirect measures including those current accomplishments that may indicate a favorable impact on the future experience of people with respect to cancer. These two sets of measures describe a dynamic system. Assessing cancer progress requires judging the strength of evidence that connects one element in that complex system with another. Examples include the links among a new form of therapy, the probable scope of its adoption, and its results in treating cancer patients; or the links between a new method to deliver state of the art therapy to cancer patients and their survival; or the links between a newly discovered dietary relationship to cancer and its use to reduce incidence rates.

Scientific findings, whether from the laboratory, the clinical setting, or epidemiologic and cancer control studies, are often exciting and may have important implications for the health and survival of the public. Assessing their potential contribution to progress against cancer, however, requires delineating their general applicability to the population or their use in hospitals and clinics across the country.

Findings (Verbatim from the body of the report)

The committee finds that:

1. Two broad sets of measures are necessary for assessing progress against cancer:

A. Measures of the impact of cancer on people, as revealed by incidence, survival and mortality statistics.

B. Measures of the actions of the general population, physicians, the health care system, and research scientists that portend significant future impact on cancer incidence, survival and mortality in the population.

Realistic assessment of the linkages between research findings and their probable impact on how cancer affects people are fundamental to understanding the progress being made and its potential for reducing the cancer burden. The most critical difference between the above two sets of measures is that the first assesses existing accomplishments in reducing the burden of cancer while the second assesses the potential effects of present activities and knowledge to reduce the future cancer burden.

2. Since cancer consists of a complex of over 100 different diseases striking various segments of the population with different force, it is often necessary to examine how specific kinds of cancer affect specific groups of people defined by their age, sex, race or ethnicity, socioeconomic status, and other descriptors, and how these effects are changing and may change in the future. Likewise, overall measures (all cancers combined) have a place in understanding progress but should generally be reported along with more detailed data on specific cancers.

3. Cancer mortality is the ultimate measure of the impact of the disease on the population. The current system for collection, quality control and analysis of mortality data is adequate. Activities such as health promotion, disease prevention, disease detection, and treatment can influence cancer mortality, and much of their importance comes from their effect on mortality. It is critically important to have current, reliable and detailed mortality data to assess trends and to evaluate the effects of these and other activities intended to reduce mortality rates.

4. Incidence rates measure the newly diagnosed cases of cancer, and are one important indicator fo the amount of disease experienced by the population. The present statistical system for assessing cancer incidence is of very high quality, but does not provide sufficient data about the occurrence of cancer in important segments of the population, such as Hispanics. Health promotion, disease prevention and detection activities can

influence cancer incidence rates. Interpretation of incidence data is not as straightforward as in the case of mortality because they are sensitive to several potentially serious biases, which can influence trends in the states.

5. Survival refers to the length and quality of life following a diagnosis of cancer. It is the measure most directly sensitive to changes in detection practices, treatment regimens, and advances in clinical care. Survival data are important, but they are sensitive to several potential biases. These biases may result in apparent trends in survival over time that do not reflect meaningful changes for the population. Information about survival, in particular about the quality of life of cancer patients, should be supplemented by special studies which should focus, at a minimum, on patterns of health care and the effect of those patterns on survival among various segments of the cancer patient population.

6. Information on the extent of smoking, cancer screening, and other behaviors related to cancer incidence and detection, along with data on access to care, and especially access to experimental and state of the art cancer care, are essential for assessing progress. This information reflects what people do, what physicians and other health professionals do, and what institutions do that may affect the overall burden of cancer.

7. Extensive statistical and epidemiologic analysis are performed on many of the measures related to progress against cancer; however, the relationships among the measures are complex and often difficult to assess and interpret. These relationships require additional exploration.

8. The reporting of information on cancer is necessary for the National Cancer Program, for the National Cancer Institute and its scientific and public constituencies, and for Congress. All need periodic, comprehensive data and interpretation to guide their efforts. The current annual publications of cancer statistics by NCI are especially useful in this regard. Continued work is necessary to preserve the high quality of this system under changing conditions, and to further strengthen and extend the system to meet new demands.

