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Studies Question PSA Screening:
PLCO Trial Finds No Survival Advantage, European Trial Finds Benefit At High Cost

By Paul Goldberg

Two large randomized studies of prostate cancer screening published earlier this week pointed to overdiagnosis and overtreatment of the disease.

The studies published online by The New England Journal of Medicine March 18 came to different conclusions. The NCI-sponsored Prostate, Lung, Colorectal and Ovarian Cancer Screening trial found no benefit to screening with prostate-specific antigen and digital rectal exam.

The European Randomized Study of Screening for Prostate Cancer found that PSA testing reduced the rate of death from prostate cancer by 20 percent, but this benefit came at a very high cost of overdiagnosis and

(Continued to page 2)

Interview:

Trial Results Contradict Widely Held Beliefs About Mortality Benefit From Prostate Screening

The Cancer Letter asked Barnett Kramer, director of NIH's Office of Medical Applications of Research and one of the investigators on the PLCO trial, to discuss the findings. The interview was conducted by Paul Goldberg.

TCL: How relevant are these findings to the clinic?

KRAMER: "I think the current analysis provides clinically important answers, and that in large measure is why the data and safety monitoring board of the PLCO unanimously voted that we should report at this time. They felt—again unanimously—that there was important enough information that went against common assumptions about the value of PSA testing so that men and their physicians ought to know about it now, even though the trial had not reached any of its formal stopping boundaries.

TCL: Of course, the European trial is also an interim analysis.

KRAMER: I am not privy to what prompted their analysis, and whether it was for similar reasoning. I don't know whether it was pure coincidence or not that they submitted at almost the same time.

TCL: I guess the question is, how do you reconcile those results between the two trials.

KRAMER: There are some important similarities in the results, and also differences. First, the differences: at the recommendation of our DSMB we were to report our data at seven to 10 years.

(Continued to page 4)

American Cancer Society Plans To Review Guideline

(Continued from page 1)
overtreatment.

The study found that 1,410 men had to be screened over nine years to find 48 additional cases of prostate cancer, preventing one death. By way of comparison, in breast cancer, about 1,400 women between 50 and 69 need to be screened for 10 years to diagnose five to 12 additional cancers and save one life, according to an analysis of published studies by the American Cancer Society.

Some biostatisticians dismiss the "lives saved" calculation as a form of data torture. However, one thing seems certain: the studies powered to detect cause-specific mortality are showing no benefit in the early years of screening and potentially a slight benefit that may accrue after a decade.

"What this report tells us is that there may be some men who are diagnosed with prostate cancer and have the side-effects of treatment, such as impotence and incontinence, with little chance of benefit," NCI Director John Niederhuber said in a statement. "Clearly, we need a better way of detecting prostate cancer at its earliest stages, and as importantly, a method of determining which tumors will progress. Many of the molecular studies we are currently sponsoring will hopefully yield new, better ways of definitively classifying which men need treatment and which can consider watchful waiting."

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If prostate cancer screening is any indication, these advances would require rigorous, costly and time-consuming validation. While these studies will probably not sway the most zealous of true believers, skeptics say that the PSA story is a cautionary tale about premature declarations of victory and the need for rigor in validation of biomarkers.

"Within a screening trial, it's particularly important to wait for the health outcomes," said Barnett Kramer, director of the NIH Office of Medical Applications of Research, a PLCO investigator, and one of the authors of the paper. "A stage shift is not enough. More favorable tumor size or tumor grade may not be enough. When you are dealing with a screening technology, two things remain important, and one is that the primary outcome should be cause-specific mortality plus an examination of overall mortality. Surrogate outcome are not sufficient. And the second issue is that the most direct way to assess the benefits and harms is through a randomized trial. Observational evidence is nearly good enough."

An interview with Kramer appears on page 1.

PSA has retained an enthusiastic following even though in recent years studies cast doubt on its usefulness. Some advocacy groups urged men to start screening at age 45 or even 40 if they are African American or are at high risk of the disease.

