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Witnesses Seek 15% Boost For NCI In 1998 As First Step To 100% Raise Over 5 Years

Representatives from cancer professional societies and advocacy organizations urged Congress to increase the NCI appropriation by 15 percent in fiscal 1998 and proceed with the proposal to double the Institute's budget in the next five years.

In testimony before the House Appropriations Subcommittee on Labor, HHS, and Education, representatives from National Coalition for Cancer Research, the American Association for Cancer Research, the

(Continued to page 2)

In Brief

Visco Named To Cancer Policy Board; Foundation Pledges $6.5 Million To Karmanos

FRAN VISCO, president of the National Breast Cancer Coalition and a member of the President's Cancer Panel, has been named to the Institute of Medicine's National Cancer Policy Board. Visco's appointment brings the membership of the board to 20. . . . **KARMANOS CANCER INSTITUTE**, of Detroit, has received a pledge of $6.5 million from The Kresge Foundation, of Troy, MI. The foundation will release the funds when the center's five-year fundraising campaign reaches its goal of raising $100 million, the center said this week. Kresge is one of the 10 largest foundations in the U.S., with assets of $1.8 billion. The grant will support renovation and expansion of facilities to create the Hudson-Webber Cancer Research Center, Karmanos officials said. Also, the funds will support the Institute's goal to achieve a five percent reduction in smoking in the Detroit area in the next three years. . . . **BRISTOL-MYERS SQUIBB CO.** presented $500,000 unrestricted five-year research grants to researchers at two cancer centers: **John Mendelsohn**, president of University of Texas M.D. Anderson Cancer Center, and **Tony Hunter**, professor of molecular biology at the Salk Institute for Biological Studies. . . . **ROY CORREA** was named president of the American Urological Association. Correa is a urologist at Virginia Mason Clinic in Seattle, and professor of urology at the University of Washington. . . . **NIH NAMED** four professors to the Advisory Committee on Research on Women's Health: **Joseph Hurd,** chairman of the department of gynecology at Lahey Clinic Medical Center in

(Continued to page 8)

In This Issue:

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In Congress

Increase Urged To Support More Grants, New Researchers

(Continued from page 1)

American Cancer Society and Friends of Cancer Research called for increased funding for cancer research, and support for legislation which would increase federal dollars for NIH and biomedical research.

The President's budget proposal for fiscal 1998 contains an increase of 2.8 percent ($61 million) for NCI. At this writing, the appropriations subcommittee was yet to learn how much money it will be able to allocate next year, Capitol Hill sources said.

Also, it remains unclear how the recent compromise plan to eliminate the budget deficit by the year 2002 would affect the proposed plan to double federal spending on biomedical research, sources said. The budget accord reached by the White House and Congress last week would require about $60 billion in cuts from domestic programs.

"The current appropriation and the fiscal year 1998 request for cancer research are too low," NCCR president Albert Owens said in his testimony before the subcommittee.

"We strongly recommend that the fiscal year 1998 appropriation for NCI be an increase of 15 percent as the first step toward doubling the appropriation for NCI within five years," Owens said.

The coalition also supports the Biomedical Research Commitment Resolution (S.Res. 15), and the National Research Investment Act (S. 124), he said.

Owens said the doubling of the budget for NCI would fund a greater proportion of investigator-initiated research applications; support the priorities identified in the NCI Bypass Budget; strengthen translational research; increase collaborative research involving the government, academia and industry; expand research in cancer prevention and detection; broaden research in cancer survivorship research; help enable outstanding new investigators in basic, clinical or population-based biomedical research to establish independent research careers.

Owens said funding must be sustained. "Interruptions to investigators and research institutions have long lasting effects," he said.

Patient-centered research is currently threatened by the restrictions imposed by managed care companies, Owens said.

"The nominal support provided by NCI to [patient-centered research]— less than 10% of NCI's total budget—is causing many talented clinical researchers to go the way of the dinosaur as they are forced away from research and into clinical practice," Owens said.

Owens said NCCR opposes earmarks not accompanied by additional resources as well as "arbitrary reductions" in indirect costs of research.

"These research costs are a legitimate cost of research," he said.

AACR: Scientist Activism

"The nation's efforts in cancer research are in grave crisis," said Richard O'Reilly, chairman of the department of pediatrics and chief of the bone marrow transplantation program at Memorial Sloan-Kettering Cancer Center.

O'Reilly, who testified on behalf of AACR, called for the doubling of NCI budget by the year 2000.