Recommendations

The committee developed the following recommendations based on its findings. They fall into two categories: recommendations on reporting, and recommendations on research and development related to the collection and analysis of cancer related data. The committee noted an urgent need to act on these recommendations to provide insight for directing the National Cancer Program. The remarks and recommendations represent suggestions for the National Cancer Program as a whole except where specific references to a federal agency or another organization are noted.

Recommendations on Reporting

1. Comprehensive reporting document--The NCI annual cancer statistics review contains much information related to progress against cancer. However, additional information could provide valuable insight into an assessment of progress. Mortality, incidence, and survival data should be coupled with information on prevalence of risk factors, cancer screening and treatment practices; and advances in basic and clinical research because of their pertinence for evaluating progress against cancer as outlined here. In essence, the nation needs a periodic profile of progress against cancer.

The frequency of producing such a comprehensive document should be decided by NCI, taking into account the following considerations. It should be sufficiently frequent to provide an instrument, for NCI as well as for other agencies and organizations, involved in the National Cancer Program, that will be useful in the planning and management of cancer research and control programs. The committee recommends that this comprehensive document be produced no less frequently than every five years, and three years might be a better interval.

2. Data collection and data generation system--The data collection system should be developed and maintained so that the data needed for the reporting of cancer progress can be produced on a routine basis. Most importantly, NCI's Surveillance, Epidemiology & End Resuslts (SEER) Program should be continued and strengthened by integrating data from other federal agencies on a routine basis, as is the current practice between NCI and the National Center for Health Statistics. The focus of the data collection efforts, and recommendations concerning appropriate agencies and data collection mechanisms, are adequately specified in the NCI monograph, "Cancer Control Objectives" (Greenwald and Sondik, 1986).

3. Collaboration with other agencies--As noted in the Cancer Control Objectives monograph, information on many measures related to progress against cancer is developed both by NCI and other agencies. In the past NCI has collaborated extensively with NCHS.

Coordination with these agencies should be continued and expanded so that a maximum amount of information can be developed efficiently and expeditiously.

4. Access to care--Ready access to care, in terms of both proximity and economics, is an important factor in assuring that state of the art cancer care is accessible and available to all patients. A comprehensive report on cancer should include information on access to cancer care and recent changes in access.

5. Treatment information--This is an important component of the cancer care reporting system. Data indicate that some Americans receive cancer care below the standards of recognized experts. As the health care system changes, with increased emphasis on outpatient treatment and prepaid health care, the cancer reporting system must also change to assure that descriptors of the care received by patients are properly reflected. The committee recommends that NCI staff explore ways of assuring that an adequate sample of cases is captured in the reporting system. Further, the committee recommends that NCI conduct appropriate studies of patterns of care to identify the level of cancer care in the general population. The cooperation of professional organizations could be helfpul in this endeavor.

6. Patterns of service--Services provided to the public and to cancer patients significantly determine the impact of cancer on the population. The committee recommends that NCI track patterns of care and assess the cancer control services available for and delivered to the public and cancer patients. These should include preventive, screening, and behavioral modification services at hospitals, public health agencies, physician offices and voluntary health organizations.

7. Tracking the impact of cancer control research--An important aspect of the National Cancer Program is research on cancer prevention and control. The committee recognizes the broad nature of this research and its potential for reducing morbidity and mortality from cancer. To assure that this potential is realized, the committee recommends that methods be determined for tracking the translation of research results into practice.

8. Reporting on basic and clinical research --Progress against cancer is not revealed in full by either a compilation of changes in incidence, mortality or survival figures or a compilation of research reports. It is essential to link the reports of new findings from basic and clinical research to the probable impact of these findings on what happens, or will happen, to people. The committee recommends that in its reports of progress, NCI discuss the linkage between research results and their probable impact, and that this reporting be included in the comprehensive cancer progress reporting document mentioned in the first recommendation, above.

9. Spinoffs from cancer research--The broad nature of the National Cancer Program has led to many collateral research advances that have no apparent or immediate special relation to progress against cancer. The committee recognizes the value of such spinoffs and recommends a periodic review of these advances.

