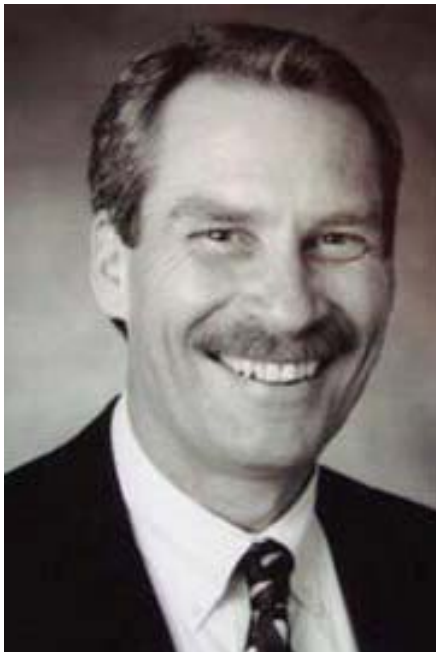
Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

December 2004

THOMAS N. KIRK JOINS *US TOO* AS NEW PRESIDENT/CEO

In the September 2004 HotSheet, Us TOO International announced that its President and CEO, John A. Page, after a successful four years with Us TOO, would be leaving this fall to pursue other interests and spend more time with his family.



THOMAS N. KIRK

After a 3-month search process, the *Us TOO* Board of Directors is happy to announce that Thomas Kirk will become President and CEO of *Us TOO* International Prostate Cancer Education and Support Network in mid-November. Tom brings over 30 years of experience as a family service leader to his new role and a personal interest in *US TOO* because his father-in-law lost his battle with prostate cancer many years ago.

"We are very much looking forward to our relationship with Tom," says Jo Ann Hardy, Secretary of the Board of Directors and Chair of the CEO Search Committee. "The breadth of his professional experience, his compassion and his understanding of the challenges faced by patient focused organizations such as ours, will help us continue to develop and live out our mission and strategic plan for the future."

He brings expertise in the care issues of an aging population having worked most recently in memory

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NEW *US TOO* BONE HEALTH INFORMATION & PROGRAM ANNOUNCED

As part of our continuing mission to provide strong, patient-focused, educational content and information, *Us TOO* is producing a bone health brochure and educational program. "Bone health is a serious issue that should not be overlooked, especially when you are a prostate cancer patient," declared Russ Gould, Vice Chairman of the *Us TOO* Board of Directors.

The brochure, to be first distributed to *Us TOO* Chapters in mid-December 2004, will focus on the following topics: the relationship between bone health and prostate cancer, background on bone function and the renewal process, steps to maintain healthy bones, bone loss risk factors, signs of bone metastases and advancing prostate cancer, and treatment options. The information will also be available on the *Us TOO* web site (www.ustoo.org) as early as mid-November.

A bone health educational program is also being planned, which will be

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US TOO PUBLICATIONS

In addition to the Hot Sheet, ***US TOO*** also publishes a FREE e-mail based news service providing updates on the latest prostate cancer related news. To subscribe or link to the archives, simply visit the ***Us TOO*** website www.ustoo.org.

Items contained in Us TOO publications are obtained from various news sources and edited for inclusion. Where available, a point-of-contact is provided

All references to persons, companies, products or services are provided for information only, and are not endorsements. Readers should conduct their own research into any person, company, product or service, and consult with their loved ones and personal physician before deciding upon **any** course of action.

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AstraZeneca

THOMAS KIRK

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support programming with Mather Lifeways in Evanston, IL and Belmont Corporation headquartered in Houston, TX. He also served as the Vice President of Operations for Garden Terrace Associates, a Life Care Centers of America retirement and long-term care company headquartered in Cleveland, TN where he managed a series of Alzheimer's disease Centers of Excellence.

Mr. Kirk worked for more than 13 years for the National Alzheimer's Association where he served as the Vice President of Patient, Family and Education Services, the Association's first Director of Patient and Family Services and as a National Field Representative working in the six-state Midwestern Region.

He played an active role in the growth and development of the Alzheimer's Association chapter network, led the Association's efforts in national demonstration programs, developed national Care Guidelines and led development of education and training materials for professional and family caregivers.

