THE CANCER LETTER

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Advisors Voted For Provenge Approval Despite Fundamental Flaws In Trials

By Paul Goldberg

Under ordinary circumstances, an unplanned analysis of data from trials that fail to meet their primary endpoint isn't the sort of evidence that leads to FDA approval of a cancer therapy.

But then there is Provenge, a prostate cancer vaccine that FDA advisors recommended for approval on March 29.

As a vaccine, Provenge (sipuleucel-T) was the first cancer therapy to go through the Office of Cellular, Tissue and Gene Therapies at the Center for Biologics Evaluation and Research. The advisory committee that provides clinical guidance to that office, the Cellular, Tissue and Gene Therapies Advisory Committee, voted 13 to 4 in favor of approving the therapy sponsored by Dendreon Corp.

The company argued that its trials, which were powered to detect time

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Professional Societies:

AACR CEO Foti Receives First Annual Leadership And Achievement Award

The Board of Directors of the American Association for Cancer Research announced that the association's CEO, **Margaret Foti**, will receive the first annual AACR Award for Leadership and Extraordinary Achievements in Cancer Research.

Foti also serves as secretary-treasurer and CEO of the AACR Foundation for the Prevention and Cure of Cancer, and managing editor of Cancer Research.

Foti joined AACR in 1965 as an editorial assistant for Cancer Research, under the editorship of Michael Shimkin. She was promoted to managing editor of the journal in 1969 and progressed through several management roles before becoming the first executive director of AACR in 1982. The award will be presented on April 15 at the AACR annual meeting in Los Angeles.

AACR also announced several other awards:

Nancy Brinker and **Lance Armstrong** will receive inaugural Centennial Medals for Distinguished Public Service for their contributions to cancer research advocacy and awareness. Brinker, founder of Susan G. Komen for the Cure, is being recognized for her work in breast cancer. Lance Armstrong, founder of the Lance Armstrong Foundation, is being honored for his excellence and leadership in advocacy for cancer survivors.

FDA Commissioner **Andrew von Eschenbach** will receive the

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Memorial's Scher Warns FDA About Flaws In Provenge Data

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to disease progression, overlooked a survival advantage, which became apparent only in an unplanned analysis after the study concluded.

Since the company is claiming a 4.5-month survival advantage among men with asymptomatic metastatic androgen-independent prostate cancer, the therapy, if approved, could become a new standard of care.

This would not be supported by the data presented to the advisory committee, wrote one of the skeptics, Howard Scher, chief of the Genitourinary Oncology Service and D. Wayne Calloway Chair in Urologic Oncology at Memorial Sloan-Kettering Cancer Center, who cast one of the four nay votes.

"My vote was based on the fact that neither of the two trials presented met their endpoint, which renders the significance of results from any subsequent analyses as 'exploratory;' and 'hypothesis generating,'" Scher wrote in a letter to FDA. A copy of the document, which was widely circulated, was obtained by The Cancer Letter, and appears on page 4.

A purist would argue that serious consideration of such data is tantamount to continuing a chess game after a checkmate. In this case, the checkmated player ended up being declared the winner.

The positive vote appears to point to a double standard for cancer therapies at FDA, observers said.

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Two years ago, when the agency consolidated its drugs and biologics operations to form an oncology office in the Center for Drugs Evaluation and Research, the unit reviewing cell, gene, and tissue therapies remained in CBER. At the time, cancer groups objected to that decision. "Moving those products to join cancer drugs and other biologics involved in cancer treatment is, in our view, necessary to a complete consolidation of the entire oncology portfolio under a single entity," the American Society of Clinical Oncology wrote to the agency (The Cancer Letter, July 8, 2004). The patient-run Cancer Leadership Council sent a similar letter.

The consolidation wasn't entirely voluntary on the agency's part. It was mandated by a Congressional oversight committee after its investigation of the ImClone controversy showed that drugs weren't evaluated in the same manner as biologics. Now, with Congressional oversight on the upswing and with investigators focused on the agency, the Provenge matter is likely to be noticed on the Hill.

Several FDA insiders said they were surprised that the agency didn't refer Provenge to the Oncologic Drugs Advisory Committee, the agency's group that has the expertise to evaluate cancer therapies. Only one permanent member of ODAC served on the advisory group that voted to approve Provenge.

Under federal law, the agency has until May 15 to decide whether to approve Provenge.