Proponents argued that the decline in prostate cancer deaths that began in mid-1990s was directly attributable to PSA screening. Screening became available in the early 1990s.

However, both PLCO the European study fail to show the rapid drop in mortality that might account for this decline in deaths. In fact, both studies suggest that the benefit—if it exists—would accrue after a decade of screening.

Both trials published by NEJM are early releases of data. The DSMB of the U.S. trial made the decision to release the data in part in order to contradict this widely held belief, sources said. The study didn't cross the boundary of either futility or clear benefit.

"However, the data that have emerged to seven years is definitive," said Christine Berg, protocol chair for PLCO and senior author of the paper. "There is a very low chance of prostate cancer death at that time, and there is a large amount of prostate cancer being diagnosed. We thought it was useful information from a public health standpoint to show that the type of diagnosis of these large numbers of prostate cancers was not translating into a short-term impact on mortality. We thought we had the responsibility to the men on the trial

to inform them of these findings."

Though the studies come to different conclusions, both appear to contradict the assertion that PSA screening is responsible for decreases in prostate cancer-related mortality, said Tim Byers, associate dean of the Colorado School of Public Health and interim director of the University of Colorado Cancer Center.

"The benefit observed in the European trial was not apparent until after 10 years, and we are not shown data after seven years in the PLCO trial, though we are told the 10-year findings for the 67% of participants out that far is consistent with the seven-year findings," Byers said. "Neither of these trials supports the notion that the down-turn in death rates from prostate cancer we began to see in the U.S. beginning in 1991 is directly due to PSA testing. We need to revisit other explanations, including improved treatments for metastatic disease, and temporal changes in the determination and coding of cause of death."

The PLCO data may understate adverse events related to prostate cancer screening, Byers said. The U.S. trial randomized 76,693 men, and by the sixth year, 52 percent of men in the control group ended up getting PSA screening. The contamination in the European trial, which pooled a series of studies that enrolled 182,000 men, was not cited in the paper.

"The criticism of the PLCO that there was 52 percent contamination of the control group by off-study PSA testing is, of course, valid, but if such contamination served to dilute the effects of screening we would have to conclude at this point that the adverse effects were underestimated, not that there is a benefit that has been masked, as the trend is toward adverse effects on mortality in the screened group," Byers said.

"Zealots Were Simply Wrong"

"These data certainly indicate, from both studies, that the zealots who have proclaimed vast benefits of prostate cancer screening, using DRE and PSA, were simply wrong," said Derek Raghavan, director of the Cleveland Clinic Taussig Cancer Institute

Nonetheless, Raghavan doesn't expect true believers to abandon their faith. "I fear that people who have always believed that screening for prostate cancer is beneficial will read these studies to support their position and those who doubted the benefits will continue to do so," he said. "The only paradigm shifting study would have required a much bigger impact on survival."

In his own practice, Raghavan said he will continue to be cautious with patients who have family histories of cancer, especially where family members died from prostate cancer. "I think that African Americans also constitute a group for special consideration," he said.

He will continue to make screening available following discussion and careful education presenting the risks and benefits of screening.

"I would have preferred to see a strong benefit from screening, which just isn't there," Raghavan said. "I have always taken the position that PSA screening is of potential benefit, but unproven. These two studies fail to show a major impact of screening—the European study suggests that there may be populations for whom screening for prostate cancer will be beneficial, but really hasn't shown who those patients are. The fact that total deaths were the same in both populations should not be ignored in the European study."

ACS To Review Guideline In Light of New Data

The American Cancer Society said it would review its current guideline in light of the newly released studies.

ACS first came out in support of mass screening in 1993. At the time, PSA screening was championed by the society's Chief Medical Officer Gerald Murphy, one of the developers of the test.

The guideline was weakened in 1997 to state that screening should be "offered" to men over 50, and as early as 45 for men at high risk and African Americans.