Tom was primary staff to the Board of Director's Program Committee and a member of the Association's Senior Management Team. He was involved in strategic planning issues such as under-served populations, grew the Association's annual National Education Conference, developed new collaborations, such as the national demonstration project on Managed Care, and developed an international education collaboration with the Research Foundation for Aged People's Health Science in Tokyo, Japan.

Tom joined the staff of the National Alzheimer's Association after extensive experience at the community level in family service development and delivery in his home state of Wisconsin. He worked for more than 12 years at Family Service Association in Northeastern Wisconsin, a large multi-service community agency, where he held key positions including Senior Program Director managing programs such as the Association's 24-hour Crisis Intervention Center and its outpatient family therapy programs. His in family and men's issues led him to head collaborative outreach programs for Vietnam veterans and their families, youth and under-served minority populations. He was serving as Interim Executive Director when he left to join the Alzheimer's Association national office.

Prior to receiving his graduate degree, he also worked for over five years in several community volunteer and peer-support organizations and in county and state government agencies as a Director and service provider. He has also been an active advocate and spokesperson and served on a variety of grant review and advisory committees for State and Federal government agencies, professional membership organizations and nonprofit Boards throughout his career.

Mr. Kirk holds a Master of Science degree from the School of Social Work at the University of Wisconsin-Madison where he focused on Planning and Administration.

Lew Musgrove, Chairman of the Board, stated, "Tom is the right person at the right time in the growth of US TOO. As we plan 2005 and beyond, he has the capacity and knowledge to allow us to take that giant step forward as the "go to" Prostate Cancer Support Organization in the world."

Tom and his wife Margaret, share a blended family with three grown children and four grandchildren.

NEW NCCN GUIDELINES FOR PROSTATE CANCER SCREENING

The National Comprehensive Cancer Network (NCCN) Prostate Cancer Early Detection Clinical Practice Guidelines in Oncology provide a set of sequential recommendations detailing a screening and subsequent work-up strategy for maximizing the detection of prostate cancer in an organ-confined state and attempting to minimize unnecessary procedures. These guidelines were developed for men who have elected to participate in prostate cancer screening; the controversy over whether to screen is not addressed. The 2004 algorithm contains several major changes including:

- A strategy for identifying high-risk men who should begin screening at age 40
- Consideration of lowering the PSA threshold for biopsy to 2.5 ng/mL
- Evaluation of complexed PSA in prostate cancer screening
- Recommendations for work-up of biopsy findings, suggestive of cancer.

A total PSA of 4.0 ng/mL has traditionally been used as the threshold for consideration of a prostate biopsy, recognizing that 30% to 35% of men in the 4 to 10 ng/mL range will be found to have cancer. Subsequent studies in men having PSA levels ranging from 2.5 - 4.0 ng/mL showed that a substantial number of men in this group had cancer.[1,2]

What is significant in these studies is that the cancers found in this population were clinically significant based on tumor volume and Gleason score and most were organ-confined. Importantly, an overdiagnosis of clinically insignificant or unimportant tumors did not occur.

Researchers have estimated that lowering the threshold to 2.5 ng/mL would double the rate of detecting cancer in men younger than 60 years old with little loss of specificity. For these reasons, the National Comprehensive Cancer Network (NCCN) approved new practice guidelines for screening and detecting prostate cancer, reducing the threshold for concern for total PSA from 4.0 ng/mL to 2.5 ng/mL.

Lowering the PSA threshold to 2.5 ng/mL has several caveats

- Approximately 75-80% of patients with a positive screening result ($\geq$ PSA 2.5 ng/mL) will not be found to have cancer on first biopsy (false positive). However, 10% of such patients may prove to have prostate cancer on subsequent biopsy.
- Based on limited data, approximately 20-25% of patients with a PSA < 4 ng/mL and a normal DRE have prostate cancer.
- Prostate cancer usually grows slowly, so some men with prostate cancer may die of something else before their cancer causes any trouble.
- Seventy to seventy-five percent of cancers that are treated are clinically significant. Methods to predict which men may harbor more aggressive cancers are not yet available.
- Complications of therapy for treatment of early stage prostate cancer.

NCCN also recommends that men choosing to begin PSA screening should consider obtaining a baseline value at age 40. Those whose PSA values are greater than the median value for men in this age group (0.6 ng/mL) should consider annual screening (whereas those with values below this value could consider foregoing annual screening. PSA velocity can be determined through serial PSA levels to help identify men at risk for harboring early prostate cancer.

Catalona WJ, Smith DS, Ornstein DK. JAMA 277:1452-1455, 1997.

Babaian RJ, Johnston DA, Naccarato W, et al. J Urol 165:757-760, 2001.

BONE HEALTH

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conducted in early 2005. Dates will be announced in the January *Hot-Sheet*, *NEWS You Can Use* e-newsletters, and on the *Us TOO* web site. The purpose of the brochure and program is to provide prostate cancer patients with an understanding of what is going on inside your bones, why men with prostate cancer need to be especially aware of bone loss risks, and what you and your doctor can do to make sure that you maintain good bone health.

Bill Blair, *Us TOO* Chairman of the Scientific Advisory Panel and advisor to the bone health content development project, stated, "The brochure is a clear roadmap on how to deal with skeletal changes that often occur to many men with prostate cancer, and what we can do to minimize the problems. The brochure lays out a plan of action that a patient can consult and follow so that they may take appropriate steps to prevent or delay the negative consequences, or seek out appropriate treatment. This is a most meaningful document for the prostate cancer community."

Funding for the program and materials come from Novartis Oncology, and is produced in cooperation with AFUD, the American Foundation for Urologic Disease .

ANNOUNCEMENTS

Us TOO held its annual Regional Directors meeting October 16 and 17 in Chicago, sponsored by Novartis. The meeting was a great success, giving Regional Directors from across the country an opportunity to share ideas and experiences. The meeting covered a variety of topics from roles and expectations, to starting new and helping existing chapters, as well as focusing on leadership skills.

We are still looking for Regional Directors in many areas. If you or someone you know would be interesting in helping, please contact headquarters.

NEW BREAKTHROUGH IN FIGHT AGAINST PROSTATE CANCER

Scientists in Oxford have discovered a new way to treat advanced prostate cancer, which could improve survival.. Cancer Research UK has found that blocking the action of a gene called IGF1R can make cancer cells more sensitive to radiotherapy and to certain chemotherapy.

Dr Val Macaulay, Cancer Research UK senior clinical research fellow at the Weatherall Institute of Molecular Medicine, said: "This is the first study to show that silencing the IGF1R gene can improve the effectiveness of treatments for prostate cancer. "I am excited at the possibility of conducting trials of IGF1R-inhibiting drugs with my own patients." Dr Macaulay said one of the most effective ways of treating prostate cancer is to starve it of the male hormone that feeds it..

But she said: "At some point these cancers always become hormone independent and this form of treatment ceases to work. Prostate cancer is also resistant to most chemotherapy so there is an urgent need for new ways to tackle the disease."

Professor Robert Souhami, director of policy and communication at Cancer Research UK, said many researchers were studying how to prevent cancer cells from spreading . He said: "IGF1R sustains many types of cancer cells, so blocking the gene could prove a powerful new way of treating tumors. This is early stage research, but holds great promise."

In July, the Oxford Mail reported that Oxfordshire's prostate cancer rate was almost 49 per cent above the national average. Mystery surrounds why the county's rate is so high, although experts say it could be because of the high number of health-conscious elderly men..

Newsquest, 25 October 2004

NEUROENDOCRINE DIFFERENTIATION EVALUATION RECOMMENDED IN PROSTATE CANCER

Neuroendocrine (NE) differentiation frequently occurs in common prostatic malignancies and has attracted increasing attention in contemporary prostate cancer research. This particular phenotype, however, usually escapes pathological and clinical detection in routine practice.

"The present review focuses on the biological properties of NE tumor cells that make them resistant to androgen deprivation and radiation therapy," wrote researchers in Germany. "NE cells produce a number of hormonal growth factors (e.g., serotonin) that may act through endocrine, paracrine, and autocrine mechanisms. Morphogenetic studies have identified intermediate phenotypes between the three basic cell types of the prostatic epithelium indicating their common origin from stem cells located in the basal cell layer," H. Bonkhoff and colleagues said.

According to the authors, "Virtually all prostatic adenocarcinomas show NE differentiation as defined by the most commonly used endocrine marker chromogranin A. Clinical studies suggest that the extent of NE differentiation increases with tumor progression and the development of androgen insensitivity.

"NE differentiation exclusively occurs in the GO phase of the cell cycle in which tumor cells are usually resistant to radiation therapy and cytotoxic drugs. In addition, NE tumor cells also escape programmed cell death. Even under androgen deprivation, only 0.16% of NE tumor cells show apoptotic activity. This indicates that the vast majority of NE tumor cells represent an immortal cell population in prostate cancer."

Although NE tumor cells do not proliferate," Bonkhoff continued, "they produce a number of NE growth factors with mitogenic properties that maintain cell proliferation in adjacent (exocrine) tumor cells through a paracrine mechanism. NE tumor cells consistently lack the androgen receptor and are androgen insensitive in all stages of the disease. They derive through a process of intermediate differentiation from exocrine tumor cells, the most prevalent phenotype in common prostatic adenocarcinoma."

Investigators concluded, "Elevated serum levels of chromogranin A in prostate cancer patients correlate with poor prognosis and are scarcely influenced by either androgen deprivation or chemotherapy. Looking for NE differentiation is recommended in the pathological and clinical evaluation of prostate cancer patients for whom radiation and androgen deprivation are therapeutic options."

Urologe A 43: 836, 2004

For additional information, contact H. Bonkhoff, Institute Pathology, Heilsbachstr 15, D-53123 Bonn, Germany. Contact Urologe at: Springer, 233 Spring St., New York, NY 10013 USA.

RADICAL RETROPUBIC PROSTATECTOMY: 10-YEAR FOLLOW-UP

Roehl and colleagues report the outcomes of a series of 3478 consecutive men who underwent radical retropubic prostatectomy (RRP) between May 1983 and February 2003.[1] All surgeries were performed by William J. Catalona, MD, Professor of Urology at Northwestern University in Chicago, author of the seminal paper on use of prostate-specific antigen (PSA) for prostate cancer screening published in The New England Journal of Medicine in 1991.[2] The current report updates previously reported 5- and 7-year results[3,4] with 10-year follow-up.

More than 60% of the patients in the series had preoperative serum PSA values between 4 and 10 ng/mL, about half had clinical stage T1c disease, and more than 70% had a Gleason score of 6 or 7 in the RRP specimen. Over 90% of the patients underwent a bilateral nerve-sparing procedure, while the remainder, with more clinically advanced disease, underwent unilateral, partial nerve sparing, or non-nerve-sparing procedures. The authors conducted a subset analysis comparing patient characteristics during the pre- PSA screening era (1983 to 1991) with patient characteristics in the PSA screening era (1992 to 2003).

Unequivocally, the data indicate that RRP produces favorable long-term survival results. And as expected, clinicopathologic parameters do correlate with treatment outcome. Multivariate analysis showed that PSA, clinical and pathologic stage, Gleason score, and PSA screening era individually predicted cancer progression after RRP. Being the largest single-surgeon series ever reported, the work represents the culmination of Dr. Catalona's 20 years of experience as one of the world's foremost prostate cancer surgeons, and defines the standard of care for almost all practicing surgeons. The data indicate a high success rate at a mean follow-up of 65 months: 10-year biochemical progression-free survival of 68%, a cancer-specific survival of 97%, and an overall survival of 83%. The 68% progression-free survival rate was somewhat lower than might be expected, although patients were being operated on in the pre-screening era, when they were generally diagnosed with more advanced-stage disease (35% had PSA > 10 ng/mL in the pre-screening era compared with only 15% in the post-screening era)

As expected, patients who underwent surgery in more recent years had a better outcome, undoubtedly the result of PSA testing. There is simply no other explanation. However, the controversy over screening remains; currently, the National Cancer Institute does not recommend screening for the reason that no randomized trials have proved that survival is extended by PSA screening. The current study, although not randomized, demonstrates extended biochemical progression-free survival with lower PSA levels compared with higher PSA levels. Actuarial 10-year biochemical progression-free probabilities were 91% for PSA < 2.6 ng/mL vs. 49% for PSA > 10.0 ng/mL. Interestingly, the 75% survival rate for individuals with PSAs between 4 and 10 was similar to those whose PSAs were between 2.5 and 4, suggesting that if PSA levels can be picked up before they reach 10 ng/mL, then patients still have a reasonably high probability of cure.

