THE CANCER LETTER INTERACTIVE

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

Vol. 29 No. 13
March 28, 2003

More Aggressive Prevention, Detection Could Save Lives, Cancer Policy Board Says

More than 60,000 Americans die prematurely each year because of the nation's failure to fully implement proven methods of cancer prevention and early detection, according to a report by the National Cancer Policy Board of the Institute of Medicine.

Behavioral interventions to promote healthy lifestyles and cancer screening could reduce cancer incidence and mortality, but have not been

(Continued to page 2)

In Brief:

Tempero, Johnson To Lead ASCO In '03-04; Oncologists Select New Board Members

AMERICAN SOCIETY of Clinical Oncology announced new officers for 2003-2004:

Margaret Tempero begins her one-year term as president on June 1, the same day as the annual meeting of the society, which will take place in Chicago. She is deputy director of the comprehensive cancer center at University of California, San Francisco, and chief of the Division of Medical Oncology in the Department of Medicine.

David Johnson will begin serving as president-elect on June 2, and will succeed Tempero in 2004 as president. He is the Cornelius Abernathy Craig Professor in Medical and Surgical Oncology and deputy director of the Vanderbilt-Ingram Cancer Center.

New ASCO board members include: **David Gandara**, secretary-treasurer, professor of medicine, University of California, Davis, School of Medicine and director, clinical research, UC Davis Cancer Center; **Patricia Ganz**, associate director, Jonsson Comprehensive Center, University of California, Los Angeles; **Michael Perry**, associate director, Ellis Fischel Cancer Center and head, Division of Hematology and Medical Oncology, University of Missouri; **Lee Helman**, chief, NCI Pediatric Oncology Branch and head, Molecular Oncology Section; **Joseph DiBenedetto Jr.**, medical oncologist in private practice, Providence, RI; **Jose Baselga**, chief, Medical Oncology Service and director, medical oncology, hematology, and radiation oncology, Vall d'Hebron University Hospital, Barcelona.

Newly elected members of the Nominating Committee include: Chairman, **Kathleen Pritchard**, head, medical oncology and hematology, and clinical trials and epidemiology, Toronto-Sunnybrook Regional Center Centre; and **Sonja Singletary,** chief, Surgical Melanoma Section and chief, Surgical Breast Section, M.D. Anderson Cancer Center.

Click Here for Photocopying Guidelines

Report Urges More Aggressive Cancer Prevention And Control

(Continued from page 1)

aggressively adopted by individuals and the health care system, the report issued March 10 concluded.

"A 19 percent decline in the rate at which new cancer cases occur and a 29 percent decline in the rate of cancer deaths could potentially be achieved by 2015 if efforts to help people change their behaviors that put them at risk were stepped up and if behavioral change were sustained," the report said. "This would equate to the prevention of approximately 100,000 cancer cases and 60,000 cancer deaths each year by the year 2015."

The health benefits of behavioral change also would extend to reductions in the rates of cardiovascular disease and diabetes, the report said. The policy board was established by IOM with funding from NCI.

"To save the most lives from cancer, health care providers, health plans, insurers, employers, policy makers, and researchers should be concentrating their resources on helping people to stop smoking, maintain a healthy weight and diet, exercise regularly, keep alcohol consumption at low to moderate levels, and get screening tests for cancer that have proven effectiveness," the report said.

While the health behaviors that increase cancer risk are well-recognized, there is growing evidence that health care providers can intervene effectively to help people change their behavior, the report said. For example, providers have been able to boost smoking cessation rates by adhering to tested guidelines.

The report, "Fulfilling the Potential of Cancer Prevention and Early Detection," reviews the evidence that cancer incidence rates can be reduced, describes effective interventions, and outlines a national strategy to increase the adoption of healthy behaviors, and cancer prevention and early detection interventions.

"The nation needs new strategies to prevent cancer and, when cancer occurs, to catch it at its earliest stages," the report said.

Recommendations of the report:

1. The U.S. Congress and state legislatures should enact and provide funding for enforcement of laws to substantially reduce and ultimately eliminate the adverse public health consequences of tobacco use and exposure.

2. A national strategy should be developed and coordinated by the U.S. Department of Health and Human Services to address the epidemic of obesity, unhealthy diet, and physical inactivity in America, which are all significant risk factors for cancer and other diseases. Effective interventions need to be identified and broadly applied to reduce cancer risk among the general population and among populations at higher risk.

3. Congress should provide sufficient appropriations to the Centers for Disease Control and Prevention to support innovative public and private partnerships to develop, implement, and evaluate comprehensive community-based programs in cancer prevention and early detection. Every state should have and implement a comprehensive cancer control plan.

4. Public and private insurers and providers should consider evidence-based cancer prevention and early detection services to be essential benefits and should provide coverage for them. These services at a minimum should include interventions recommended in the 2000 U.S. Public Health Service's clinical practice guideline on treating tobacco use and dependence, screening for breast cancer among women age 50 and older, screening for cervical cancer among all sexually active women with an intact cervix, and screening for colorectal cancer among adults age 50 and older.

THE CANCER LETTER

Member, Newsletter and Electronic Publishers Association

World Wide Web: http://www.cancerletter.com

Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg
Editorial Assistant: Shelley Whitmore Wolfe

Editorial: 202-362-1809 Fax: 202-318-4030
PO Box 9905, Washington DC 20016
E-mail: news@cancerletter.com

Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
E-mail: info@cancerletter.com

Subscription $305 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd

5. Congress should increase support for programs that provide primary care to uninsured and low-income people (Community and Migrant Health Centers and family planning programs of Title X of the Public Health Service Act). These programs increase the use of cancer prevention and early detection services among medically underserved populations.

6. Support for the CDC's National Breast and Cervical Cancer Early Detection Program should be increased so that the program can reach all uninsured women using innovative delivery strategies. Support is also needed for a similar program at the CDC to provide screening for colorectal cancer for uninsured and low-income men and women.

7. HHS should complete a comprehensive review to assess whether evidence-based prevention services are being offered and successfully delivered in federal health programs.

8. Programs are needed for health care providers to improve their education and training, monitor their adherence to evidence-based guidelines, and enhance their practice environments to support their provision of cancer prevention and early detection services.

9. Congress should provide sufficient support to HHS for the U.S. Preventive Services Task Force and the U.S. Task Force on Community Preventive Services to conduct timely assessments of the benefits, harms, and costs associated with screening tests and other preventive interventions. Summaries of recommendations should be made widely available to the public, health care providers, and state and local public health officials and policy makers.

10. Public and private organizations (e.g., the National Cancer Institute, the American Cancer Society) should take steps to improve the public's understanding of cancer prevention and early detection with a focus on promoting healthy lifestyles and informed decision making about health behaviors and cancer screening.

11. Public and private initiatives to reduce disparities in the cancer burden (e.g., initiatives of NCI and ACS) should be supported.

12. Public and private sponsors of research should expand their support of applied behavioral research and how best to disseminate evidence-based prevention interventions.

The policy board's report is available for for purchase or for reading online at no charge at http://search.nap.edu/books/0309082544/html/.

NCI Budget:

NCI To Fund 122 More Grants Under FY2004 Budget Proposal

NCI funding for research project grants would increase by 4.4 percent, or $91.92 million, under the Bush Administration's proposed $4.77 billion budget for the Institute in fiscal year 2004.

Under the budget proposal submitted to Congress last month, NCI would receive a 3.5 percent increase, or $162 million, over the FY 2003 budget of $4.608 billion.

The increase would allow the Institute to fund 4,902 research project grants, an increase of 122 grants over the FY 2003 number of 4,780, NCI Chief Financial Officer John Hartinger said to the National Cancer Advisory Board at its Feb. 11 meeting.

The average payment to RPGs, currently at $414,500, would increase by 1.9 percent, or nearly $8,000, to $422,400.

The RPG "success rate," the number of competing applications funded divided by the total number of competing applications reviewed, is expected to decrease by 1.7 percent, due to the continued increase in the number of grant applications that NCI has been receiving, Hartinger said.

In FY 2002, NCI reviewed 4,588 competing applications and funded 1,192 at a cost of $408.9 million, for a 26 percent success rate. In FY 2003, NCI expects to receive 5,006 competing applications and fund 1,346, at a cost of $492.6 million, for a 26.9 percent success rate. In FY 2004, the Institute expects to receive 5,405 competing applications and fund 1,361, at a cost of $509 million, for a success rate of 25.2 percent.

The "payline" for investigator-initiated (R01) grants also would fall from the current 20th percentile to the 18th percentile. Again, the decrease is due to the increasing number of applications NCI expects to receive, Hartinger said.

More Money, Grants, Competition

"We have worked hard to continue to fund investigator-initiated research," NCI Director Andrew von Eschenbach said to the NCAB. "It is the engine that drives discovery. The number of investigators continues to grow."

NCAB Chairman John Niederhuber, professor of surgery, University of Wisconsin, said declines in the success rate and paylines tend to negatively affect how young investigators view their chances of winning

a grant. "They don't focus on the fact that there are more grants and more money, but only that there is more competition," he said.

Von Eschenbach said young investigators tend to receive support from "other revenue streams." The R01 success rate "is not the only milestone for defining success," he said.

In addition to the RPGs, NCI funding plans under the proposed FY 2004 budget include:

—Cancer Centers and other specialized centers: $280.2 million, an increase of $11.1 million, or 4.1 percent, over the current year's funding of $269.1 million.

—Specialized Programs of Research Excellence: $131.7 million, an increase of $8.6 million, or 7 percent, over this year's $123 million.

—Research Career Program: $66.8 million, an increase of $2.2 million, or 3.5 percent, over this year's $64.5 million.

—Cancer Education Program: $30.2 million, an increase of $1 million, or 3.4 percent, over this year's $29.2 million.

—Clinical Cooperative Groups: $180.3 million, an increase of $6 million, or 3.4 percent, over this year's $174.3 million.

—National Research Service Awards: $75 million, an increase of $1.7 million, or 2.4 percent, over this year's $73.2 million.

—Research and Development Contracts: $329.9 million, an increase of $13.5 million, or 4.3 percent, over this year's $316.4 million.

—Intramural Research: $707 million, an increase of $12.7 million, or 1.8 percent, over this year's $694.2 million.

—Research Management and Support: $170 million, an increase of $3 million, or 1.8 percent, over this year's $167.7 million.

—Cancer Prevention and Control: $551.7 million, an increase of $12 million, or 2.2 percent, over this year's $539.7 million.

—Construction: No funding, a decrease of $5 million from this year's budget.

According to the NCI "Congressional Justification," NCI will have 51 fewer full-time equivalent employees (FTEs), 3,090, compared to 3,141 in FY 2003, under the Administration's budget proposal.

The NCI Center for Cancer Research will lose 23 FTEs; the Office of the Director will lose 12; the Division of Cancer Treatment and Diagnosis will lose four; the Division of Cancer Control and Population Sciences and Division of Cancer Epidemiology and Genetics will each lose three; the Division of Extramural Activities and the Division of Cancer Prevention will each lose two; and the Division of Cancer Biology will lose one.

The Congressional Justification is available at http://www3.cancer.gov/admin/fmb/2004cj.pdf.

* * *

The NCI budget has increased by $1.65 billion, or 65 percent, since FY 1998, according to the Institute's "Fiscal Year 2002 Annual Report," given to NCAB members at the board's Feb. 11 meeting.

The annual report was requested by NCAB, and provides information on the distribution of the NCI budget at the end of each year.

Fund available to NCI in FY 2002 totaled more than $4.176 billion, an increase of 11 percent, or $423 million, over the previous year.

According to the report, 60 percent of the NCI budget was allocated for research grants. The number of RPGs funded grew to 4,976. For the third year in a row, R01 grants were funded to the 22nd percentile.

NCI Programs:

Advisors Renew CCOP, EDRN; OK Physical Activity Program

The NCI Community Clinical Oncology Program, begun 20 years ago to bring the benefits of clinical research to cancer patients where they live, was approved for another round of funding by NCI advisors earlier this month.

There was no question that the Board of Scientific Advisors would approve the concept for the annual CCOP Request for Applications at the board's March 3 meeting. The popular program has become well-entrenched in the Institute for accruing patients to cancer treatment and prevention trials.

The BSA also approved in concept the renewal of the Minority-Based CCOPs, as well as Early Detection Research Network, the Pediatric Brain Tumor Consortium, and an new concept for Mechanisms of Physical Activity Behavior Change, a grant program that would support studies that further the understanding of how physical activity interventions work.

The CCOP program involves 4,037 physicians, of which 2,505 accrual trial participants, while 1,532 physicians refer trial participants.

In fiscal year 2002, NCI spent $91.3 million on the CCOP program. That included $32.8 million for

50 CCOPs in 31 states; $4.6 million for 11 Minority-Based CCOPs in eight states, Washington, DC, and Puerto Rico; $14.1 million for 12 research bases at seven cooperative groups and five cancer centers; and $2.9 million for prevention members.

NCI also provided CCOPs with $15.8 million for the selenium and vitamin E (SELECT) trial, $13.9 million for the study of tamoxifen and raloxifene (STAR), and $7.2 million for the prostate cancer prevention trial (PCPT).

In FY 2003, NCI plans to fund two new research bases.

Excerps of the concept statements follow:

Community Clinical Oncology Program. RFA, cooperative agreement, first year set-aside $9.5 million, 15 awards, three to five years, estimated total cost $44.3 million. Program director: Lori Minasian, chief of the Community Oncology and Prevention Trials Research Group, Division of Cancer Prevention.

The CCOP network was initiated in 1983 to bring the benefits of clinical research to cancer patients in their own communities by providing support for community oncology physicians to enter patients onto NCI-approved treatment research protocols and build a network for future prevention and control trials. In the first three years, 62 community programs in 34 states were funded and accrued 14,000 patients to NCI-approved treatment clinical trials.

One-third of all patients accrued to NCI-approved cancer treatment trials are done so at these CCOP sites. Since its inception, CCOPs have accrued over 92,500 patients to NCI treatment trials. The second CCOP RFA, issued in 1986, expanded the focus to include cancer prevention and control research based on the rationale that the multi-institutional clinical trials model essential for testing new treatment regimens is also central for conducting large-scale cancer prevention and control trials.

With both CCOP I in 1983 and CCOP II in 1986, a prospective evaluation of the program was conducted. The first evaluation demonstrated that community physicians could participate in NCI-sponsored treatment trials and that their participation accelerated the adoption of new treatment regimens in the community. The second evaluation demonstrated that cancer control could be integrated into the program. In 1989, the Board of Scientific Counselors approved CCOP as an ongoing program with an annual release date for the RFA and staggered lengths of award. This means that each year the RFA is released, one-quarter to one-third of the program undergoes competitive review. It also provides an opportunity for new programs to apply.

CCOP also funds research bases to design, develop, and conduct cancer prevention and control clinical trials. The member and affiliate institutions of the research bases are funded to participate in this research as well.

The CCOP network has matured over the years into a significant vehicle for conducing large prevention trials. The network successfully implemented four large-scale prevention clinical trials. The results of the breast cancer prevention trial published in 1998 showed that women at increased risk for developing breast cancer have a 49 percent reduction in the development of the disease with five years on tamoxifen. The other three large-scale prevention trials include the prostate cancer prevention trial with finasteride, for which results are expected in 2004, the study of tamoxifen and raloxifene in the prevention of breast cancer, and the selenium and vitamin E trial in the prevention of prostate cancer. Over 66,000 patients and persons at risk have been accrued to cancer prevention and control clinical trials by this network.