Later this summer, the society's guidelines committee is likely to meet to consider substituting the word "discussed" for the word "offered," said Otis Brawley, the society's chief medical officer and a ling-time skeptic about the procedure.

"That's something the committee will ultimately have to decide, but virtually every committee member I have talked to, which is two-thirds of the committee in the last day or two, said, 'You know, maybe it's time to retire the word offered,'" Brawley said.

Also, the committee would decide whether men at high risk and African Americans should consider the test at an earlier age. Last November, ACS tweaked the guideline to state that even men at high risk and African Americans should be "offered" screening.

"It was our perception that people were misunderstanding the guideline," Brawley said. "The guideline used to say that men at high risk and black men should begin screening at the age of 45. A lot of people thought that we were saying that black men should be screened, white men should be given a choice."

The PLCO trial includes data for all participants at

seven years after they joined the trial and for 67 percent of participants at 10 years after they joined the trial.

According to the paper, the vast majority of men in both groups who developed prostate cancer were diagnosed with relatively early stage II (out of IV stages, of which IV is late stage) disease, and the number of later-stage cases was similar in the two groups. However, using the Gleason scoring system, men in the control group had more prostate cancers that fell into the Gleason 8 to10 range.

The smaller number of men with prostate cancer with a Gleason score of 8 to10 in the intervention group may eventually lead to a mortality difference between men in the two groups, but data analyzed so far have not shown such a difference.

"NCI wants to understand why some prostate cancers are lethal even when found early by annual screening, and what approaches can be used to identify these more aggressive cancers when they can be effectively treated," NCI's Berg said. "The PLCO biorepository is an invaluable resource for such research, with nearly three million biological samples collected from our participants. Our hope is that through all aspects of the PLCO, we will gather the information that tells us whom to treat aggressively and whom to avoid overtreating."

The trials are not entirely compatible. In the U.S., annual testing was done with DRE and PSA, and biopsies were performed on men whose PSA reached 4 ng/mL. In the European trial, follow-up testing began at 3 ng/mL. The European test didn't use DRE, and screening was repeated every four years. The p-value for the European trial was 0.04, which is marginally statistically significant.

"Approaches such as lowering the threshold for what is considered an abnormal PSA level to 3.0 ng/mL will diagnose more cases, but it is not at all clear that it will identify the prostate cancers that are more likely to lead to a man's death," said Berg.

Interview:

PSA Is A Case Study In Role Of Biomarkers In Screening

(Continued from page 1)

At seven years, the data are 100 percent complete, and therefore will never change. And they concluded that even the seven-year landmark is important because so many people have been assuming that the benefits of PSA are likely to start accruing much earlier than seven years.

They also voted to report the data out to 10 years, at which time the data are 67 percent complete. Even though our median follow-up time of about 11.5 years is longer than ERSPC, they reported their Kaplan-Meier curved to 14 years.

After about 10 years, the data in both trials is becoming thinner and thinner. Their median follow-up was nine years. It's certainly possible that at the far right of the curve—10 years and beyond—our data could change. So it's not clear that our results are really that different.

If you look at seven to 10 years, they show little or no separation of their two curves, and you just start to see something happening at about 10 years: their curves split slightly in favor of screening, and our curves split slightly in favor of the control arm.

TCL: What about the value of 3 ng/mL vs. 4 ng/mL? Your trial did 4 ng/mL, the European trial did 3. Does it matter?

KRAMER: Of course, that's not really knowable. At the time we launched the trial, most people were using 4 ng/mL as a PSA cut-off. I think that's still true. But at least some groups and some physicians are dropping the threshold to 3 or sometimes even to 2.5.

The lower the PSA threshold, the more prostate cancers you are going to pick up, but the issue of overdiagnosis becomes even more important. So it's not clear that you are going to achieve a net benefit by detecting more cancers. It might actually increase the harm, because you may simply increase overdiagnosis and increase unnecessary treatment without any benefit.

TCL: As a practicing physician, what will you do?

KRAMER: I think it's important to point out several things to the man who is asking about PSA screening. And screening, in my opinion, should always be a result of informed decisionmaking where the man fully understands the pros and the cons.

There is increasing evidence that there simply are few or no benefits for at least seven or 10 years, which probably cuts against the early widespread assumptions. And men ought to know that the harms are front-loaded.

The harms include bleeding and infection that are related to the actual screening and diagnostic follow-up, and then the morbidity and even low risk of death that are associated with some of the treatments such as radical prostatectomy. The harms are front-loaded.

They occur soon after diagnosis and persist for years. However, the benefits, if they occur, are delayed

for almost certainly at least seven to 10 years. An understanding of this issue is very important, especially when screening for a disease that tends to occur quite late in life.

The average age of diagnosis prior to the PSA screening era was about 72. At that average age, there are other competing causes of death, translating into a greater potential for overdiagnosis (that is, the detection and cure of cancers that didn't need to be cured in the first place). Therefore, the issue of overdiagnosis becomes progressively greater as men start to reach their seventies and beyond.

TCL: At what point do you say it's over, don't do it?

KRAMER: I don't think that either trial can give a definitive answer, that you should do it or shouldn't do it. I think both trials give reason to exercise caution about screening, especially beyond age 74 or so.

In the ERSPC trial, which is in essence a positive trial, they go to great lengths in their paper to make clear it's not enough to simply find out if there is any benefit at all.

We've shown none so far, they've shown some evidence of benefit emerging after eight or nine years. They point out that it's a quantitatively very small benefit, if it's there.

Their p-value is .04, so it's sort of on the edge for an interim analysis in a trial. And they point out that if you choose to screen, it looks like you would have to screen 1,410 men over about a decade in order to avoid one prostate cancer death—if their result is correct.

Another way of expressing the effort that you would have to go through is that you need to diagnose an additional 48 cases of prostate cancer that wouldn't have been diagnosed otherwise in order to avert one death from prostate cancer.

Therefore I think even the ERSPC investigators—although they report their trial as positive—urge a lot of caution and state that we don't know yet about the net benefit.

TCL: So why wouldn't you say, just don't do it?

KRAMER: No one knows what will happen beyond 10 years, when all the data settle out. Some men who are apprised of this new evidence may indeed choose not to be screened, but others may choose to be screened.

At this point, if the reason they are doing it is looking beyond 10 years and hoping that benefits may emerge after a decade, it remains a personal choice. I think what's pretty clear is that the assumptions that the decrease in mortality from PSA screening would occur relatively quickly based on assumptions about SEER mortality trends are incorrect.

Within about five years into the PSA era, prostate cancer mortality rates started to fall. Strong proponents of PSA screening pointed to that as a clear and rapid benefit attributable to screening. I think we have to be even more cautious about that attribution now, with the results of these two trials.

TCL: What about the broader issue of biomarkers, surrogates vs. correlates. Is there a cautionary tale here?

KRAMER: I would say that within a screening trial, it's particularly important to wait for the health outcomes. A stage shift is not enough. More favorable tumor size or tumor grade may not be enough.

When you are dealing with a screening technology, two things remain important, and one is that the primary outcome should be cause-specific mortality plus an examination of overall mortality.

Surrogate outcome are not sufficient. And the second issue is that the most direct way to assess the benefits and harms is through a randomized trial, I don't think that observational evidence is nearly good enough.

TCL: Looking at the data, isn't the drop in mortality from prostate cancer a worldwide trend?

KRAMER: Yes, and that's irrespective of how much screening is going on in the given countries. In the developed world, where treatment has been increasing and the use of hormonal therapy has been increasing, there is a downturn in prostate cancer mortality. In countries that screen a lot and countries that screen very little and in between, there is no convincing association between the amount of screening and the decrease in prostate cancer mortality.