10. Timeliness of data and reporting--Categories of information should be considered in terms of their urgency. Early impact of improved treatment should be seen in survival rates, for example. NCI should periodically review its data collection and reporting system specifically to determine whether data are available in as prompt a manner as is needed for effective program management.

Recommendations on statistical research and development

1. The relationship between incidence and mortality is complex. The committee recommends that NCI conduct research on the accuracy of both incidence and mortality rates and on their relationship to survival rates.

2. The impact of competing causes of death on cancer statistics is not well understood. While the impact is thought by many experts to be small for age adjusted rates, additional research is necessary on how cancer statistics are affected by changes in other causes of death. Another important question concerns changes in risk factors common to cancer and other diseases, and differential lags in the impact of a change on mortality.

Edward Sondik, chief of the Surveillance & Operations Branch in the Div. of Cancer Prevention & Control, was executive secretary of the committee. Other staff members who provided support were Larry Kessler, John Young, Lynn Ries, John Horm and Eric Feuer.

Pastan's Lab Creates "Chimeric" MoAB With Human, Mouse Cells

NCI scientists headed by Ira Pastan reported this month on a major step toward designing and creating anticancer weapons by recombining genes for antibodies from a

variety of sources in the cells that manufacture monoclonal antibodies.

Pastan, chief of the Laboratory of Molecular Biology in the Div. of Cancer Biology & Diagnosis, announced in the Aug. 1 issue of the "Journal of Immunology" the cloning of the tumor binding portion of a monoclonal. Pastan's group also inserted the cloned gene into an antibody producing cell and detected antibody production from the new gene. This demonstrates that the technology is available to create recombined monoclonal antibodies from the genes of a variety of sources, including human, animal, plant and bacterial.

The scientists hope to use this technology to design and create monoclonal antibodies that target and kill cancer cells more powerfully and with fewer side effects.

The new hybrid monoclonal antibody is synthesized by cells with genes from two sources. Genes for a mouse antibody were inserted into a mouse hybridoma, a cell culture that grows continually, producing a specific homogeneous antibody. The cell is a hybrid of a mouse tumor cell and a mouse antibody producing cell.

In this case, the hybridoma had a genetic error and could not produce antibody; its gene for a portion--the heavy chain--of the antibody had been lost, preventing its synthesis. However, when the cloned gene for the heavy chain was inserted, the hybridoma then synthesized antibody. The new, recombined antibody incorporated the heavy chain synthesized from the inserted gene, the investigators reported.

The original, nonrecombined antibody binds to human tumor cells, but it has no antitumor activity. Consequently, Pastan's group is trying to modify the antibody genetically in an attempt to improve its value as therapy.

Eventually the scientists plan to create a monoclonal antibody containing mice and human portions. This is called a chimeric antibody, because, like mythological chimeras such as the sphinx, satyr or manticore, it combines parts from different species into one.

In this article, Pastan reports early attempts to create a hybridoma from recombined antibody genes that produces a chimeric monoclonal antibody. The goal is to produce a more potent agent for killing tumor cells.

Antibodies are weapons of the immune system; they have a spearhead end that attaches to and acts on molecules (antigens) on tumor cells, and the other end is like a spear handle. It interacts with other parts, including the soldier cells, of the immune system.

Pastan's lab is incorporating the portion of the mouse antibody that attaches to the tumor antigen, because that is the easiest and best way to produce antibody binding, or recognition, site.

The investigators plan to incorporate a human gene for the region that interacts with the immune system. Adding the human portion of the monoclonal antibody would solve several problems encountered when using mouse monoclonal antibodies to treat human diseases. This is the portion of the molecule--the spear handle--that interacts with the immune system to elicit a complex series of actions by the various soldier cells of the immune system that collaborate to kill tumor cells.

Incorporating a human gene would signal a more powerful immune attack by eliciting a cascade of proteins that burst tumor cells. The human handle would also elicit a more powerful response by immune cells that are called into the fray by antibodies' interactions with antigens. On the other hand, the human antibody portion would not elicit so powerful an allergic reaction--the production of antibodies against the foreign antibody--by the immune system. The human handle would not be seen as foreign. Consequently, larger and more doses of antibody could be given.