Changing Questions in Mid-Vote

Members of FDA advisory committees often need clarification of approval standards. Yet, at the March 29 meeting, as some committee members stated that their goal was to stimulate development of immunotherapy, FDA staff didn't jump in to clarify that the committee should limit itself to the data on the table.

Later, as the committee was heading toward turning down the drug, FDA staff rephrased the approval question in such a manner that those voting nay switched to yea.

As three committee members in a row said that the data failed to "establish the efficacy" of Provenge, FDA staff altered the wording, asking whether the sponsor had provided "substantial evidence" of efficacy.

Consider the vote switch by Richard Alexander, of the VA Maryland Health Care System:

No, the data didn't establish efficacy of Provenge, Alexander said initially.

"Does the evidence that's here so far *establish* the therapy, that with full confidence I can look my patient in the eye and say that this is established to be

an efficacious therapy for your disease?" he said. "Does the data establish that this therapy has efficacy? I think it's a very strong suggestion, but it is not in my mind definitive in establishing that this therapy is the reason we see the difference in the data so far. I would say that the trial that's ongoing must continue, and I would urge the company to redouble their efforts to get that finished. So my vote is No. Not yet, but very close."

Two more members agreed with Alexander, prompting Celia Witten, a physiatrist who serves as director of the FDA Office of Cellular, Tissue and Gene Therapies, to paraphrase the question.

"The question we are really asking [is] Do you believe that this product works, that it's efficacious?" Witten said. "That's really what we are asking. If somehow some of the words are not clear, we would like to know whether you believe as individuals that this works, that they have shown that it works… The regulatory definition is 'provided substantial evidence.' So that's our standard. Is there *substantial evidence* that it works?"

This restarted the vote tally, producing a radically different result.

"Yes, there is substantial evidence," said Alexander, switching his vote. "The 150-some patients, there is substantial evidence. Is it evidence enough to be conclusive to the standard that we need to be approving something? That's up to the FDA to decide.

"From my standpoint, as design of clinical trials where there is definitive evidence that something is conclusive based on secondary—or not even a secondary endpoint—is statistically not a valid thing.

"If you are going to design a study to answer a question, you have to design the best study possible, and that study is ongoing. Is there substantial evidence that the drug has efficacy? I would say, 'Yes, this qualifies as substantial evidence, but it's not enough for me, that if I were in CBER saying yea or nay, I would say nay.'"

While these comments suggested that Alexander regarded the new wording as more forgiving, it was, in fact, defined in a 1998 agency guidance on establishing efficacy, http://www.fda.gov/CDER/GUIDANCE/1397fnl.pdf. Under that guidance, marketing approval of oncology drugs requires substantial evidence of efficacy from adequate and well-controlled clinical trials.

Still, his rationale made it clear that while his vote changed, his position did not. As two other members similarly changed their votes, it appeared that the committee needed a clarification of regulatory terminology FDA. Yet, agency staff members offered no such help.

Not everyone was confused. Maha Hussain, a prostate cancer expert at the University of Michigan and chairman of the FDA Oncologic Drugs Advisory Committee, was in the minority of committee members who understood the approval standard.

"To me, substantial and established are the same, and No to both," she said, casting one of the four nay votes.

"We Are Opening a New Field"

Some committee members were enthusiastic about the drug. "Let's put it this way: If I had prostate cancer, I would try this before chemotherapy," announced Francesco Marincola, director of the Immunogenetics Laboratory at the NIH Clinical Center. Being "harsh" on Provenge would be tantamount to "missing the point," he said.

"We are opening a new field," he said. "Even if we make a mistake, even if the [therapy] is not this effective, there is so much to learn by starting to see patients being treated with this and see what else can be added. We should not underestimate the importance of this decision. I don't think it's just about the drug and what the drug does, but it's about opening a field, and the investigation on that field."

The patient advocate on the committee didn't object to this uncertainty.

"I am doing hormonal therapy, and at some point it's going to fail; I know that," said Robert Samuels, a 13-year cancer survivor who heads the Florida Prostate Cancer Network. "When it does fail, I will look around and say, what do I do next? And I look upon this as an opportunity for me to make a choice. That's all the patients want: an opportunity to make a choice. That's what this is about, because as they look down the road, they don't have a very bright future, and if we can buy them a couple of minutes, a couple of months or a couple of years, it is our obligation to do that.

"At the end of the day, it's not statistics," Samuels said during committee discussion. "It's about people's lives. And indeed we have an obligation to give patients like us a choice to say, we'll take the risk. We understand it's a risk. But it's a risk that I think most of us are willing to take."

Judging by the applause, many survivors in the audience agreed.

Meanwhile, the company and outside investigators acknowledged that the data were soft.

Reviewing a paper from the pivotal trial, Scher found that even the principal investigator on the trial couldn't state with certainty that the findings were more

than a fluke. "In summary, this study suggests that while sipuleucel-T fell short of demonstrating a statistically significant difference in TTP, it *may* provide a survival advantage to asymptomatic HRPC patients," the paper states (Eric Small et al.: JCO 24:3089, 2006).

"All the difficulties cited, and the investigators' own conclusions, show how there are simply too many altertnative explanations for the observed survival difference beyond treatment with supuleucel-T," Scher wrote in a letter to FDA.

Biostatistician Brent Blumenstein similarly acknowledged the flaws. "Here I am, a statistician, and I know the rules," acknowledged Blumenstein, an affiliate professor of biostatistics at the University of Washington, who was presenting for Dendreon. "I sit on committees, and I often invoke those rules. But this time I am sitting on the other side of the podium."

Blumenstein argued that the post hoc analysis picked up the survival advantage after failing to detect any improvement in time to progression because the therapy was having a "delayed effect."

"One of the things that haven't been mentioned is the special status that survival has with respect to time to progression," Blumenstein said. "There is a putative surrogacy relationship between these two endpoints. If you accept the fact that there is that possibility—I know that it's not been proven; it's not validated—one has to take into account that there is a possibility that the outcomes of time to progression are correlated in some manner."

"This says to me that this is a treatment that men probably should have access to," Blumenstein concluded. "And then in the end of the game, if the other trial isn't significant, nobody will buy it."

Hussain and other skeptics were less willing to let the market decide, especially since the company is conducting a 500-patient trial powered to provide the definitive answer on the safety and efficacy of Provenge. The trial is 100 patients short of its accrual target.

"So within 100 patients, we will have these results in the next two to three years," Hussain said. "The definitive trial is being done. If the decision is made to approve, there would [have to] be guarantees that the trial would be continued."

The data presented to the committee are not convincing, Hussain said. "When I sit down on Monday to talk to patients, I would have to feel 90 percent confident that everything that was presented today is related to the treatment and that this is the best drug for Mr. Smith," she said.

"Generally, disease manifestation goes together with survival. So when you see a survival advantage, you see a time to progression advantage, you see a pain response benefit. This has not occurred here. That to me says something. Maybe the vaccine didn't really work.

"Maybe something else was the reason why these patients lived longer."

Scher agreed. The Dendreon presentation didn't make it possible to identify the effect of the treatment, he said at the meeting.

"As we look back at what was presented, we didn't really see any evidence of a direct anti-tumor effect," Scher said at the meeting. "There has to be some point where this is affecting the natural history, but we just haven't seen that."

The approval of the drug based on inconclusive data could harm the patients instead of benefiting them, Scher said. The data made it impossible to balance these uncertain benefits against an elevated risk of cerebrovascular events, including deaths, on the Provenge study. The difference was not statistically significant.

"I don't think there is any debate here about the need for more options and more effective treatments," Scher said. "But the lack of availability of drugs is not the fault of the FDA.

"It's really our fault in terms of how we design trials."

The text of Scher's letter to FDA follows:

I am writing to express concerns about the recent review of Sipuleucel-T at the FDA Advisory Meeting on March 29, 2007. These concerns are: a recommendation for approval based on data that fall short of the regulatory requirements; an inadequate statistical construct to determine definitive benefit; incomplete data on product safety; and what appear to be different criteria for approval by two Advisory Committees to the Agency. All but the latter were discussed in the open meeting, but warrant further consideration given the outcome. The concerns are based on my experience as a voting member on several ODACs representing the Agency, and separately, as a Presenter to ODAC for Industry Sponsors. I have been one of the Academic Leaders of the Prostate Cancer Clinical Trial Endpoints initiative begun under the joint Sponsorship of the FDA, AACR, ASCO and PCF in 2004, which were presented at the February 2007, Prostate ASCO Meeting in Orlando. The final manuscript is currently under review at the NCI, FDA and the Group of established Prostate Cancer Clinical Trial experts who together, formulated the

recommendations. I am also the Principal Investigator of a Multicenter Prostate Cancer Clinical Trials Consortium funded by the Department of Defense that focuses on phase 1 and 2 trials in this disease.

Let me state at the outset that I was one of the four Committee Members who voted "no" to the question whether the trials presented by the Sponsor established the efficacy or demonstrated substantial evidence of benefit to justify an approval recommendation to the FDA. **My vote was based on the fact that neither of the two trials presented met their primary endpoint, which renders the significance of results from any subsequent analyses as "exploratory" and "hypothesis generating."** As such, theresults do not constitute "proof" of benefit or justify a conclusion that they are "reasonably likely" to predict benefit. The trial data were not consistent. Even if one accepts the post-hoc survival analysis results of the larger 127 patient trial (82 men treated with Sipuleucel-T and 45 men treated with a "placebo"), the second trial of 98 patients (65 treated with Sipuleucel-T and 33 with placebo) was not confirmatory. Consequently, the only conclusion that can be reached is that the survival difference observed may have occurred by chance alone, and that the results do not support an approval recommendation. This, and the Sponsor's recognition that an additional prospective study was needed, mandates deferring any decision on whether an approval should be granted until the results of the ongoing 500 patient phase 3 trial that is powered on a primary endpoint of survival, is accrued and analyzed.

Concerns about the validity of the findings were reinforced by the absence of other signals of an antitumor effect. Specifically there were no data provided of a favorable effect on PSA, regression or stabilization of soft-tissue or boney disease radiographically, health related quality of life, or that administration of the product delayed the development of pain. Even the time to the administration of chemotherapy, an indication to the treating Physicians that the clinical course had worsened, was similar between the two groups. Reinforcing the uncertainty was the fact that in response to a direct question at the meeting, none of the Physicians representing the Sponsor could articulate how treatment with the product had "helped" any individual patient.

There were also methodologic concerns. Trial 9901 was designed to show an increase in time to disease progression from 16 weeks for placebo treated to 31 weeks for Sipleucel-T treated patients (HR = 1.92, alpha =0.05, two sided, with 80% power). A total of 127 patients were enrolled using a 2:1 randomization in favor of the experimental therapy. The study was double blind and included an independent review of all imaging results. The estimated time to progression on which the trial was powered proved to an overestimate, as the actual observed median time to progression was 9 to 11 weeks for both arms: a difference that was not statistically significant. A summary of the progression events showed that 90% (97/114) were by imaging, 10 were clinical, and 7 were for the new onset of disease related pain. Unrecognized at the time of the design of the trial, was that the eight week interval between disease assessments was too short to observe clinically significant changes by bone scan, and that in many cases, apparent "progressions" eight weeks after the start of a therapy are more a reflection of disease worsening that led to trial entry, and not a failure of the treatment.(CCR 13:1488, 2007) This is similar to what was observed in the trial with the endothelin antagonist, atrasentan, in which a 12 week disease assessment interval was used and a large proportion of patients were withdrawn at the time of scheduled scans in the absence of clinical worsening of disease (ODAC, September 13, 2005). Recognizing this, the Prostate Cancer Working Group 2 has advised that an apparent progression on bone scan at a three month assessment, be confirmed by documenting further progression on a subsequent scan six or more weeks later before considering a patient to have failed the treatment.(ASCO Multidisciplinary Prostate Cancer Symposium, (Abstract #221) February 22-24, 2007, Orlando, FL, 2007). Although the Sponsor suggested that the effect of the product was delayed, this hypothesis could not be explored because serial imaging to assess disease at defined intervals were not performed once a patient was considered to have "progressed" and taken off study. As a result, individual sites of disease were no longer being monitored, so that no statements could be made regarding a possible "delayed effect" of the product on disease status.

