THE CANCER LETTER

Vol. 34 No. 20
May 23, 2008

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

Studies Give Stronger Justification For Use Of Finasteride To Prevent Prostate Cancer

By Kirsten Boyd Goldberg

Two new analyses from the NCI-sponsored Prostate Cancer Prevention Trial show that the drug finasteride prevents prostate cancer that would be clinically significant and that men taking finasteride may not have an overall increased risk of high-grade prostate cancer, as initial study results from 2003 had suggested.

The analyses were presented May 18 at the American Urological Association meeting and released online in Cancer Prevention Research, a journal of the American Association for Cancer Research.

The PCPT was a randomized, controlled clinical trial of 18,882 men age 55 and older without prostate cancer who were given either finasteride

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Guest Commentary

Kennedy's War On Cancer Began With National Cancer Act Of 1971

By Richard A. Rettig

The historic National Cancer Act of 1971 has often been called "Nixon's War on Cancer," but it could as easily have been called "Kennedy's War on Cancer," and with perhaps greater justification.

In 1969, in his first year as president, Richard Nixon proposed a fiscal 1970 budget with only a 3 percent increase in appropriations for the National Institutes of Health. Significantly, the proposed appropriation for the National Cancer Institute was $181 million, down 2 percent from the prior year. These actions galvanized philanthropist Mary Lasker to organize a task force on behalf of cancer research that included Benno Schmidt Sr., Laurence Rockefeller, Elmer Bobst, Sidney Farber of Boston's Children's Cancer Research Foundation, Lee Clark of M.D. Anderson, and others as members.

Lasker had close ties to the Democratic Party dating back to President Harry Truman; she and others on the panel had very close ties to the Kennedy family. In December 1970, the task force reported to the Senate Subcommittee on Health, recommending markedly increased funding and the creation of a National Cancer Authority independent of the NIH.

The then-chair of the committee was Sen. Ralph Yarborough (D-Tex.), who would soon leave the Senate, having lost the Democratic primary to Lloyd Bentsen earlier that year. Ted Kennedy, the junior senator from Massachusetts,

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Finasteride Doesn't Increase High-Grade Prostate Cancer

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(Proscar) or a placebo for seven years to see whether the drug prevented the disease.

The trial was stopped in June 2003 when an analysis showed that finasteride reduced the development of prostate cancer by 25 percent. Results also showed an apparent slight increase in high-grade disease in men who developed prostate cancer while taking finasteride (The Cancer Letter, June 27, 2003).

Investigators at the AUA meeting presented data showing that the majority (75%) of all cancers in the PCPT, and 60% of tumors with a Gleason score of 6 or less (the cancers finasteride is known to prevent) were found to be clinically significant.

In the second analysis presented at AUA, investigators adjusted for the known improvements that finasteride has on prostate cancer detection and found that high-grade tumors (graded 7-10) were no more likely in men taking finasteride than in men taking placebo.

"These careful follow-up studies of the Prostate Cancer Prevention Trial are wonderful news and a major step forward for cancer prevention," said Peter Greenwald, director of the NCI Division of Cancer Prevention. "The benefits of finasteride are greater than first reported and it is reassuring that there appears to be no overall increase in risk of high-grade disease. I would like to again thank the thousands of participants, the SWOG leadership, and the many CCOP and other health professionals who made the trial a success."

The two studies were published online in advance of the June 2008 issue of Cancer Prevention Research.

Finasteride (Proscar, sponsored by Merck) is FDA-approved for controlling prostate growth, but is not approved for preventing prostate cancer.

These new findings suggest that men should take an "individualized" approach to prostate cancer prevention, said Ian Thompson, chairman of the Department of Urology at the University of Texas Health Sciences Center at San Antonio, who is senior author on both studies, and was also lead author for the Southwest Oncology Group on the original PCPT results paper, which was published in July 2003.

"Because we now know that men with even low PSAs can develop prostate tumors, if a man is worried about his risk, regardless of PSA score, he can take an agent that is now proven to be effective in lowering that risk," Thompson said.

Researchers looked at whether finasteride actually increased aggressive cancers in some men, and by studying biopsies and prostate gland tissue that had been removed, concluding that it did not.

"Finasteride actually shrank the prostate gland, so it appeared in initial studies that more cancer was being found in biopsies of men who took the drug," said Mary Redman, a biostatistician at the Fred Hutchinson Cancer Research Center.

"What that means is that the cancer took up more prostate tissue in men who were treated, and that is why it was easier to find in a biopsy," Redman said. "Cancer was probably missed more often in biopsies of men on a placebo drug because the prostate gland itself was larger."

Redman found that in addition to a 25 to 30 percent reduction in prostate cancer development overall in men taking finasteride, there was no evidence that the drug increased the rate of aggressive tumors and likely decreased their rate by 27 percent. "We think men should not be concerned about finasteride increasing their risk of these aggressive tumors" she said.

The second study examined whether the cancers detected in the men in the trial who had a low PSA level had clinically significant disease. With about 75 percent of the tumors detected on the study were classified as those which could potentially take a man's life, researchers concluded that there is no clear-cut PSA threshold that can be considered normal.

All patients in PCPT were to have a biopsy of their

THE CANCER LETTER

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PO Box 9905, Washington DC 20016
Letters to the Editor may be sent to the above address.

Subscriptions/Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
General Information: www.cancerletter.com

Subscription $375 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.
Founded Dec. 21, 1973, by Jerry D. Boyd.

prostate gland at some point during the seven-year trial, so investigators evaluated characteristics of the biopsy in relation to each man's PSA score. Current practice is to consider a PSA score of below four as normal and above four as abnormal.

The study found that while a large majority of the participants diagnosed with prostate cancer had a PSA that was considered normal, 72 percent of all tumors diagnosed from biopsies in both treated and untreated men were considered significant. The finding of significant disease couldn't be predicted by the PSA score, said lead author Scott Lucia, a pathologist at the University of Colorado, Denver.

Most patients in the study who had a PSA score of four or less and then had prostate cancer diagnosed by a routine biopsy were found to have significant prostate cancer, while some men who had a high PSA were found to have insignificant cancer.

That doesn't mean that the researchers support reducing the level by which PSA scoring should trigger therapeutic intervention, Lucia said.

"Over 90 percent of men in the country diagnosed with prostate cancer opt for treatment, yet we also found that even at higher PSA levels, men are being treated for tumors that would not have threatened their health," he said. "This is the dilemma of PSA screening. While lower cut-off levels, those below four, increase risk of detection of insignificant disease, cure is more likely; conversely, more significant disease is detected with higher levels but at a greater risk of incurable disease."

Men need to speak with their physicians about their PSA, when they should be biopsied, and about potential use of finasteride, which can reduce their risk, so that they will make a decision that is right for them, researchers say.

For example, a man whose family members have been diagnosed with the disease may decide to have a biopsy even though his PSA is below four, Lucia said. If cancer is found, he then may opt to undergo treatment; if cancer is not found, he may choose to use finasteride to prevent the cancer from developing. Another man may decide to put off a biopsy, regardless of PSA score, if he is worried about side effects of treatment.

"These are not easy decisions, especially when we know now that we cannot rely on what the PSA looks like it is telling us," Lucia said.

The NCI-funded Prostate, Lung, Colorectal and Ovarian Trial could provide more definitive information on the effectiveness of PSA as a screening tool for prostate cancer.

Capitol Hill:

NIH Drops Objections To Bill For Breast Cancer Research

By Paul Goldberg

NIH has dropped its objections to a bill that seeks to invigorate research into environmental causes of breast cancer.

The bill, which has been championed by the National Breast Cancer Coalition and introduced at every Congressional session since 1999, would authorize up to $40 million a year for five years to support broad collaborations in the study of the role of the environment in the causation of breast cancer.

Under the legislation, NIH would employ a peer review system that would mimic the structure used by the Department of Defense breast cancer program, which was created as a result of lobbying by NBCC.

The DOD program relies on an "integration panel" of scientists and advocates to recommend a research strategy, review the results of the peer review panels' deliberations and comparison of scorings across panels, recommends the applications to be funded, and assists in program evaluation.

"The DOD Breast Cancer Research Program has spearheaded concepts such as team science that proposed combining expertise to address significant issues by promoting funding mechanisms that require disparate disciplines and investigators to communicate, cooperate and jointly address problems," Kim Lyerly, director of the Duke Comprehensive Cancer Center and former chairman of the DOD panel, said at a congressional hearing May 21.