Pastan's lab also plans to add another gene to this recombined, chimeric antibody gene. By attaching a gene for a bacterial toxin to the handle of the antibody gene, the scientists would enhance the killing power of the monoclonal antibody. In the past, researchers have chemically attached toxins to monoclonal antibodies, but now they are attempting to cause the hybridoma to synthesize a biological toxin, a peptide, attached to the antibody.

One obstacle they must hurdle is to find a hybridoma that is not killed by the toxin. There is some evidence that that is possible.

Working with Pastan in the study are Maria Gallo, Vijay Chaudhary, David Fitzgerald and Mark Willingham.

DCPC Developing Hispanic Cancer Control Intervention Program Concept

NCI's Div. of Cancer Prevention & Control is in the process of developing a Hispanic Cancer Control Intervention Program, with the intent of presenting one or more concept proposals to the division's Board of Scientific

Counselors at its meeting next January.

The division's Special Populations Branch, part of the Cancer Control Science Program, has held one working group meeting, in Miami, which provided information on cancer incidence and risk factors among Cuban Hispanic Americans. Another working group meeting is planned Sept. 15-16 in San Antonio, when data will be gathered on Mexican Americans and Puerto Ricans.

Elva Ruiz, director of the Special Populations Branch's Hispanic Cancer Control Program, said that findings of the two working group meetings will be presented at a meeting in Washington DC prior to the DCPC Board's Oct. 6-7 meeting. No date has been scheduled.

The working groups have been identifying key priority cancer research interventions which will be built into the proposal to be submitted to the Board for concept approval. Basically, the plan is to establish a community and research network for cancer prevention and control in Hispanic populations.

When Ruiz discussed the program with the Board's Cancer Control Science Program Committee, members suggested that interventions be considered which preserve the healthy behaviors that currently exist in the Hispanic population, especially the low prevalence of smoking among Hispanic females.

The committee identified some additional sources of data that should be evaluated. Business and industry, which track the health status of their work force; state registries where present; the Hispanic HANES; the cancer control supplement to the Health Interview Survey; and the CDC behavioral risk factor survey were other potential sources of data.

Ruiz told **The Cancer Letter** that work is in progress on gathering data from those sources.

John Horm, director of data coordination and analysis, and possibly Carlos Caban, program director in CCSP, will participate with Ruiz in the San Antonio working group session.

Another concept under development, this a joint effort by the Surveillance & Operations Research Branch and the Health Promotion Sciences Branch, will support an effort to test the effect of dietary interventions by mail.

Gladys Block presented the concept to the committee, which expressed some reservations about the potential success of mail interventions. The committee asked that staff prepare a thorough literature review.

Boston Meeting To Look At Federal Research, Human Subject Regulations

Public Responsibility in Medicine & Research, a national organization concerned with ethical issues in research and medicine, is sponsoring a meeting entitled, "IRBs at the Crossroads: Expanding Roles and Expanded Problems." The meeting will be held Oct. 27-28 at the Boston Park Plaza Hotel.

The conference will look at federal regulations on research with human subjects, and will reassess their breadth as their 10th anniversary approaches. Other issues to be examined will include the problems of fraud and misconduct in medical research; the conduct of clinical trials in general, and subject payment for research drugs and devices in particular; IRB review of innovative therapies, including sequencing the genome, genetic testing and genetic research; input by pharmaceutical companies into the IRB review process; researcher responsibility in determining appropriate uses of confidentially acquired research data, including those derived from HIV related projects; the use of cell lines and tissues, including fetal tissues; research with the elderly; the IRB's role in educating investigators and other institutional staff; reviewing research involving biohazards, and reviewing AIDS research, including vaccine development.

The conference will include two specially designed educational series, one for committee administrators and the second for new IRB members. This series serves as a basic orientation course for any new member, chair or administrator.

The meeting will consist of both plenary sessions and workshops, and will have a faculty of over 30 experts from the fields of IRB operation and administration, research and clinical lpractice, the federal government, legal profession and practicing ethicists.

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Published forty-eight times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter.