Andrew von Eschenbach, the director of the National Cancer Institute, who last week took on the added duties of acting Food and Drug Administration commissioner after the abrupt resignation of Commissioner Lester M. Crawford, said yesterday that he will temporarily step down from his day-to-day leadership of the cancer institute.

The Bush administration came under criticism from members of Congress and others in recent days for allowing the Texas urologist and longtime Bush family friend to take the reins at the FDA while he continued to run the cancer institute, given the many conflicts of interest the dual assignment engendered.

As interim FDA commissioner, for example, von Eschenbach has final authority over requests by the cancer institute to test experimental medications in people. The NCI also has many collaborative efforts underway with pharmaceutical companies whose economic fates are intimately tied to FDA decisions.

Von Eschenbach also faces potential conflict-of-interest issues because of his ongoing role as vice chairman of the board of C-Change, a nonprofit organization headed by George H.W. and Barbara Bush, according to yesterday's issue of the Cancer Letter, a Washington-based investigative newsletter. Others on that board include executives from Bristol-Myers Squibb Co. and Johnson & Johnson.

More generally, some watchdog groups had expressed concern that von Eschenbach -- a vocal supporter of faster drug approvals -- was the wrong person to take the helm of the FDA, which in the past year has suffered a crisis of confidence for its rapid approval of several drugs that subsequently had to be withdrawn from the market because of safety concerns.

In a memorandum sent to all FDA employees yesterday and later made public by the Department of Health and Human Services, von Eschenbach said HHS Secretary Mike Leavitt had asked John
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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 loved ones and personal physician before deciding on any course of action.

VON ESCHENBACH
(Continued from page 1)

Niederhuber to serve as "chief operating officer to handle day-to-day management at NCI." Von Eschenbach recently hired Niederhuber as deputy director for translational and clinical sciences at the cancer institute.

In his memo, von Eschenbach also said that "as a prudential matter," he will not participate in certain FDA matters in which the cancer institute is a party.

"I look forward to bringing my experience on the discovery side of medicine to the delivery side of medicine," he wrote, "making sure patients get the drugs and treatments they need as quickly and safely as possible."

Sen. Edward Kennedy (D-Mass.) said yesterday in a statement that von Eschenbach's decision to reduce his duties at NCI "does not go far enough. . . . FDA deserves a Commissioner who can commit completely to this important responsibility, and the National Cancer Institute deserves a full-time Director."

Sen. Barbara A. Mikulski (D-Md.) also expressed lingering dissatisfaction with the current state of affairs. "I look forward to the swift appointment of a full-time, permanent, competent FDA commissioner," she said in a statement.

Mystery continues to swirl around Crawford's sudden decision to resign as FDA commissioner. On Thursday, Kennedy and Sen. Mike Enzi (R-Wyo.) asked HHS Inspector General Daniel R. Levinson to look into Crawford's departure, including published allegations that he had failed to disclose financial conflicts of interest before he was confirmed to the post in July.

The Washington Post 1 October 2005

SEX DRUG SUBSIDIES TO PAY HURRICANE AID

Buying your own Viagra will become an act of altruism under a House-passed bill that pays for hurricane relief with federal funds now devoted to Medicare and Medicaid coverage for erectile dysfunction drugs.

Rep. Nathan Deal, R-Ga., sponsor of the bill, said the government would save $690 million over five years by prohibiting the two government health care programs from subsidizing prescriptions for sexual performance drugs.

The money will be used to provide $500 million in federal unemployment funds to hurricane-affected states to help them pay benefits to out-of-work people: $400 million to Louisiana, $85 million to Mississippi and $15 million to Alabama.

The bill also extends several health programs that assist low-income families nationwide.

Deal has previously backed legislation to end federal aid for impotence drugs, saying taxpayers should not be required to pay for drugs that do not determine life or death and are often used for recreational purposes.

Under Medicaid, the state-federal program for the poor, states are allowed to determine which drugs are medically necessary, and Deal said most states now consider Viagra and other erectile dysfunction drugs in that category.

A survey by The Associated Press earlier this year showed nearly 800 convicted sex offenders in 14 states, including Georgia, got erectile dysfunction drugs.

The Senate has also approved legislation to end federal funding for such drugs and the House earlier this year approved a similar amendment to a spending bill covering health programs. But no bill banning federal payments for the drugs has cleared Congress.

Associated Press, 6 October 2005
POSSIBLE NEW BIOMARKER FOR PROSTATE CANCER FOUND
Early Results Suggest It's More Accurate Than PSA

Summary:
Researchers say they have found a new marker for prostate cancer that may be better than a PSA test at finding the disease. The marker is a collection of antibodies that seem to be produced when prostate cancer is present. The researchers say the new marker could one day be used to help men and their doctors decide when a prostate biopsy is necessary. But more research will be needed to know for sure. The study appears in the New England Journal of Medicine (Vol. 353, pp. 1224-35, 2005).

Why it's important:
Prostate cancer is the most common cancer in US men, other than skin cancer. Each year more than 230,000 men develop the disease and more than 30,000 die from it. A blood test for PSA (prostate-specific antigen, a substance made only by the prostate gland) can find the disease early, but the test isn't always accurate. Some men with a normal PSA level may still have cancer, and some men with a high PSA may have a condition that isn't cancer. To know for sure, men have to get a prostate biopsy, a potentially painful and expensive procedure. Doctors hope to find markers that would be better at predicting whether a man has prostate cancer or not. That might spare some men from unnecessary biopsies.

"We don't yet know if our new findings will save lives, but there could be a major cost saving by decreasing the number of prostate biopsies performed each year," he added in a prepared statement.

What's already known:
Recent studies have shown that the body sometimes responds to cancer by revving up the immune system, which then makes antibodies to fight various substances produced by the tumor. If doctors can learn which antibodies are made to fight a particular type of cancer, they might be able to find the cancer earlier simply by testing the blood for those antibodies. This is a relatively new area of cancer research called "cancer immunomics."

How this study was done:
The researchers, led by a team at the University of Michigan Comprehensive Cancer Center, used blood samples from prostate cancer patients who had not yet been treated and from men who never had cancer. With sophisticated testing of these samples they narrowed the field of potential antibodies to a set of 22 that seemed to be present in the blood of prostate cancer patients, but not the other men. Then they tested this group of antibodies (the new marker) on more blood samples to see how accurately it could signal prostate cancer.

What was found:
This new marker performed better than the PSA test, identifying more cases of prostate cancer with fewer false-positive results. What's more, the new marker was better at finding cancers in samples from men whose PSA levels were between 4 and 10 ng/ml, a range where the standard PSA test gives uncertain results. Only about 25% of men with a PSA level in this range actually have prostate cancer.

"Initially we envision this new test could be used as a supplement to PSA," said senior study author Arul Chinnaiyan, MD, PhD, a pathology professor at the University of Michigan Medical School. "A physician might suggest a patient with an elevated PSA have this test before a biopsy to better determine whether it's a cancerous or benign condition. In the future, I think this could replace PSA."

The bottom line:
Although the study results are promising, other experts caution that one study is not enough to know for sure that this new marker will perform better than -- or even as well as -- the PSA test in the long run.

"There is a way to go before we can determine whether this particular test can be taken into the clinic as a simple, effective part of the screening program for prostate cancer," said Len Lichtenfeld, MD, deputy chief medical officer for the American Cancer Society. "Testing on a handful of patients may not translate to the same results when thousands or millions of men are being tested."

The new marker also cannot answer another crucial question: whether a man has aggressive prostate cancer that must be treated or slow-growing disease that does not need therapy. Doctors hope to find some marker that can tell them that, so they can spare men from unnecessary treatment that often has unwelcome side effects.

Yahoo! Health: Cancer News
6 October 2005
Key Republican lawmakers say the threat of the majority losing control of one or both houses in the upcoming mid-term elections, along with Bush's falling poll numbers, could convince the administration to delay or repeal implementation of the Medicare prescription drug benefit.

During a recent media briefing in Washington, D.C., Sen. John McCain (R-Ariz.) and Rep. Jeff Flake (R-Ariz.) argued that a potential backlash from seniors and other constituents over the Medicare Part D program could continue to hurt the president's poll numbers and cause Republicans to lose seats in the upcoming mid-term election. This development could help convince the White House, along with leadership in both houses, to delay or drop the plan, the lawmakers said.

Senate and House leadership, including Finance Committee Chairman Chuck Grassley (R-Iowa) and former House Majority Leader Tom DeLay (R-Texas), recently rejected the idea. The thought of delaying the Medicare drug benefit has also been discarded by the Centers for Medicare & Medicaid Services (CMS). "We're going to implement this on time," CMS spokesman Peter Ashkenaz told FDAnews late last month.

But McCain and Flake said political factors could change the administration's stance on the Rx benefit. While the lawmakers have argued that funding needs for Hurricane Katrina recovery should drive the move, politics might have to do. "If we can't do this for policy reasons, we should do this for political reasons, as Republicans," Flake said.

Flake said seniors would blame Republicans for the plan's flaws as well as its high costs, hurting the party's prospects in the 2006 mid-term elections. All of the House and a third of the Senate will be up for re-election in November 2006, Flake said. The cost of the Part D program combined with a gap in coverage that could leave 4 million seniors without healthcare will leave the Republican party "in danger of losing one or more houses of Congress," Flake predicted.

Starting Jan. 1, 2006, the Medicare Rx benefit is expected to account for roughly 40% of all prescriptions dispensed in the U.S. Cost estimates for the benefit passed in 2003 were originally estimated at $400 billion over 10 years. The nonpartisan Congressional Budget Office in March estimated the plan's price tag would rise to $850 billion over 10 years. But some lawmakers have predicted the costs will top $1 trillion.

FDA News, 11 October 2005

Cytogen has presented data from a Phase II study of Quadramet.

The study, known as TAXSAM1, was designed to evaluate the toxicity and efficacy of Quadramet in combination with docetaxel in 29 patients with progressive hormone-refractory prostate cancer.

According to the results of the study, within 12 weeks after start of the first TAXSAM cycle, PSA declines greater than 50% and 75% were seen in 34% and 21% of the patients, respectively. The time from start of the TAXSAM regimen until the PSA declines was 38 and 34 days respectively. PSA progression was seen in 69% of the patients, with a median time to PSA progression of 126 days.

FDA News, 4 October 2005

Prostate cancer is the most common invasive malignancy and the second leading cause of cancer-related deaths among U.S. males, with a similar trend in many Western countries. One approach to control this malignancy is its prevention through the use of agents present in diet consumed by humans. Pomegranate from the tree Punica granatum possesses strong antioxidant and anti-inflammatory properties. We recently showed that pomegranate fruit extract (PFE) possesses remarkable antitumor-promoting effects in mouse skin. In this study, employing human prostate cancer cells, we evaluated the anti proliferative and proapoptotic properties of PFE. PFE (10-100 µg/ml; 48 h) treatment of highly aggressive human prostate cancer PC3 cells resulted in a dose-dependent inhibition of cell growth/cell viability and induction of apoptosis. Immunoblot analysis revealed that PFE treatment resulted in (i) induction of Bax and Bak (proapoptotic); (ii) down-regulation of Bcl-XL and Bcl-2 (antiapoptotic); (iii) induction of WAF1/p21 and KIP1/p27; (iv) a decrease in cyclins D1, D2, and E; and (v) a decrease in cyclin-dependent kinase (cdk) 2, cdk4, and cdk6 expression. These data establish the involvement of the cyclin kinase inhibitor-cyclin-cdk network during the antiproliferative effects of PFE. Oral administration of PFE (0.1% and 0.2%, wt/vol) to athymic nude mice implanted with androgen-sensitive CWR22Rv1 cells resulted in a significant inhibition in tumor growth concomitant with a significant decrease in serum PSA levels. We suggest that pomegranate juice may have cancer-chemopreventive as well as cancer-chemotherapeutic effects.
Us TOO recognizes Founders and Founding Partners with award for supporting Us TOO from the beginning.