So, again, this provides another cautionary note pointing out how difficult it is to interpret population trends and how important it is to do randomized controlled trials.

TCL: What could be causing the drop in mortality?

KRAMER: Better treatment and increasing application of effective treatment, more surgery and more hormone treatment.

Over the same era, in which PSA came into much more common use for screening, hormone therapy came into much more common use for various stages of prostate cancer, and we do know through randomized controlled trials that hormone therapy decreases the risk of dying of prostate cancer.

Washington In Brief:

Obama To Name Hamburg As FDA Commissioner

President Obama said in his radio address March 14 that he would nominate former New York City Health Commissioner **Margaret Hamburg** as FDA commissioner and Baltimore Health Commissioner **Joshua Sharfstein** as the agency's principal deputy commissioner.

Hamburg was assistant secretary of HHS in the Clinton administration and currently is associated with the think tank Nuclear Threat Initiative. Also, she was commissioner of the New York City Department of Health and Mental Hygiene.

"Dr. Hamburg brings to this vital position not only a reputation of integrity but a record of achievement in making Americans safer and more secure," Obama said.

The nomination requires Senate confirmation.

Sharfstein served as a health policy aide to House Energy and Commerce Committee Chairman **Henry Waxman** (D-Calif.). In his remarks, Obama praised Sharfstein's work to challenge the safety of cold medicines for children.

NIH News:

Average Cost of Grants To Rise 3 Percent For FY09, NIH Says

NIH earlier this week provided guidance to its institutes and centers on grant funding policies for fiscal 2009.

The omnibus appropriation provided NIH with $30.4 billion, a 3 percent increase over FY 2008. The institute said it will emphasize support for new investigators and sustaining established investigators who have little or no additional research support.

The following NIH fiscal policies are instituted in FY2009:

—Non-Competing Research Awards: The FY 2009 appropriation allows NIH to support investments in research by funding research grants at the most recently committed levels. Non-competing awards previously issued in FY 2009 at reduced levels will be revised to restore funds to the level indicated above. (See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-002.html). This policy does not apply to Career Awards, SBIR/STTRs, and Ruth L. Kirschstein-National Research Service Award Individual Fellowships & Institutional Training Grants.

—Competing Research Awards: Each NIH institute and center will manage its competing portfolio using funds that have not been committed for non-competing awards. Consistent with the FY 2009 appropriation, the FY 2008 average cost of competing grants is allowed to increase by 3 percent over FY 2008 when compared to similar policies. It is estimated this will allow ICs to support the NIH investigator pool with approximately 9,800 new and competing RPGs.

The following guidelines will apply to competing research awards in FY 2009:

1. Maintain the number of new investigators comparable to the average of the five most recent years as described at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html.

2. Continue to use the NIH Director's Innovator Awards within the Common Fund (http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-09-003.html) and NIH Pathway to Independence Awards (http://grants.nih.gov/grants/guide/pa-files/PA-09-036.html) as previously described.

3. Continue to use the NIH Directors Bridge Award Program (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-037.html) which provides continued but limited bridge funding to meritorious investigators whose applications were close to the funding range of the relevant IC and have minimal other support. This program provides NIH with a flexible NIH-wide tool to help balance the grant cycling variation challenges and support other approaches to sustain established grantees and first time competing renewals. As in FY 2008, this program is designed to provide only one-year of continued but limited funding.

Each IC will establish fiscal policies consistent with these NIH-wide policies according to its specific scientific and programmatic imperatives. Additional information on FY2009 Fiscal Operations, including specific funding strategies for ICs will be posted at http://grants.nih.gov/grants/financial/index.htm.

—Ruth L. Kirschstein National Research Service Awards: NIH will support a 1 percent increase in all stipend levels.