"These collaborative grants encourage not just individual scientists but also institutions to work together," Lyerly said to the Health Subcommittee of the House Committee on Energy and Commerce. "I have seen the results of promoting team science and interactions through the multi-disciplinary and multi-institutional model, and I fully support inclusion of this model in the Breast Cancer and Environmental Research Act. Team-oriented science can work, it is especially critical for complex environmental research, and it requires novel funding mechanisms to ensure that teams are both recognized for their successes, and accountable for their shortcomings."

Opponents of the bill have said that it amounts to an earmark, and that the recently created NIH common fund can foster similar collaborations.

"As science advances through discovery, it increasingly converges," Deborah Winn, associate

director of the NCI Epidemiology and Genetics Research Program, said at the hearing. "We know that the answers to the most vexing scientific questions involving one disease often come from areas of unrelated research. As scientists, we know that it would be a mistake to focus on one disease without understanding the underlying biological mechanisms that affect multiple diseases. This is one of the great lessons learned from recent advances in genomics and molecular biology."

Nonetheless, Winn said that NIH no longer objected to a recently amended version of the bill that is working its way through the Senate. "The Senate bill, as amended, is not opposed by NIH," Winn said. "However, the administration doesn't have a position on the bill."

"Obviously, you had some input into the changes," said Rep. Frank Pallone (D-NJ), chairman of the subcommittee. "I understand your basic concern, is there anything additional that you would like to see addressed here?"

"The changes in the Senate bill are very satisfactory to the National Institutes of Health," Winn responded.

If the number of co-sponsors is an indication, the bill creates the appearance of political inevitability. The House version, H. 1157, introduced by Nita Lowey (D-NY), has 270 co-sponsors. The Senate version, S. 579, introduced by the majority leader Harry Reid (D-Nev.), has 70 co-sponsors.

According to Fran Visco, president of NBCC, the Senate bill was amended recently in order to get NIH to withdraw its opposition, and the House bill will likely be amended accordingly.

First, the bill was changed to remove references to "centers" that would conduct the research. "The intent of the legislation was never to establish brick and mortar centers, but rather, as I have said, the grantees would be a collaboration of scientists and consumers from various disciplines and institutions," Visco said in submitted testimony. "The reference to centers in the language was confusing and distracted from the true intent of the legislation."

In other changes:

—A peer review clause was added. "The bill was never intended to override or otherwise interfere with the peer review process at NIH," Visco said. "The panel takes the peer-reviewed research and makes recommendations for funding based on the strategy that has been developed, to make sure that not only the most scientifically important research is funded, but also the research that will have the most impact."

—NIH requested and received greater control over the panels. "First, an NIH representative was added to the panel, and language was added so that the selection of the chairperson of the panel is subject to the approval of the NIH director," Visco said. "Finally, language regarding how the HHS secretary adopts the recommendations of the panel was changed at NIH's request."

The number of co-sponsors notwithstanding, the bill's passage is by no means assured, as Sen. Tom Coburn (R-Okla.) pledges to stop the legislation, as he has done in the past. Coburn, a physician who liberally uses the prerogative to place holds on legislation, argues that scientists rather than legislators should be setting health research priorities and that breast cancer should not receive special treatment.

At the May 21 Energy and Commerce hearing, Rep. Joe Barton (R-Tex.) voiced a similar objection to the bill.

"It's a disease-specific bill for earmarked research at the National Institutes of Health," Barton said. "We have tried to fund each of the institutes and centers that comprise the NIH with a single appropriations line item. I had my staff look and we can't find one instance over the last five or six years where the appropriators of the House of Representatives funded a research project to benefit one specific disease. Disease-specific earmarks are bad policy, they are bad for science, and we shouldn't do it."

In addition to "micro-managing," the bill would address the problem that doesn't exist, Barton said. "It's already being done," he said. "We don't need the bill before us today to make that happen. An investigator that wants to work across the silos at NIH can form a coalition with other investigators and other institutes and apply for research grants to that common fund.

"It's good public policy for members of this committee and this congress to be interested in research to find cures to all the various diseases. But we should try to have a policy where we put priorities on certain research and then let the NIH under this new reform package that we just passed find the best way to allocate the available resources. I hope we don't go back to the way used to do business, that is whichever advocacy group has the most political clout in a specific congress, they get their research funded at the top of the list."