"We are deeply concerned that the support requested in the [Administration's] proposed budget is grossly inadequate," O'Reilly said. "At this time of national need and exceptional opportunity, research into cancer must not be viewed as a 'contracting scientific enterprise.'

"Scientists and clinicians have often sat back and remained silent when activism was required,"

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O'Reilly said. "The reality of cancer, however, is too monstrous, too ghastly a reaper of human life to be allowed to persist. This crisis in national will must be met.

"The time is now," he said.

O'Reilly said additional resources should be devoted to investigator-initiated research grants, translational and clinical research, and training programs for clinical investigators.

"The [Administration proposal] does not adequately address the need for training programs for physician investigators who aspire to careers in clinical investigation," he said.

New approaches may have to be developed to funding clinical research, O'Reilly said.

"In certain plans patients are specifically precluded from entering clinical trials," he said. "Unless more substantive funding is provided and a better approach is developed to sustain clinical research, the possibilities for translating discoveries made in the laboratory into meaningful treatments will be severely diminished and tragically delayed."

Recent breakthroughs in basic science are likely to require a new commitment to translational and clinical research, O'Reilly said.

"Right now, NCI can devote less than 10% of its budget to this priority," he said. "These programs will require more than a doubling of the NCI budget to adequately address research needs.

ACS: Eight-Point Plan

The American Cancer Society said that in addition to doubling the NIH budget by the year 2000, Congress should create a uniform tobacco control program throughout the US and increase support for the Center for Disease Control & Prevention programs.

These programs include cancer registries, breast and cervical cancer control initiatives, development of a plan on controlling skin cancer, and a program in screening for colorectal cancer.

"ACS fully supports the leadership in Congress calling for doubling the budget of NIH, including NCI," said Myles Cunningham, the society president and surgeon at St. Francis Hospital in Evanston, IL.

Cunningham said ACS funding recommendations for CDC include an expansion of the Center's National Program of Cancer Registries. ACS requested $30 million for the program.

The society requested $200 million for the CDC Breast and Cervical Cancer Control Program, which is targeted at minorities and older women.

"Our funding request could greatly increase the numbers of women being treated, improve and enhance data-collection, and expand the Wise Woman pilot program to make available additional critical health tests at the same time women are being screened for breast and cervical cancer," Cunningham said.

The society requested $3 million for CDC to step up efforts to establish an action plan on skin cancer prevention and control and another $3 million in fiscal 1999 to fund a CDC initiative in colon cancer screening, he said.

"Funding for tobacco control should be coordinated and uniform across all states," Cunningham said. "Because of fragmentation of funding for state tobacco control activity between a variety of public and private funders, and federal, state and local government, we have not been able to effectively build on the successes we have seen.

"All residents should have access to the same preventive measures and education rather than just the fortunate few who reside in a well-funded state," Cunningham said.

Cunningham presented the society's eight-step plan for the prevention and control of cancer:

1. Prevent the use of tobacco, particularly by children.

2. Enhance the availability of cancer screening and cancer care to the underserved.

3. Improve health care delivery in all settings, with particular attention paid to implications of managed care for cancer prevention and control.

4. Achieve consensus on standards of cancer information, screening, treatment, and care in all health care settings.

5. Create collaborations among government, business, non-profit entities, and advocacy organizations to mobilize the resources required to overcome barriers to changing health behaviors.

6. Accelerate the public commitment and financial support of biomedical research.

7. Expand behavioral research to develop more effective cancer interventions and define information needs of the public and cancer survivors.

8. Expand public health education on cancer prevention, risk reduction, and early detection to promote healthy life styles.

ASCO and Friends: More Clinical Research

"The national goal of containing costs is

laudable, but inadequately funding biomedical research with its long-term potential to save money and lives is shortsighted," John Durant, executive vice president of the American Society of Clinical Oncology, said to the subcommittee.

"We need much more funding, as well as an improved system to support clinical investigators who are in the vital position of translating the exciting work of basic scientists into improved bedside care," Durant said.

Durant testified on behalf of Friends of Cancer Research, a coalition of organizations formed to mark the 25th anniversary of signing of the National Cancer Act.

"Right now, the opportunities in cancer research justify at least a doubling of the budget of NIH over five years," Durant said. "The NCI specifically should receive its fair share of this increase to ensure that scientists are able to take advantage of current knowledge by expanding our understanding of the fundamental nature of cancer and translating basic research into clinical practice."

Durant said NIH needs to improve its grant review procedures and provide better mentoring for young investigators.