NIH Funding Opportunities

PA-09-122 Research on Clinical Decision Making in People with or at Risk for Life-Threatening Illness (R01). http://grants.nih.gov/grants/guide/pa-files/PA-09-122.html

PA-09-124 Exploratory/Developmental Clinical Research Grants in Obesity (R21). http://grants.nih.

gov/grants/guide/pa-files/PA-09-124.html

PA-09-125 Biobehavioral Methods to Improve Outcomes Research (R01). http://grants.nih.gov/grants/guide/pa-files/PA-09-125.html

PA-09-126 Biobehavioral Methods to Improve Outcomes Research (R21). http://grants.nih.gov/grants/guide/pa-files/PA-09-126.html

PA-09-130 Exploratory Grants for Behavioral Research in Cancer Control (R21). http://grants.nih.gov/grants/guide/pa-files/PA-09-130.html

PAR-09-129 Solicitation of Assays for High Throughput Screening in the Molecular Libraries Probe Production Centers Network (R03). http://grants.nih.gov/grants/guide/pa-files/PAR-09-129.html

Industry News:

Alex Matter To Leave Novartis For Singapore Science Agency

ALEX MATTER, who spearheaded the discovery of Gleevec while global head of oncology research at Novartis Pharmaceuticals, has been appointed chief executive officer of Singapore's Experimental Therapeutics Centre.

For the past six years, Matter has been founding director of the Novartis Institute for Tropical Diseases, a position that he accepted after retiring as leader of oncology R&D at Novartis' headquarters in Basel, Switzerland.

Matter, who is retiring from the Novartis institute, next month will join ETC, one of the research programs sponsored by A*STAR (Agency for Science, Technology and Research), which is driving Singapore's massive R&D investment in the biomedical and physical sciences.

"With his vast experience and deep knowledge of drug discovery and development, Alex will bolster A*STAR's ability to close the gap between the bench and the bedside," said A*STAR Chairman Lim Chuan Poh.

Matter plans to enhance A*STAR's capabilities in pre-commercial/pre-clinical drug development, and help to translate scientific discoveries from A*STAR's labs into potential new drugs and treatments.

Matter succeeds Sir David Lane, who founded ETC in 2006. Lane will become chief scientist of A*STAR and return to lab research.

Matter has served as an advisor to several A*STAR research programs, including the Institute of Molecular and Cell Biology, the A*STAR Investigator Selection Panel, and the ETC Project Review Committee.

Matter's position at ETC is one of four new leadership appointments announced by A*STAR and that will take effect on April 1. The other appointments include: Sir George Radda as chairman of A*STAR's Biomedical Research Council; Low Teck Seng, as deputy managing director (research) of A*STAR; and Lane as the chief scientist.

FDA News:

FDA, Eight Institutions To Collaborate On Nanotech

FDA said it will collaborate with the Houston-based Alliance for NanoHealth and its eight member institutions to help speed development of safe and effective medical products in the emerging field of nanotechnology.

Under a Memorandum of Understanding, the FDA/ANH Nanotechnology Initiative will work to expand knowledge of how nanoparticles behave and affect biologic systems, and to facilitate the development of tests and processes that might mitigate the risks associated with nanoengineered products. All outcomes from this public-private partnership will be placed in the public domain for the benefit of all stakeholders

The eight academic institutions include Baylor College of Medicine, the University of Texas' M.D. Anderson Cancer Center, Rice University, the University of Houston, the University of Texas Health Science Center at Houston, Texas A & M Health Science Center, the University of Texas Medical Branch at Galveston, and the Methodist Hospital Research Institute.

"We are delighted with this partnership between the FDA and the eight institutions that constitute the Alliance for NanoHealth," said Larry Kaiser, president of the University of Texas Health Science Center, on behalf of the ANH. "We see this agreement as an important step on the path to taking advantage of the enormous power of nanotechnology to improve the diagnosis and treatment of disease."

Professional Societies:

Oncology Training Programs Need to Expand, Survey Finds

The American Society of Clinical Oncology released the results of a survey of medical oncology and hematology/oncology fellowship program directors, which found training programs have limited plans to increase the number of oncology training positions over

the next five years.