Rep. Henry Waxman (D-Calif.) disagreed. "Some will say that it's not the business of Congress to tell the NIH what their research priorities should be," he said. "And I say—Nonsense! Of course we shouldn't micromanage the work at NIH. We shouldn't make scientific judgments, or select specific projects, but it

is our business to establish broad priorities.

"Had we not taken that role in the past, we would not have seen the tremendous progress in AIDS research. We would not have had policies to ensure that women were involved in clinical trials. And we would not have been able to push for addressing racial disparities in health care. It is appropriate that we establish a priority for examination of environmental effects in breast cancer.

"And that's why this bill is so important."

Senate Passes Supplemental Appropriation

The Senate May 22 passed a supplemental appropriations bill that would give another $400 million to NIH and $275 million to FDA. The Senate voted 75-22 in favor of the bill.

The biomedical research funding measures were attached to the bill that funded war spending and increases veterans' benefits and would cost $250 billion over ten years.

The measure's future in the House is uncertain. President Bush, too, said he would veto any measure that boosts domestic spending. However, any veto may be overridden by the increasingly independent legislature that earlier that day overrode the President's veto of a $307 billion farm bill.

In the Cancer Centers:

Business Students Help RPCI Assess Viability Of Spin-Offs

ROSWELL PARK Cancer Institute Office of Technology Transfer announced the winners of the first Thomas Dougherty Award in Entrepreneurial Studies. The awardees are four teams of MBA students from the University at Buffalo School of Management.

RPCI and UB asked students to create an economic development business plan based on an actual biotechnology initiative being developed by Roswell Park faculty. The purpose was to assess the commercial viability of a spin-off business being formed around an emerging technology at the cancer center. Successful submission of the business plan also fulfilled a curriculum requirement in the MBA program.

"The competition united UB and Roswell Park in providing the competitors with practical, real-world experience that could turn their discoveries at Roswell Park into solid opportunities for economic development," said **Donald Trump**, RPCI president and CEO.

The first place team will share $15,000 in tuition reimbursement: **Michael Brako-Bismarck**, **Max Buetow**, **Scott Eidens**, **Luke Kankiewicz**, and **Ezra Staley**. The second-place team award of $7,000 in tuition reimbursement will be shared by **Nicole Crapez**, **Nathan MacFarlane**, and **Haleh Mousavi**. Two other teams tied for third place and split the $3,000 award. The students have taken courses under **John Hannon**, professor of entrepreneurship at UB.

ALBERT EINSTEIN College of Medicine of Yeshiva University received a $25 million gift from Ruth and David Gottesman for stem cell and epigenomic research and clinical skills training. The gift will support research projects at the College of Medicine, most to be conducted in the Michael F. Price Center for Genetic and Translational Medicine at the Harold and Muriel Block Research Pavilion, which opens in June. Funds will be allocated as follows: $15 million to establish the Ruth L. and David S. Gottesman Institute for Stem Cell and Regenerative Medicine Research; $7 million for The Center for Epigenomics, headed by **John Greally**; and $3 million to create The Ruth L. Gottesman Clinical Skills Facility in the Van Etten Building, which Einstein has leased from the Jacobi Medical Center as part of its expansion. The gift will support an endowed chair at the Gottesman stem cell institute and a faculty scholar in epigenomics. . . . **USC/NORRIS** Comprehensive Cancer Center and the Keck School of Medicine received a $5 million gift from the L.K. Whittier Foundation. The gift extends for five years the funding of the L.K. Whittier Foundation Innovative Tailored Therapies Initiative, begun in 2002 to develop cancer therapies. "The initiative has enabled 40 faculty physicians to conduct pilot research studies and led to additional federal funding, clinical trials and publications," said **Peter Jones**, director of USC/Norris. . . . **UNIVERSITY OF ROCHESTER Medical Center** announced the opening of the new James P. Wilmot Cancer Center. The four-story, 164,000-square-foot building doubles the medical oncology clinical space. The building is the centerpiece of the center's five-year, $65-million plan for expansion and is one of the cornerstones of the medical center's plan for growth. The strategy includes recruiting two dozen scientists and clinicians, and expanding programs in lung, breast, prostate and colon cancers as well as lymphomas and leukemias. Plans are to add two more linear accelerators in the Radiation Oncology Department. The center also has invested $10 million to install the Trilogy image-guided radiation therapy system. **Richard Fisher** is director of the Wilmot Cancer Center. . . . **ROBERT H. LURIE Comprehensive Cancer Center**