Another self-evident finding is that cancers with Gleason scores of 8 to 10 are bad cancers. Even so, the cure rates in these patients are still about 20% to 30%. We also need to be mindful of the fact that there are still people who develop very rapidly growing prostate cancers. All the screening in the world is not going to pick up their tumors any earlier. Another important issue is that the cure rate for patients with lymph node metastases, traditionally regarded as a poor prognostic indicator, is 15% and not zero.

In this series, race was not a significant prognostic factor, although the study was neither powered nor designed to detect such a difference. By contrast, PSA, clinical and pathologic stage, Gleason score, and PSA screening era individually predicted cancer progression after RRP. This finding serves to confirm what clinical experience has already taught us.

Reviewed by Nicholas J. Vogelzang, MD for UPDATE - Clinical Care Options™ for Oncology. 2003-2004 iMedOptions, LLC. 1894 Preston White Dr., Ste. 110, Reston, VA 20191-5433

1. Roehl KA, Han M, Ramos CG, et al. J Urol 172:910-4, 2004
2. Catalona WJ, Smith DS, Ratliff TL, et al. N Engl J Med 324:1156-61, 1991
3. Catalona WJ, Smith DS. J Urol 160:2428, 1998
4. Catalona WJ, Smith DS. J Urol. 152:1837, 1994

PUNGENT ONIONS MAKE POTENT CANCER FIGHTERS

Pungent onions may make you cry, but they may also help protect you against cancer, according to a new study. Researchers found strongly flavored onion varieties, such as New York Bold, Western Yellow, and shallots have the highest total antioxidant activity, which may enhance their ability to fight off cancer-causing cell damage.

Antioxidants, such as the phenolics and flavonoids found in fruits and vegetables, have been heralded as potential cancer fighters due to their ability to destroy free radicals that can damage cells and increase the risk of chronic diseases, such as cancer, heart disease, and diabetes.

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INFORMATION-SEEKING BEHAVIORS OF PROSTATE CANCER PATIENTS' PARTNERS STUDIED

Researchers from England studied information-seeking behaviors of partners of prostate cancer patients. C.E. Rees and coauthors wrote, "This pilot study explores in depth the information-seeking behaviors of partners of men with prostate cancer. Six men with prostate cancer and their partners participated in one mini focus group discussion or four couple interviews.

"Theme analysis by two independent analysts produced three related themes: partners' information-seeking behaviors; partners' information-avoiding behaviors; and the conflict between seeking and avoiding information." The authors noted, "The information-seeking behaviors of partners were individualistic, with some partners seeking voluminous information and others avoiding information.

"Partners sought information to help reduce their feelings of anxiety and uncertainty, to help them participate in the decision-making process, to help them care for their partner and to ensure that they had their information needs met."

"Partners avoided information to reduce their levels of fear and worry and to maintain a sense of normality. They failed to seek information from healthcare professionals because they felt disempowered and pressurized for time during patient-physician consultations" they added.

"The information-seeking behaviors of partners changed over time and across situations and their behaviors were sometimes different from those of their partners (the patients), with some partners exhibiting more information-seeking behavior than patients," they concluded.

Rees and colleagues published their study in Patient Education and Counseling (The information-seeking behaviors of partners of men with prostate cancer: a qualitative pilot study. Patient Educ Couns, 2004; 54(2): 179-185).

For more information, contact C.E. Rees, Institute Clinical Education, Peninsular Medical School, Tamar Science Pk, ITTC Bldg, Davey Rd., Plymouth PL6 8BX, Devon, England.

Publisher contact is: Elsevier Science Ireland Ltd., Bay 15, Shannon Industrial Estate CO, Clare, Ireland

PUNGENT ONIONS

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"No one knows yet how many daily servings of onions you'd have to eat to maximize protection against cancer, but our study suggests that people who are more health conscious might want to go with the stronger onions rather than the mild ones," says researcher Rui Hai Liu, MD, PhD, of Cornell University, in a news release.

In the study, researchers analyzed fresh, uncooked samples of 10 common onion varieties and shallots for their total antioxidant content and activity, as well as their ability to fight cancer growth in human cells.

Researchers found shallots had the greatest antioxidant content and activity, followed by Western Yellow, New York Bold, and Northern Red. Although shallots resemble onions, they are actually a different species, but were included in the analysis.

These same pungent onion varieties and shallots were also the most potent inhibitors of human cancer cells. Milder onion varieties, such as the Vidalia, had among the lowest antioxidant content and activity.

The results appear in the Nov. 3 issue of the *Journal of Agricultural and Food Chemistry*.

WebMD Medical News
22 October 2004

HORMONE THERAPY FOR RADIATION-TREATED PROSTATE CANCER

This multicenter, randomized trial by D'Amico and colleagues[1] adds to the body of knowledge indicating that early hormone therapy improves survival in patients with prostate cancer. The trial included 206 patients with localized prostate cancer receiving 3-dimensional conformal radiation therapy (3D-RT) and found that the addition of 6 months of androgen suppression therapy (AST) significantly improved overall survival. At a median follow-up of 4.52 years, the unadjusted hazard ratio for overall mortality was 2.07 (95% CI, 1.20 - 4.20), P = .04. In addition, AST decreased the frequency of prostate-specific antigen (PSA) failure (P < .001) and increased the time to disease progression (P = .002) without increasing toxicity.

These findings are important because they continue to show that early hormone therapy provides a survival advantage, thus supporting the current shift towards earlier treatment of the disease in the United States. Indeed, a recent longitudinal analysis of urologists indicated that the percentage of men receiving AST and RT for locally advanced prostate cancer has risen to nearly 50% from about 10% in the mid-1990s.[2]

By itself, the trial would not be sufficiently compelling, but it is consistent with other data that demonstrate the efficacy of AST in localized prostate cancer.[3-5] In addition, a series of Radiation Therapy Oncology Group (RTOG) trials[6,7] have demonstrated a clinical benefit when hormone therapy is added to radiation therapy in patients with higher Gleason scores and more advanced-stage disease. The only trial that failed to show superiority for early

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HORMONE THERAPY

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vs. delayed treatment was published by Schroder and colleagues.[8] This study suggests a nonsignificant advantage for early treatment; however, the wide confidence interval range from a 12% benefit in favor of delayed treatment to a 71% detriment for that approach, made interpretation difficult.

The current study is relatively small with a short median follow-up of 4.52 years. In addition, the P value of 0.04 that confers statistical significance to the AST arm's survival advantage is not robust. Nonetheless, a 10% difference in survival was observed with only 6 months of AST, without incurring additional toxicity. Thus, the cumulative data suggest that intermediate- and high-risk patients with T1/T2 prostate cancer, PSA > 10 ng/mL, and Gleason score of 7 should receive AST. The duration of AST and the specific risk groups to be treated need to be clarified. For example, men with a PSA > 20 ng/mL may require longer courses of AST. We have not, by any means, finished addressing these and other issues. Further studies may provide us with the information necessary to answer these questions.

Reviewed by Nicholas J. Vogelzang, MD for UPDATE - Clinical Care Options™ for Oncology. 2003-2004 iMedOptions, LLC. 1894 Preston White Dr., Ste. 110, Reston, VA 20191-5433

1. D'Amico AV, Manola J, Loffredo M, et al. JAMA 292:821-7, 2004
2. Cooperberg MR, Grossfeld GD, Lubeck DP, Carroll PR. J Natl Cancer Inst. 95:981-9, 2003.
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BOOK REVIEW

Wednesday at the Fluff 'n' Fold ~ A Caregiver's Oasis, by Elizabeth Cabalka. Healthy Insights Press. $14.95 (paper).

Elizabeth Cabalka does more than simply philosophize about the topic of caring for a loved one with cancer. She lived the experience. For three and one-half years she and her husband, Charles, lived with cancer. Charles experienced it in his body; Elizabeth experienced it in her soul. She remained by his side through treatments, tests, remission, recurrence and finally death, while striving to learn and grow from the lessons cancer offered.

When her husband was ill with the cancer that finally took his life, Elizabeth escaped from it all to an unlikely refuge—the local laundromat. While the machines cleaned and dried the laundry, she poured her thoughts and feelings into her journal. Eventually she wrote the first chapter of a book there and used the laundromat as its theme. The result is Wednesday at the Fluff 'n' Fold ~ A Caregiver's Oasis.

"More than anything, this book is about embracing life in the midst of death, and staying healthy in the midst of disease," said Cabalka. Elizabeth is a Minnesota author and professional speaker/facilitator who speaks to groups all over the USA.