At 3-years, a prespecified survival analysis was performed which showed a 4.5 month difference in median survival favoring Sipuleucel-T, and while a significant p-value for the difference was determined, the type 1 error rate is surely inflated by this additional analysis. Imbalances in disease aggressiveness and disease extent were noted between the Sipuleucel-T and "control" groups including a higher proportion with Gleason 6 disease or less at diagnosis (26.8% vs. 15.6%), and a lower proportion with both bone and soft tissue disease (52% vs. 69%) at the time therapy was started. Both factors favored the Sipuleucel-T arm,

predicting a longer survival for the "treated" patients independent of therapy. The 2:1 randomization increased the power of the experimental arm, but it may have inadvertently made the small 43 patient control group more heterogeneous and less representative of the global population of men for whom the indication was proposed. The potential impact of heterogeneity in small patient cohorts was shown when a post-study change in the progression times of two patients (a change not accepted by the Agency), resulted in a change in the significance estimates.

The first question the Agency posed to the Committee was whether the product was "reasonably safe" for the intended population. While the vote was yes, the issue of cerebrovascular events as a potential safety signal was raised. This concern was based on the finding that 4.9% (17/345) of the Sipuleucel-T and 1.7% (3/172) of "placebo" treated patients who were enrolled on randomized trials for the indication, experienced a cerebrovascular event (p=0.092). The odds ratio for developing a cerebrovascular event was 2.92, with wide confidence intervals (0.82 to as high as 10 fold). Deaths due to CVA's were recorded in 1.5% of Sipuleucel-T patients and 0.9% of those receiving "placebo." Unclear is why there is no mention of CVA's in the published report of the study in the Journal of Clinical Oncology (JCO 24:3089, 2006). Given that the product is released for administration based on the increase in the proportion of CD54+ cells and not the absolute number of any particular cell type and that CD54+ cells actually represent only 20% of the final product, the contribution of the other cell populations and cytokines that may be present in the administered product on the development of a cerebrovascular event is not known. More important, and perhaps underappreciated during the discussion, is the recognition that the "placebo" used in this trial, a portion of the leukopheresis product that is cultured without the immunizing antigen and reinfused, may not be inert and in itself contributed to a relative worsening of survival for the control group in this trial. To place the frequency of the neurologic events in perspective, no cerebrovascular events were observed in TAX-327, a 997 patient three arm randomized trial that evaluated two different dose schedules of docetaxel in comparison to mitoxantrone,(NEJM 351:1052, 2004) or ASCENT1, a 251 patient randomized comparison of docetaxel weekly with or without high dose calcitriol (DN-101)(JCO 25:669, 2007). Neurologic events that were not detailed further were observed in 7% of the 338 patients who received estramustine which is known to be thrombogenic, in combination with docetaxel on the SWOG 99-16 trial (NEJM 351:1513, 2004).

Another concern is that the requirements for regulatory approval appear to differ between the ODAC and CBER Advisory Committee. As an example, ASCENT1 was a prospective randomized phase 2 trial of weekly docetaxel with or without high dose calcitriol (DN-101). The trial was powered to detect a 20% difference in the PSA response rate at six months between the two groups as the primary endpoint, but also included a pre-specified survival analysis, similar to that included in the Sipuleucel-T 9901 trial as one of the secondary endpoints. PSA response was defined as a 50% or greater decline from baseline according to Consensus Criteria (JCO 17:3461, 1999). A total of 250 patients, 125 per arm were enrolled and followed. The 9% difference in the PSA response rate observed at six months was not statistically significant (P<.16), yet here too, the pre-specified survival analysis showed a difference for docetaxel plus DN-101 vs. docetaxel plus placebo: median not reached but estimated to be 24.5 months vs. 16.4 months respectively with a hazard ratio for death of 0.67 (p=0.04)(JCO 25:669-74, 2007). The safety of the combination was no worse and perhaps better than docetaxel alone. Appropriately in my view, the results were not considered definitive by ODAC, no approval filing was made, and a new 900 patient phase 3 trial powered to test the hypothesis whether the combination of docetaxel in combination with DN-101 conferred a survival advantage relative to docetaxel alone was designed, initiated and continues to accrue. I am the International Principal Investigator on this trial. Contrast this with the regulatory filing history of Sipuleucel-T where the primary endpoint of the registration trial was also not met, yet, it is being considered for approval based on a similar post-hoc analysis with roughly half the total number of patients, and a control arm that is roughly one third the size. Why do the Sipuleucel-T results establish efficacy, while the DN-101 results do not?