of Northwestern University had its status renewed as an NCI-designated comprehensive cancer center. The center received its first comprehensive designation from NCI in 1998. . . . **COALITION OF CANCER Cooperative Groups** online cancer clinical trial navigation and patient matching service, **TrialCheck**, won 2008 Best in Show honors from Consumer Health World, a national organization for consumer-directed healthcare, said **Robert Comis**, president and chairman of the coalition. The service also received the award for Best Application for Enhancing Patient Access for Information. TrialCheck asks a series of questions and patients receive a list of trial matches they can download. The site it available at www.cancertrialshelp.org. . . . **ERIC RUBIN** was named vice president of oncology clinical research, Merck Research Laboratories. Rubin will head the design, analysis and reporting of the oncology clinical development programs. He is known for research that identified a topoisomerase I-binding protein, TOPORS, involved in chromatin regulation and prostate cancer progression. He was professor of medicine and pharmacology, associate director of clinical sciences, and director of the investigational therapeutics division at the Cancer Institute of New Jersey. . . **JEANETTE LEE** has joined the faculty of the Department of Biostatistics at the University of Arkansas for Medical Sciences Little Rock. She will direct statistical activity within the Winthrop P. Rockefeller Cancer Institute. Lee was professor in the Department of Medicine with the Biostatistics Unit of the University of Alabama at Birmingham Comprehensive Cancer Center. She is director of the statistical center for the NCI-funded AIDS-Associated Malignancies Clinical Trials Consortium.

Professional Societies:

IARC Elects New Director

INTERNATIONAL AGENCY for Research on Cancer's Governing Council elected **Christopher Wild** as director at its meeting May 14-16. He will take office Jan. 1, for a five-year term.

Wild, former chief of the Unit of Environmental Carcinogenesis at IARC, is professor of molecular epidemiology and director of the Leeds Institute of Genetics, Health, and Therapeutics. He was also chairman of the UK Molecular Epidemiology Group, and is a senior editor of Cancer Epidemiology, Biomarkers and Prevention, and a member of the UK Biobank Ethics and Governance Council.

Wild will succeed **Peter Boyle**, who will remain in office until the end of his five-year term in December.

Also at the meeting, IARC officially welcomed the Federal Republic of Austria as its 21st Participating State.

NCI News:

NCI Fills Pathology, Pediatric Intramural Positions In CCR

J. CARL OBERHOLTZER was named chief of the Laboratory of Pathology in NCI's Center for Cancer Research. He is an internationally recognized pathologist and is board certified in anatomic pathology with expertise in neuropathology. Oberholtzer came to NCI in 2006 as associate director for training. . . . **CRYSTAL MACKALL** was appointed chief of the Pediatric Oncology Branch in NCI's Center for Cancer Research. She has served as acting chief since August 2005. Mackall is an international leader in pediatric oncology translational research, with a primary focus on development of effective immune response therapies for pediatric cancer and immune reconstitution. . . . **JAN CASADEI** was appointed chief of the Regulatory Affairs Branch in the NCI Division of Cancer Treatment and Diagnosis, Cancer Therapy Evaluation Program. Before joining CTEP in 1991, Casadei was a research scientist at IGEN Inc., where she developed bioluminescent antibody fusion proteins as tools for immunoassays.

Funding Opportunities:

Sarcoma Alliance Offers Career Development Award

Sarcoma Alliance through Research Collaborations announced a request for applications for the 2009 SARC Career Development Award.

The award supports clinician-scientists conducting research in sarcoma or related diseases. Applicants must be no more than five years post subspecialty training, have a full-time faculty level or equivalent position at an academic medical institution and have available effort of 50-75 percent dedicated to research during the award period. Applicants may not be supported by another career development award. Awardees will receive a total of $100,000 per year for a total of three years. Two SARC Career Development Awards granted annually. Application Due date: Oct. 1. Inquiries: http://www.sarctrials.org/public/pag1.aspx.

RFP N02-RC-81020-56: Patient Recruitment. Full text: http://www.fbodaily.com/archive/2008/05-May/21-May-2008/FBO-01576039.htm. Inquiries: Juana Diaz, 301-496-8613; diazj@mail.nih.gov. or Richard Hartmann, 301-496-8620; Richard.Hartmann@nih.gov.