Signed copies at a discount off the cover price are available from the publisher or author

* *Healthy Insights Press (320-274-2778)*

* *elizabeth@elizabethcabalka.com*

Unsigned books are available at the standard price from *www.amazon.com, www.barnesandnoble.com* and others.

ANTIOXIDANTS BLOCK PROSTATE CANCER IN TRANSGENIC MICE

Antioxidants appear to block prostate cancer in lady transgenic mice, according to a new study. "The development of chemopreventive agents against prostate cancer would benefit from conclusive evidence of their efficacy in animal models that emulate human disease," researchers in Canada report.

"To date there has been little in vivo evidence supporting their preventive capabilities. The 12T-10 Lady transgenic model spontaneously develops localized prostatic adenocarcinoma and neuroendocrine cancer followed by metastases, recapitulating the natural history of human prostate cancer in many respects," wrote V. Venkateswaran and colleagues, Sunnybrook & Women's College Health Science Center, Division Urology.

"Using male Lady version of the transgenic adenocarcinoma of the mouse prostate mice, we show that administration of antioxidants (vitamin E, selenium, and lycopene) in the diet dramatically inhibits prostate cancer development and increases the disease free survival."

"Treatment of animals with the antioxidants resulted in a 4-fold reduction in the incidence of prostate cancer compared with the untreated animals. Prostate cancer developed in 73.7% (14/19) and 100% (19/19) of the animals from the standard and high fat diet, respectively. In contrast, only 10.5% (2/19) and 15.8% (3/19; $P < 0.0001$) of the animals in the standard and high fat diets supplemented with antioxidants developed tumors. The micronutrients were well tolerated with no evidence of antioxidant-related toxicity. Histopathological analysis confirmed absence of cancer in the additive treated groups," they wrote.

"Immunohistochemistry demon-

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FDA ANNOUNCES MAJOR INITIATIVES FOR DIETARY SUPPLEMENTS

The Food and Drug Administration (FDA) announced three major regulatory initiatives designed to further implement the Dietary Supplement Health and Education Act of 1994 (DSHEA). These initiatives -- a regulatory strategy, an open public meeting, and a draft guidance document for industry -- are significant steps FDA has taken in the implementation of DSHEA.

"These initiatives refine the direction the agency is taking to regulate dietary supplements," said FDA Acting Commissioner Lester M. Crawford. "We now have a clear roadmap to share with the dietary supplement industry, while at the same time giving consumers a higher level of assurance about the safety of dietary supplement products and reliability of their labeling."

FDA intends to improve the transparency, predictability, and consistency of its scientific evaluations and regulatory actions to protect consumers against unsafe dietary supplements and dietary supplements making unauthorized, false, or misleading claims. The agency will continue its ongoing efforts of monitoring and evaluating product safety, ingredient safety, and product labeling, as well as ensuring product quality. FDA has published a Federal Register notice about the public meeting as well as two notices describing the other initiatives.

Another aspect to the strategy is ensuring product quality. This initiative addresses the need to establish industry-wide standards to help ensure that dietary supplements are manufactured consistently as to identity, purity, quality, strength, and composition. FDA will also continue to monitor and evaluate dietary supplement labeling and take enforcement action, as appropriate. This measure will include monitoring of labeling claims, including claims in accompanying literature and in Internet labeling.

FDA is soliciting comments from the public and industry on both the regulatory strategy and the topics to be discussed at the public meeting, which will be held on November 15, 2004. Written comments may be addressed to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 or electronically through the FDA website.

FDA News, 4 November 2004

ANTIOXIDANTS

(Continued from page 7)

strated a strong correlation between disease-free state and increased levels of the prognostic marker P27 (Kip1) and a marked decrease in proliferating cell, nuclear antigen expression." wrote V. Venkateswaran and colleagues.

The researchers concluded: "These observations provide support for the chemopreventive effect of these micronutrients and some clues as to their mechanism of action."

Venkateswaran and colleagues published their study in Cancer Research (Antioxidants block prostate cancer in Lady transgenic mice. Cancer Res 64: 5891-6, 2004).

For additional information, contact L. H. Klotz, Sunnybrook & Women's College Health Science Center, Division Urology, MG 408, 2075 Bayview Avenue, Toronto, ON M4N 3M5, Canada.

Publisher contact information for the journal Cancer Research is: American Association Cancer Research, 615 Chestnut St., 17th Floor, Philadelphia, PA 19106-4404, USA.