"The changing health care environment with its increased focus on generating clinical revenues has made this so-called 'socialization' process more difficult," Durant said.

"Senior staff have less time and fewer resources to devote to the mentoring process, despite the fact it is well accepted that individuals working with mentors are more successful and more satisfied in their professional life," he said.

ASCO is proposing the establishment of a new NIH award program for clinical research mentors, Durant said. The program would be focused on teaching trainees to develop research grant proposals.

"By establishing a grant mechanism specific to mentorship, we will send our senior scientists the message that this is an important and rewarded activity in which they should participate," Durant said.

Patient Advocacy

NBCC Delivers Signatures, Demands $2.6 Billion By 2000

The National Breast Cancer Coalition earlier this week presented to the President and Congress a 2.6 million-signature petition demanding that $2.6 billion be spent on breast cancer research by the year 2000.

"We have to recognize that breast cancer is a political issue," said NBCC President Fran Visco, at the coalition's annual advocacy training conference which coincided with the presentation of the petition.

"When we first began the group, we were accused of politicizing breast cancer," Visco said. "Everything we do in breast cancer is rooted in public policy, is rooted in politics. So when we are accused of politicizing breast cancer, we should say thank you."

In addition to the $2.6 billion, the coalition is asking for $590 million in fiscal year 1998 to be allocated to NIH for breast cancer research.

NIH will spend $401.1 million on breast cancer research during fiscal 1997. Of those funds, NCI receives $332.9 million, according to NCI estimates.

NBCC is requesting $175 million for the DOD Breast Cancer Research Program, a $69 million increase from the current year's appropriation.

NBCC also advocates $20 million for peer reviewed cancer research at other federal agencies, including the Environmental Protection Agency and the Veteran's Administration.

The coalition's other requests include a $20-million boost for the Center for Disease Control Breast and Cervical Cancer Control Program, bringing the total allocation for the program to $150 million. The additional funding would be used to treat those women whose cancer was detected as part of the CDC program, said NBCC field director Sharon Ford Watkins.

Visco: "Keep Our Eye On The Goal"

The annual conference, designed to create a network of informed breast cancer research advocates, included workshops, lectures, and a "Lobby Day" where advocates were brought to Capitol Hill to speak with their representatives.

Addressing the conference, Visco urged that the coalition maintain its focus on basic science and clinical trials.

"We can not afford to take after every issue just because it's breast cancer," Visco said. "We need to keep the big picture in mind. We need to keep our eye on the goal of eradicating breast cancer, and we need to focus and design our strategy so that it is going to get us to that goal."

Earlier this year, NBCC became embroiled in debates over the usefulness of mammographic

screening of women between the ages of 40 and 50. In those debates, the coalition argued that the value of the procedure in that age group is not supported by scientific evidence.

"We need to move the debate about breast cancer beyond mammography," Visco said. "We need to make certain that this nation understands that mammography is not the only issue in breast cancer.

"We cannot afford to have our membership fooled by pink ribbons and empty rhetoric," Visco said. "Last year, I got very tired of hearing members of Congress tell me how they were at the ribbon cutting ceremony at the new breast center in their community.

"But that same member did not sign on to the letters requesting more money," Visco said.

Action Plan Earmark Not Resolved

In another battle last year, NBCC attempted to reverse the earmark of $14.7 million in NCI funds for use by the National Action Plan on Breast Cancer **(The Cancer Letter**, Nov 15, 1996) . Though the Action Plan steering committee voted to return nearly all of the money to NCI, the controversy is yet to be resolved.

The earmark was originally advocated by Susan Blumenthal, head of the PHS Office of Women's Health and co-chair of the Action Plan.

Visco said the steering committee's decision is being undermined as proponents of the earmark are soliciting letters aimed at keeping the money in the Action Plan, which is administered by the Public Health Service Office of Women's Health.

Said Visco:

"Calls are being made from people who didn't want to abide by the steering committee vote, to organizations around the country, saying, 'We can use [the $14.7 million] for something that will be gainful to your organization and to your cause. Send a letter saying, don't send the money back to NCI.'"

Visco did not name the officials who she said were placing the calls to the advocacy groups.

NIH Director's Testimony

Targeted Increases Favor Established Scientists

Increases in funding focused on specific diseases would benefit established investigators, and would not necessarily advance science, NIH Director Harold Varmus said at a recent hearing.

"A mere increase in financial support of a field, without efforts to enlarge its scope, opportunities, and personnel, is likely to benefit only those investigators already established in the area," Varmus said at a hearing of the Senate Labor and Human Resources Subcommittee on Public Health and Safety.

"This approach is unlikely to make optimal use of scarce resources," Varmus said in his testimony May 1.

List Scientific Opportunities

"To augment research on specific topics in a more responsible fashion, it is necessary to show that under-explored opportunities exist and that they can attract investigators who will then propose meritorious projects," Varmus said.

Advocacy groups seeking to advance research on specific diseases should be promoting their agendas to scientists as well as politicians, Varmus said.

"Advocates for the study of specific diseases can be effective at the local or national level by visiting individual scientists or professional societies, thereby stimulating the interest of working investigators in unappreciated implications of their work," Varmus said.

Varmus's testimony before the subcommittee was part of the NIH reauthorization process.

Last year, the Senate passed a reauthorization bill for NIH, but the House did not take up the legislation.

"Healthy" Tension Between Congress, Scientists

The tension between legislators trying to set a budget, and scientists who insist that they should be free to control the research agenda, is "both healthy and inescapable," said Sen. Bill Frist (R-TN) chairman of the Public Health and Safety Subcommittee.

"The advances in biomedical and behavioral research over the past decades have come about precisely because individual scientists have made their best judgments about what research to conduct," Frist said at the hearing.

"At the same time, the American people are contributing $13 billion of their hard-earned dollars to this enterprise and they have an obligation to exercise oversight, to influence direction, and to demand accountability," Frist said.

Pharmaceutical Industry

IVAX Official Broder Objects To FDA Orphan Drug Policies

FDA policies on granting Orphan Drug exclusivity discourage small companies from conducting studies of new uses for an approved drug, the former NCI director, Samuel Broder, now an official of IVAX Corp., said at a Congressional hearing this month.

"FDA should be encouraged to develop fair and constructive policies in the arena of Orphan Drug Exclusivity, when more than one sponsor has undertaken a meaningful clinical trials program," Broder said to the House Commerce Subcommittee on Health and Environment, at an April 23 hearing on FDA reform. "Our current system is a 'winner take-all' outcome in terms of who can actually go to market."

IVAX, of Miami, FL, last March filed a New Drug Application with FDA for Paxene (paclitaxel) for the treatment of Kaposi's sarcoma. The company is seeking the Orphan Drug designation for the indication (**The Cancer Letter**, April 18).

Last February, Bristol-Myers Squibb Co., of Princeton, NY, filed a supplemental NDA for the KS indication for Taxol, and for the Orphan Drug designation.

"In the case of drugs already marketed for a well-recognized large indication or many indications, the current system, if not changed, will certainly discourage a small company from undertaking an economically-risky but clinically important program for studying scientifically a new use for an indication in an Orphan Disease," said Broder, senior vice president, research and development, at IVAX.

"FDA rules and policies unintentionally encourage and could reward the larger sponsor for waiting until the very last moment to put together a study and submit an application whose primary purpose is to block the smaller sponsor from entering the market for seven years," Broder said.

Remove FDA Patent Responsibilities

Congress should consider moving FDA's "patent-enforcement" responsibilities to the Patent and Trademark Office, and allowing patent disputes involving drugs and biologics to be handled exclusively by the courts, Broder said.

"FDA is required to serve as a repository for essentially any patent that a given sponsor wishes to submit," Broder said. "These patents serve as a list in what is called the Orange Book to block or delay the approval of generic drugs and certain new drug forms.

"The current system requires the agency to maintain a patent list without determining their relevance or validity," he said. "The agency might better concentrate all of its resources on the scientific, medical, economic and most important, public health implications of the applications before it."

Emphasize NDA Review

Further commenting on FDA issues, Broder said candidates for the job of FDA commissioner should have a strong background in pharmaceutical sciences.

"The commissioner should primarily focus on the speed and efficiency of approving new drugs and biologics, as well as generic alternatives to marketed products, since this is the most fundamental mission of the agency," he said. "Efficient drug approvals encourage small biotech companies to tackle and solve big problems, which might otherwise be avoided by a risk-averse, large company."

FDA should emphasize reviews of new drug applications, while allowing third parties to take over other functions, Broder said. "Certain kinds of Investigational New Drug Applications could be delegated to state authorities, local universities, and others in much the same way that the Nuclear Regulatory Commission has devolved some radiation safety monitoring functions to other organizations."

Broder also called for stronger external oversight of FDA. "During my time within NIH, I became convinced that an ongoing process of quality control and independent peer review is absolutely essential for any taxpayer-supported scientific program," Broder said. "FDA would benefit by having an advisory council somewhat similar to the National Cancer Advisory Board.... Such boards could provide a neutral forum for discussing science policy issues.

"At present, particularly for small companies, disagreements and disputes about science policy are often argued out during a new drug application—a process guaranteed to shed more heat than light," Broder said. "The current system offers substantial opportunities for misunderstandings, for *ad hominem* attacks, and for self-censorship in the case of small sponsors who may rightly or wrongly fear agency retribution someday."

Professional Societies

National Academy Of Sciences Elects 60 New Members

The National Academy of Sciences elected 60 new members and 15 foreign associates during the Academy's annual meeting last week in Washington.

Election to membership in the Academy is considered one of the highest honors that can be accorded a U.S. scientist. Those elected bring the total number of active members to 1,773.

Following are newly elected members who are associated with the biomedical sciences:

ALLISON, JAMES; professor of immunology and director, Cancer Research Laboratory, University of California, Berkeley.

BEACHY, ROGER; Scripps Family Chair and co-director, International Laboratory for Tropical Agricultural Biotechnology, Scripps Research Institute, University of California, San Diego.

CAVENEE, WEBSTER; director, Ludwig Institute for Cancer Research, and professor of medicine, University of California, San Diego.

CRABTREE, GERALD; investigator, Howard Hughes Medical Institute; and professor of pathology and developmental biology, School of Medicine, Stanford University.

CROTEAU, RODNEY; professor of biochemistry, Institute of Biological Chemistry, and Arthur M. and Kate E. Tode Distinguished Professor of Forest Biochemistry, Washington State University, Pullman.

DALY, JOHN; chief, Laboratory of Bioorganic Chemistry, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD.

ENGELMAN, DONALD; professor, department of molecular biophysics and biochemistry, Yale University.

ENGLANDER, S. WALTER; Jacob Gershon-Cohen Professor of Medical Sciences, department of biochemistry and biophysics, University of Pennsylvania, Philadelphia.

GARRUTO, RALPH; research biologist, Laboratory of Central Nervous System Studies, National Institute of Neurological Disorders and Stroke; and co-director, Qinghai Project, People's Republic of China, Frederick Cancer Research and Development Center, Frederick, MD.

GIMBRONE, MICHAEL, JR.; director, vascular research division and pathologist, Brigham and Women's Hospital; and Elsie Freedman Professor of Pathology, Harvard Medical School.

KIM, PETER; investigator, Howard Hughes Medical Institute; member, Whitehead Institute, Cambridge, MA; and professor of biology, Massachusetts Institute of Technology.

LANDER, ERIC; member and professor, Massachusetts Institute of Technology Center for Genome Research, Whitehead Institute; and professor of biology, Massachusetts Institute of Technology.

LINDQUIST, SUSAN; investigator, Howard Hughes Medical Institute; and professor of molecular genetics and cell biology, department of molecular genetics and cell biology, University of Chicago.

MCEWEN, BRUCE; professor and head, Laboratory of Neuroendocrinology, and dean of graduate and post-graduate studies, Rockefeller University.

METZENBERG, ROBERT; professor of research and biological sciences, department of biological sciences, Stanford University.

MILLER, LOIS; research professor of entomology and genetics, departments of entomology and genetics, University of Georgia, Athens.

MURAD, FERID; chair, department of integrative biology and pharmacology, Health Science Center, University of Texas, Houston.

NEI, MASATOSHI; Distinguished Professor, department of biology, Pennsylvania State University, University Park, PA.

RANDALL, LINDA; professor of biochemistry, department of biochemistry and biophysics, Washington State University, Pullman.

RAYMOND, KENNETH N.; professor and chair, department of chemistry, University of California, Berkeley.

SMITH, KIRK; professor of public health and environmental health sciences, University of California, Berkeley.

SOLL, DIETER; professor of molecular biophysics and biochemistry, department of molecular biophysics and biochemistry, School of Medicine, Yale University.

STOSSEL, THOMAS; American Cancer Society Professor, School of Medicine, Harvard University; and director of experimental medicine, Brigham and Women's Hospital.

TSIEN, RICHARD; professor of molecular and cellular physiology, Stanford University; and director, Silvo Conte Center of Neuroscience Research, Beckman Center, Stanford, CA.

TULLY, JOHN; professor of chemistry, department of chemistry, Yale University.

VERMA, INDER; professor, Laboratory of Genetics, Salk Institute for Biological Studies, La Jolla, CA.