An approval recommendation has far reaching implications beyond making the product available that the data simply do not support or justify. For one, it provides the Agency's endorsement of Sipuleucel-T as a "standard of care" treatment for an asymptomatic population of men with androgen independent (castration resistant) disease that represents upwards of 45,000 men in the U.S. The second is that by extension, it elevates Sipuleucel-T to a position of being the new "control" arm for future randomized phase 3 trials that are being designed for the regulatory approval of any new experimental agent or approach. It also opens

the door to the premature approval of drugs based on inconclusive data.

Finally, the original question posed by the Agency to the Advisory Committee at the meeting was: "Does the submitted data establish the efficacy of Sipuleucel-T (APC-8015) in the intended population?" The first 4 respondees on the Committee voted "no." The question was then changed to: Do the data show "substantial evidence." A series of "yes" votes followed.

Consider the conclusion in the manuscript describing the results of trial 9901, published in the Journal of Clinical Oncology in Volume 24, page 3093, in 2006.(JCO 24:3089, 2006) In it, the Investigators state **"that while sipuleucel-T fell short of demonstrating a statistically significant difference in TTP, it *MAY* provide a survival advantage to asymptomatic HRPC patients. Supportive studies are underway to confirm this effect."** All of the difficulties cited, and the Investigator's own conclusions, show how there are simply too many alternative explanations for the observed survival difference beyond treatment with Sipuleucel-T. Couple this with that fact that were no secondary signals of an antitumor effect and no confirmatory trial however flawed, mandates that any decision for approval be deferred until the phase 3 study, currently underway, has been completed and analyzed.

Obituary:

RODGER J. WINN, an oncologist and expert in the quality of cancer care, died April 4 at his home in Washington, D.C., of complications from esophageal cancer. He was 69.

Winn was Editor-in-Chief of the journal JNCCN, which publishes clinical practice guidelines in oncology. He served as co-chairman of the National Quality Forum's Quality of Cancer Care Steering Committee from 2002-2003. Since 2004, he was a clinical consultant to NQF, where he directed reports to endorse national quality standards for palliative and hospice care, symptom management, and quality of breast and colorectal cancer care.

He served as a consultant to projects on healthcare-associated infections, in particular surgical site infections and ambulatory care quality. He also was a medical director for Quality Oncology, an oncology disease management company.

Prior to joining NQF, Winn was an independent consultant serving as chairman of the National Comprehensive Cancer Network's Guidelines Steering Committee, consisting of 45 panels charged with writing over 100 cancer treatment guidelines. In addition, as first chairman of the American Society of Clinical Oncology's Health Services Research Committee, he initiated the ASCO guideline program.

Winn was in private practice from 1970 to 1985 at Memorial Sloan-Kettering Cancer Center, Overlook Hospital, and St. Barnabas Medical Center. At St. Barnabas, Winn was one of the founders of the Memorial Sloan-Kettering Associates Oncology Group. In 1985, he returned to academia as associate professor of medicine at University of Texas M. D. Anderson Cancer Center, where he founded and directed the community outreach program, encompassing both research and managed care activities. He was chairman of the MDACC Community Clinical Oncology Program, a network of 35 community centers collaborating with the academic center in clinical trials.

Winn received his undergraduate degree from Harvard University in 1959 and his medical degree from Jefferson Medicine College of Philadelphia in 1963. His postgraduate training included an internship and residency at Jefferson Medical College and a medical oncology fellowship at MSKCC.

Winn is survived by his wife Patricia Blank; son, Matthew of Atlanta, GA; daughter, Amanda Winn Lee of Altadena, CA; three grandchildren; and his sister Dilys Winn of Ashville, NC.

Professional Societies:

AACR Honors Its CEO

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Distinguished Service Award for his leadership as NCI director from 2002 to 2006.

Harold Freeman, founder, president, and medical director of the Ralph Lauren Center for Cancer Care and Prevention at Memorial Sloan-Kettering Cancer Center, will receive the Public Service Award for his leadership in reducing cancer health disparities.

LaSalle Lefall Jr. will receive the Public Service Award for his leadership in the fight against cancer through excellence in teaching, research, scholarship, patient care, and public service. He is the Charles R. Drew Professor at Howard University.

* * *

RICHARD REILING was appointed president of the Association of Community Cancer Centers at the association's annual meeting last month. Reiling is medical director of the Cancer Center at Presbyterian Hospital, Charlotte, N.C., and is a surgical staff member at both Presbyterian Hospital and Presbyterian Matthews. He plans to focus on the issue of survivorship.

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