Reissuing the CCOP RFA is crucial to preserving the integrity of this program, since approximately one-third of the CCOPs are due to submit competing renewal applications in the summer of 2003. Delayed funding of these grantees would severely disrupt accrual to NCI-sponsored protocols at these sites, and have a major impact on the conduct of the large prevention trials.

Minority-Based Community Clinical Oncology Program. RFA, cooperative agreement, first year set-aside $1.9 million, five awards, three to five years, estimated total cost $8.7 million. Program director: Worta McCaskill-Stevens.

The Minority-Based CCOP began in the fall of 1990. Eligible applicants must demonstrate a catchment area that has more than 40 percent minority patients. University hospitals are eligible to become MBCCOPs. In 2002, there are 11 programs in eight states, the District of Columbia, and Puerto Rico, involving approximately 40 hospitals and more than 470 physicians. These MBCCOPs contribute more than 10 percent of all minority accrual to NCI-sponsored cancer treatment trials. This is the only competitive peer-reviewed mechanism with a concentrated focus on minority accrual to NCI-sponsored clinical trials.

Minority-Based CCOPs will: 1) provide support for expanding clinical research in minority community settings; 2) bring the advantages of state-of-the-art treatment and cancer prevention and control research to minority individuals in their own communities; 3) increase the involvement of primary health care providers and other specialists in cancer prevention and control studies; 4) establish an operational base for extending cancer prevention and control and reducing cancer incidence, morbidity, and mortality in minority populations; and 5) examine selected issues in Minority-Based CCOP performance (e.g., patient recruitment, accrual, eligibility).

Early Detection Research Network. RFA, cooperative agreement, first year set-aside $13 million, 30 awards, five to six years, estimated total cost$173 million. Program director: Sudhir Srivastava, Cancer Biomarkers Research Group, Division of Cancer Prevention.

NCI began EDRN in April 2000. The network is the nation's premier program providing systematic

identification, development, and initial validation of the novel biomarkers for early stages of cancer pathogenesis. The network has produced a system for evaluating biomarkers as tools to clinically detect cancer before symptoms appear, and to identify people at risk (www.cancer.gov/edrn).

The EDRN was conceived on the premise that a "vertical" approach to biomarker research—that is, an established, integrated, multidisciplinary environment—would facilitate collaboration among technology developers, basic scientists, clinicians, epidemiologists, biostatisticians, and other health professionals, and therefore would expedite efficacious clinical applications of the molecular knowledge that has burgeoned in recent years.

The network includes 18 Biomarkers Development Laboratories, three Biomarkers Validation Laboratories, nine Clinical and Epidemiologic Centers, and a Data Management and Coordinating Center.

Four federal agencies participate in EDRN through interagency agreements: National Institute of Standards and Technology, which serves as a validation laboratory; Centers for Disease Control and Prevention, which serves as a clinical and epidemiologic center; Food and Drug Administration; and Jet Propulsion Laboratory, NASA, provides the informatics support.

EDRN extends collaborative opportunities to those not initially funded by instituting an Associate Membership Program. The Associate Members are non-network investigators who propose collaborative studies within the scope and objectives of the network and often contribute by sharing available technologies, specimens, high-risk registries and cohorts, and other resources.

The total cost of $173 million spread over seven years is to be split to fund Biomarkers Development Laboratories (up to 18 laboratories, $7 million), Biomarkers Validation Laboratories (up to three laboratories, $2 million), Clinical and Epidemiologic Centers (up to eight centers, $7 million), and one Data Management and Coordinating Center ($2 million). $6 million will be set aside as core funds to the Steering Committee to support the Associate Membership Program, informatics, and validation studies with investigators within and outside the network on a competitive basis. The recompetition will begin in FY 2004 with the reissuance of the RFA with three receipt dates for the BDLs. Other RFAS will follow in FY05.

Mechanisms of Physical Activity Behavior Change. Concept for a new RFA, first year set-aside $1.75 million, six to 10 awards, two to five years, total estimated cost $8.75 million. Program director: Louise Masse, Division of Cancer Control and Population Sciences.

The purpose of this RFA is to support studies that further the understanding of how physical activity interventions work. Specifically, the focus is in supporting studies that elucidate the causal pathways that lead to physical activity behavior change. Studies that consider the psychological, environmental, and physiological factors that influence the mechanisms of physical activity behavior change are of interest. The physiological and psychosocial influences that are affected by disease status/cancer diagnosis are of particular interest to NCI (e.g., weight change, obesity, shift in muscle and fat mass, physical activity capacity, resting metabolic rate, hormonal change, immune functions, depression, anxiety, and quality of life). The proposed RFA will utilize both the R01 and R21 funding mechanisms.

All applications should explicitly state apriori the underlying assumptions tested, even if the project uses theories to study the causal pathways that lead to physical activity behavior change. The RFA does not require that a given theory or model be tested, but it requires that when a theory or model is employed, all relevant constructs from these theories/models be included. The RFA is not interested in studies that assess the efficacy of a "kitchen sink intervention," even if the intervention used theories in its development. NCI is particularly interested in understanding how physiological and psychological factors interact to influence the causal pathways of physical activity. All studies should focus on understanding these influences. In addition, contextual variables should be included to control for environmental influences by either manipulating these influences or accounting for their effects (i.e., statistically or in the design of the study).

Pediatric Brain Tumor Consortium. RFA, cooperative agreement, first year set-aside $2.5 million, one award, five years, estimated total cost $12.75 million. Program director: Malcolm Smith, Division of Cancer Treatment and Diagnosis.

This RFA is intended to continue support for the Pediatric Brain Tumor Consortium, consisting of 10 institutions in the U.S. The consortium's activities are coordinated by the PBTC Operations and Biostatistics Center at St. Jude Children's Research Hospital. The PBTC has made substantial progress since its first protocol concept was approved by CTEP on Oct. 12, 1999. The PBTC has reviewed 31 protocol concept proposals through Nov. 1, 2002, and 10 of these proposals have been advanced as therapeutic protocols, with one additional protocol still under development. One concept proposal was referred to the Children's Oncology Group and has been approved for further development as a COG groupwide phase II study. Five correlative biology studies have been opened. The first patient enrolled on a PBTC protocol on Feb. 26, 2000, and the total enrollment on PBTC therapeutic studies through 2002 is 210. During the most recent seven quarters in which accrual to PBTC studies has plateaued, accrual has averaged 100 patients per year, meeting the RFA-prescribed accrual target.

In the coming five-year funding period, the PBTC will continue spearheading research efforts to identify more effective local control methods for children with high-

grade gliomas and other aggressive pediatric brain tumors. The PBTC will also continue research to identify and develop new agents for the treatment and/or prevention of neoplastic meningitis resulting from primary brain tumors and from non-CNS tumors. Evaluating anti-angiogenesis agents will remain a focus for the PBTC, as evidenced by a study of the alpha(V)beta(3) integrin antagonist EMD-121974 that will open for enrollment in 2003.

The letter RFA will solicit single application from the PBTC. The consortium should have approximately 10 member institutions, an increase of one above the number of member institutions during the first 3.5 years of the PBTC award. This number of institutions should allow the PBTC to complete approximately three to four trials per year and to enroll 100-120 patients.

The PBTC will be expected to obtain additional funds from other sources to supplement those provided by NCI.

Letters to the Editor:

Advocate Says ODAC Member Shows "Disdain" For Patients

To the Editor:

In the Feb 21 issue of **The Cancer Letter**, Otis Brawley is quoted in a story regarding the ODAC open-mike policy as saying: "Unfortunately, many of the people we have heard over the past year at ODAC default on their responsibility to stay informed," Brawley said. "For example, at the most recent meeting, a representative for a major prostate cancer advocacy group interpreted two-year data as an indication that the drug he was advocating was associated with two years of progression-free survival. Even the sponsors were laughing at this."

His comments only serve to reflect the disrespect and disdain that ODAC panel members such as Brawley show to those without a medical degree, including those from the patient community. The arrogance of his comments only serve to highlight the situation that Ms. Delaney so courageously brought to your attention.

As the person to whom Brawley undoubtedly referred, I take exception to his mischaracterization of my response to a question he posed at the Dec. 18, 2002, ODAC hearing on Casodex. My presentation, following several hours of presentation of all the data, focused on informed patient choice.

Nowhere in my presentation did I misinterpret the data continuum, which incidentally was significantly more than two-year data. My statement, "perhaps a two-year disease progression-free life," came only in response to a question posed to me by Brawley that he did not even allow to be answered without interruption.

I also did not misinterpret or argue the specific point of two years of progression-free disease. Since I was referring to the data continuum presented, a specific assignment of disease-free progression cannot be established. What is apparent from these data, however, is that the proportion of patients progressing at any particular point in time for each of the cohorts presented was significantly less with Casodex 150mg than with placebo. By simple recall of the graphs of the data presented prior to my comments (I did not have the luxury of having the data before me during his interrogation), there was a fairly consistent 1 to 2-year difference in the time to reach any particular proportion of patients progressing. For example, in reviewing progression in high-risk RT patients, at three years (a reasonable point which most if not all enrolled patients had safely passed so data would not fluctuate) approximately 15 percent of patients on the Casodex arm had progressed. That same cumulative plateau was reached by those on the placebo arm in only 1-1.5 years, a significant difference which my unaided recall indicated approached 2 years. My recall and response correctly interpreted this fact and also reflected my understanding that the data presented were a continuum of experience. My response, following Brawley's interruption of my answer, also reflected such an understanding when I stated, "It may be one year, it may be two years, it may be three months. . . . There does appear even in the FDA analysis to be a benefit in time to progression."

Perhaps if Brawley had himself reviewed the data presented and listened to what was being said at the time he would have shown a respect for the process—and the people—that is due. The answer to his initial challenge to me was clearly lost on him as he perhaps attempted to illustrate his intellectual superiority to a 'mere mortal'. He should have known that without approval and appropriate labeling of this drug, patients who are being given Casodex 150mg as monotherapy will not be fully informed of the potential risks and benefits of such a treatment option.

While I am admittedly not a clinical professional, I do interact with patients on a daily basis. I do listen to them and I and many of my colleagues and associates do keep informed on progress being made in the fight against prostate cancer. For this reason I am offended at Brawley's assertion that "many of the people we have heard over the past year at ODAC default on their responsibility to stay informed." In

fact, it is my experience that many in the patient community are unfortunately better informed about their disease than those that are charged with their care. If a default on responsibility is to be charged, it should be on the part of practicing physicians and ivory tower academicians who are woefully unprepared to provide the level of care and compassion necessary to meet patient needs.

Rather than trying to find ways to trip up and belittle an open-mike presenter, perhaps ODAC members and the FDA should focus on the larger picture—protecting the rights of patients and their personal caregivers to be afforded access to and fully informed about potential therapies to increase both the length and the quality of their life. Unlike Brawley, I recall no laughter in the room that day. To those patients and others sitting with me in the audience at least, this was a serious discussion of utmost importance to all too many men suffering from prostate cancer.

Perhaps participants such as Brawley should be required to go back to the elementary school and the nun he cites in his quote for a refresher course in respect before being invited to participate in another ODAC panel.

John Page

President and CEO, Us Too! International Prostate Cancer Education and Support, Downers Grove, IL

ODAC Member Brawley Responds

To the Editor:

I have reviewed the transcript of the ODAC meeting available at http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3916T2.htm and stand by my initial statements. It is my belief that being an advocate does not give one license to selectively interpret, misinterpret, or exaggerate data without challenge, especially data from a company that supports the advocate's organization. Mr. Page's letter to the editor is further proof of my point, as it appears he still does not understand his misinterpretations. Advocates, like physicians, have an obligation to understand and not exaggerate the scientific data when they speak to the public.

I am not against public comment at FDA Advisory Committee meetings, but I see no reason for FDA officials or ODAC members to have to tolerate advocates who misinterpret data, do not understand their misinterpretations and then make their point in less than collegial fashion. This tends to be more of a problem from a small group of advocates and not all.

In his statement to ODAC, to his credit, Mr. Page declared his organization receives funding from the sponsor of the drug being considered. He then apologized for "being aggressive" in his talk and declared that he had some understanding of statistics and that he had had access to the data for nearly a year. He then called for patients to be informed, noting that there is an "NIH mandate that a patient be responsible for his or her care." He goes on to blur a number of different response criteria, quote retrospective subset analysis without caveat, and declare that data show "there is substantial benefit with little risk." After he finished, I did ask the chair for permission to ask questions about his statement. I never interrupted his prepared statement to the committee. I did say "really" during his astounding answer to a question. Perhaps, I am an ODAC member being criticized for listening to an advocate.

Mr. Page in his remarks, before and after my question, exaggerated the positive affect of the treatment and ignored the negative effects. His estimates of efficacy are far greater than the claims of the drug sponsor. The drug's sponsor presented data from three randomized trials. They found no significant differences in treatment outcomes among those on the drug and control arms in the only trial enrolling Americans. Nearly one-third of men dropped out of the treatment arm of that study due to side-effects.

Many of us in the scientific community cherish and welcome conversation and work with advocates. I have personally benefited from the support of and work with advocates. Having said that, a few very loud advocates need to realize that the overwhelming majority of us in medicine and even FDA officials are as anxious to find effective treatments for disease as they are.

We all serve patients best by being truthful to the data. It is vitally important not to misinterpret or exaggerate scientific data. Scientific fantasy benefits few, and those few are rarely patients. While I do not know if the NIH has "mandated" informed decision making, as Mr. Page stated, I strongly feel it is important that patients be informed. I also believe patients should be informed with truthful, accurate information in the proper context.

Otis Brawley

Director, Georgia Cancer Center; Associate Director for Cancer Control, Winship Cancer Institute; Professor of Medicine, Oncology, & Epidemiology, Emory University

Copying Policy for The Cancer Letter Interactive

The software that comes with your issue allows you to make a printout, intended for your own personal use. Because we cannot control what you do with the printout, we would like to remind you that routine cover-to-cover photocopying of The Cancer Letter Interactive is theft of intellectual property and is a crime under U.S. and international law.

Here are guidelines we advise our subscribers to follow regarding photocopying or distribution of the copyrighted material in The Cancer Letter Inc. publications in compliance with the U.S. Copyright Act:

What you can do:

--Route the printout of the newsletter to anyone in your office.

--Copy, on an occasional basis, a single story or article and send it to colleagues.

--Consider purchasing multiple subscriptions. Contact us for information on multiple subscription discounts.

What you can't do without prior permission:

--Make copies of an entire issue of the newsletter. The law forbids cover-to-cover photocopying.

--Routinely copy and distribute portions of the newsletter.

--Republish or repackage the contents of the newsletter.

We can provide reprints for nominal fees. If you have any questions or comments regarding photocopying, please contact Publisher Kirsten Boyd Goldberg, phone: 202-362-1809, email: kirsten@cancerletter.com

We welcome the opportunity to speak to you regarding your information needs.

Click Here for
Photocopying Guidelines