WILLIAMS, LEWIS; president, Chiron Technologies, Emeryville, CA; and professor of medicine, University of California, San Francisco.

WITTE, OWEN; investigator, Howard Hughes Medical Institute; and professor of microbiology and molecular genetics, University of California, Los Angeles.

Following are the newly elected foreign associates involved in the biomedical sciences and their country of

origin:

CORY, SUZANNE; professor and joint head, molecular biology unit, Walter and Eliza Hall Institute of Medical Research, Royal Melbourne Hospital, Victoria (Australia).

DE LA CHAPELLE, ALBERT; professor and chair, department of medical genetics, University of Helsinki (Finland).

DEISENHOFER, JOHANN; investigator, Howard Hughes Medical Institute; and Regental Professor and professor of biochemistry, Southwestern Medical Center, University of Texas, Dallas (Germany).

POLGE, ERNEST; co-founder and scientific director, Animal Biotechnology Cambridge Ltd., Cambridge (U.K.)

REUTER, HARALD; professor and chair of pharmacology, University of Bern (Switzerland).

SIMONS, KAI; coordinator, cell biology program, European Molecular Biology Laboratory, Heidelberg, Germany (Finland).

In Brief

Wolpert Named Grants Chief, NCI Div. Of Cancer Treatment

(Continued from page 1)

Burlington, MA; **Barbara Koenig**, executive director and senior research scholar at Stanford University Center for Biomedical Ethics; **Angela Barron McBride**, distinguished professor and dean of Indiana School of Nursing; and **Linda Niessen**, professor and chair of the department of public health sciences at Baylor College. . . . **MARY WOLPERT** has been named chief, Grants and Contracts Administration Branch, Developmental Therapeutics Program at the NCI Division of Cancer Treatment, Diagnosis, and Centers. She succeeds J.A.R. Mead, who retired last March.

Funding Opportunities

Program Announcement

PA-97-057

Title: **Epidemiology Of AIDS/Retroviral-Associated Cancers**

The NCI Division of Cancer Epidemiology and Genetics invites research project grant applications for innovative interdisciplinary studies to better understand the occurrence and molecular epidemiology of pre-neoplastic conditions and cancers that occur within the contexts of underlying infection with human retroviruses such as HIV/AIDS, non-infectious causes of immunosuppression such as organ transplantation, or subsequent to anti-retroviral therapies, particularly zidovudine and other nucleoside reverse transcriptase inhibitors. The mechanism of support will be research project grants (R01), First Independent Research Support and Transition (FIRST) (R29), exploratory/developmental (R21) grants, and supplements to existing NIH-funded research projects and cooperative agreements.

Examples of research areas of interest to NCI include:

—Active surveillance of the prevalence, incidence, molecular epidemiology, and temporal trends of all cancers and pre-neoplastic changes occurring in persons already infected with or at high risk for infection by HIV/AIDS or other human retroviruses, or immunosuppressed from other conditions such as organ transplantation.

—Studies conducted through population-based registries or programs to enhance and utilize tumor registries in areas with high prevalence of human retroviral infections, or in conjunction with existing cohorts of persons infected with, or at high risk of acquiring, human retroviral infections such as HIV/AIDS.

—The (treated) natural history of cancers and pre-neoplastic changes in situations where the temporality of observed events, including timing of first infection or reactivation of existing infections, may be addressed.

—The seroepidemiology and modes of transmission of human oncogenic agents, particularly human herpes virus 8/Kaposi sarcoma-associated herpes virus, and the relationship of new infection or reactivation of latent infection to subsequent development of cancers or pre-neoplastic conditions in the context of host immunosuppression from co-infection by HIV/AIDS or other human retroviruses, or organ transplantation.

—The association of anti-HIV chemotherapeutic agents on the occurrence and natural history of ensuing cancers and pre-neoplastic changes.

—The role of co-infection by infectious agents, including, but not limited to, human polyoma/papilloma viruses, human herpes viruses, hepatitis viruses, and Helicobacter pylori in the etiology and molecular epidemiology of cancers and pre-neoplastic changes associated with host immune suppression from conditions such as HIV/AIDS, infection with other human retroviruses, and organ transplantation.

—The effects of host genetics, hormonal changes, environmental conditions, and human behaviors on the clinical and molecular epidemiology of infection-associated pre-neoplastic conditions and cancers occurring within the context of immunosuppressive conditions, such as those resulting from HIV/AIDS, other retroviral infections, and organ transplantation.

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