ASCO surveyed 159 medical oncology and hematology/oncology program directors to determine how likely they were to increase the number of oncology training positions in their institutions in the next five years. Of the 124 who responded, only one in four said they planned to increase the number of oncology training slots from 2007 to 2013, and none had plans to increase the number of training slots by more than two positions. The survey results are being published in the March 2009 issue of the Journal of Oncology Practice.

"Although the overall quality of the applicant pool remains strong, there remain several barriers that could prevent additional increases in training positions," said Dean Bajorin, co-chairman of ASCO's Workforce Advisory Group, which is developing recommendations to increase the oncology workforce in light of an anticipated future shortage. "The most significant barriers seem to center on financial concerns, namely the availability of funding to support fellows and the cost of expansion."

In fact, of the program directors who said they were very likely or somewhat likely to increase the number of oncology training program slots at their institutions, one in four said that they did not know how they would fund the new positions.

Increasing the number of oncology training positions is a tactic in ASCO's strategic plan to address looming oncology workforce shortages. A 2007 ASCO study projected a significant shortage of medical and gynecologic oncologists in the United States by 2020, due to the aging of the Baby Boomer generation, an increase in the number of cancer survivors, and slower growth in the supply of oncologists.

"The projected oncology workforce shortage is partly due to the limited number of oncology training positions currently available," said Michael Goldstein, co-chairman of ASCO's Workforce Advisory Group. "ASCO will work with oncology programs to advocate for their expansion and support program directors in their efforts to train oncologists to practice in a time of shortage."

For more information on ASCO's workforce initiatives, visit www.asco.org/workforce.

SOCIETY OF SURGICAL ONCOLOGY presented its James Ewing Layman Award to **Anne Gioia** and her sister-in-law **Donna Gioia**, for their support of the Roswell Park Cancer Institute.

After losing her daughter Katherine to cancer in 1989, Anne Gioia, with Donna Gioia, formed the Roswell Park Alliance in 1990 in support of RPCI. The institute, then operating under the New York State Department of Health, was facing significant economic and capital improvement challenges that jeopardized its future.

The Gioia family and the volunteers they recruited were instrumental to the success of the first fundraising program in the institute's history. The group became the lynchpin needed to successfully lobby Albany legislators starting in 1992 for an unprecedented $241 million major modernization for RPCI. The Alliance also began rallying behind Roswell Park's research, recruitment and patient needs. The volunteers' efforts have since raised nearly $180 million—despite Buffalo's ranking as one of America's most economically challenged cities.

The Gioias also have dedicated their own resources to the cause. The Gioia family recently made a $1 million gift toward the establishment of an endowed chair in Cancer Medicine at Roswell Park, held by Alex Adjei.

AMERICAN NURSES ASSOCIATION Board of Directors voted to endorse the Oncology Nursing Society's statement on Nursing Leadership in Global and Domestic Tobacco Control.

"Tobacco continues to be the leading cause of preventable death and illness in the United States," said Brenda Nevidjon, president of ONS. "All nurses are in an ideal position to help solve the tobacco problem through patient education about prevention of tobacco-related disease, and we are pleased with the ANA's endorsement of this position."

ONS states that the tobacco epidemic can be controlled through the active participation of nurses. Methods outlined in the ONS position paper include:

—Restricting promotion, increasing the price, and strengthening the warning labels of tobacco products.

—Ensuring that tobacco assessment and dependence treatment is an expected part of care in all cancer treatment programs.

—Ongoing federal support for public media campaigns about tobacco prevention and treatment.

—Education for practicing and student nurses on the health effects of tobacco use and tobacco control interventions.

—Nursing research on tobacco use, prevention, cessation interventions, and reduction of exposure to secondhand smoke.

—Nurses serving as tobacco-free role models.

The position paper can be found at: http://www.ons.org/publications/positions/GlobalTobaccoUse.shtml.

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