Guest Commentary:

Kennedy Plans New Version Of National Cancer Act

(Continued from page 1)

was assuming the chairmanship, a position from which he would exercise substantial authority and leadership for his entire Senate career. He welcomed the initiative to expand funding for cancer research and to reorganize the NCI as an independent entity.

Nixon, fearing a challenge from Kennedy in 1972 presidential election, quickly submitted legislation in early 1971 to counter this threat, both on money and organization.

Throughout that year, Kennedy would display the characteristics that have made him an effective legislator over nearly five decades. He had the votes to prevail in the Senate committee, the full committee, and on the Senate floor. Graciously, he allowed the bill to carry the number and title of the legislation sponsored by Sen. Peter Dominick (R-Co.) on behalf of the Administration. He merely substituted the contents of his bill for theirs.

The architect of the legislation emerging from the House of Representatives was Rep. Paul Rogers (D-Fla.). The principal difference between the two bodies was whether to create a National Cancer Authority as a NASA-like independent agency, which the Senate bill proposed, or to keep NCI within the NIH, as the House bill provided. The House prevailed on this issue.

"What was it like to deal with Ted Kennedy in the Conference Committee," I asked Rogers.

"It was great to work with Ted on the cancer legislation. He always made his points strongly. But he was also realistic. He felt the goal of getting going on the research was more important than the mechanism," Rogers said.

In December 1971, Nixon signed the National Cancer Act of 1971 into law, "a Christmas gift" to the American people, he said at the time. Although present at the signing and as responsible for the legislation as any legislator, Kennedy never sought credit in a way that would diminish Nixon's claim to leadership. But where Nixon had acted out of political expediency, Kennedy had acted out of political conviction. Clear-eyed and bold in purpose, assiduous in seeking common ground with adversaries across the aisle, practiced in the art of compromise on details without compromise of principle, more concerned about practical outcomes than about personal credit—these were then and remain the marks of his legislative efforts.

What impact did the National Cancer Act have? The easiest metric to use is money. Over the years, Kennedy has been indefatigable in support of medical research funded through the NIH, including cancer research supported by the NCI.

The NCI appropriation for fiscal 1971 was $233 million, up from the $190 million final amount for the prior year. By fiscal 1977, the appropriation had climbed to $815 million, three and one-half times that for fiscal 1971.

Notwithstanding the vicissitudes of federal government budgets, the funds continue to be appropriated; the NCI appropriation for fiscal 2005 was nearly $4.9 billion. (The NCI budget dropped to $4.8 billion in fiscal 2006 and remained flat for the past four years.) On the scientific side, advances in the past several decades have been substantial. Clinically, the payoff is being realized steadily.

On May 8, Kennedy chaired a hearing of the Senate Health Subcommittee on "Cancer: Challenges and Opportunities in the 21st Century." With Sen. Kay Bailey Hutchison (R-Tex.), he announced legislation that they would introduce to address cancer comprehensively, to break down the barriers between research, prevention, and treatment, and to support translational and clinical research. "We must build on what the nation has already accomplished and launch a new war on cancer for the 21st century," he said (The Cancer Letter, May 9).

Through all of this, Kennedy has never lacked for personal reminders of the scourge of cancer. His son, Edward Kennedy Jr., was treated for bone cancer in 1973; his daughter, Kara Kennedy Allen, was treated for lung cancer in 2003; and his first wife, Joan, was treated for breast cancer in 2005.

Then, barely 10 days after the recent hearing, the country learned that the Senator from Massachusetts had a malignant brain tumor. The news generated "a sharp intake of breath" across Washington and the country, Robert Kaiser would write.

The American people have been fortunate indeed to have such an articulate and tireless advocate for medical research, and especially for cancer research. Kennedy's understanding of the issues is broadly philosophical, brilliantly political, and deeply personal. One could not ask for more.

Richard A. Rettig is author of "Cancer Crusade: The Story of the National Cancer Act of 1971" (Authors Choice Press, 2005); and recently, with Peter Jacobson, Cynthia Farquhar, and Wade Aubry, of "False Hope: Bone Marrow Transplantation for Breast Cancer" (Oxford University Press, 2007).

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