The presentation was made Sept 17, 2005 in conjunction with the Us TOO / Wellness Place gala event held in Chicago, Illinois.

Twelve retirement community friends take it all off for a good cause. The calendar features nude-but-strategically-covered mature women in a light-hearted manner. Order your "Blue Ribbon Girls for Prostate Cancer" 2006 calendar today!

$15 each, shipping and handling included. Checks only please (make out to "Blue Ribbon for Prostate Cancer"). PLEASE WRITE Us TOO IN THE MEMO SECTION OF THE CHECK so a portion of your purchase can be directed to Us TOO International.

Mail your check, along with your name and complete mailing address to:
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Questions? Email blueribbongirls@aol.com

“BLUE RIBBON RECIPES FOR A HEALTHY PROSTATE – COOKING HEALTHY WITH JOHN DODSON”

John Dodson is a gourmet chef, and a prostate cancer survivor. Soon after his diagnosis in 1999, he joined a support group - the Prostate Cancer Support Group of Greater Kingsport, Tenn. (affiliated with Us TOO International) - and began learning about the importance of healthy diet for prostate health from Dr. Charles E. “Snuffy” Meyers.

He shares his love of cuisine in the form of a cookbook titled Blue Ribbon Recipes for Prostate Health - a collection of 170 of his favorite recipes adapted to promote prostate health. The cookbook includes recipes for appetizers & beverages, soups & salads, vegetables & side dishes, main dishes, breads & rolls, desserts, cookies & candy, and “This & That” miscellaneous items, all for only $15.50 each, shipping and handling included.

Checks or money orders only please (make out to "Prostate Cancer Support Group"). All proceeds benefit prostate cancer support group services. PLEASE WRITE Us TOO IN THE MEMO SECTION OF THE CHECK so a portion of your purchase can be directed to Us TOO International.

Mail your check, along with your name and complete mailing address to:
Prostate Cancer Support Group
Attn: John Dodson
1252 Catawba Street
Kingsport, TN 37660
Questions? Call 423-245-3234 or Email Kathryn_W_Visneski@wellmont.org

More information about both items can be found at:
http://www.ustoo.org/ProductInfo_NoPayPal.asp
US TOO FEATURED RESOURCES
To order, visit <www.ustoo.org>

1) NEW! The Circles of Love Care Kit – $24.99 includes S+H
   Our new care kit is an excellent resource collection for friends and loved ones of those facing
   the battle against prostate cancer. Our care kit includes:
   - The Circles of Love Collection: Stories of Companions and Families Facing Prostate
     Cancer This new book, an Us TOO original publication, is a compilation of interviews
     with friends and loved ones of prostate cancer patients. These supportive and inspirational
     stories are meant to help others who are facing similar challenges. Also available sepa-
     rately for $17.00 includes S+H
   - Circles of Love Music CD – This original collection of upbeat and inspirational songs
     was written to celebrate the love and support between the patient and his companions and
     family members. Contributing artists include Soozie Tyrell of the E Street Band, Alan
     Glass (who has written hits for Aretha Franklin, Earth, Wind and Fire, Kenny G and oth-
     ers), Jerry Peters (who has written for Luther Vandross and others), country artist Deborah
     Allen, and folk artist Kat Eggleston. 12 songs including pop, R&B, soul, country, folk and
     dance. Also available separately for $15.00 includes S+H.
   - Intimacy with Impotence: The couples guide to better sex after prostate disease – This
     book, authored by Ralph and Barbara Alterowitz, is written for couples who have survived
     prostate cancer and whose normal sexual function has been disrupted. The authors bring a
     unique and personal perspective to the topics as they too live this experience. 220 pages.
   - What You Need to Know about Prostate Cancer – from NIH and NCI

2) NEW! Prostate Cancer Car Magnets “Know Your PSA” – $5.00 – includes S+H

3) STRIVE Initiative Wristbands – $1.00 each plus S+H

4) HotSheet Subscriptions – $35 for 12 issues
   HotSheets are distributed FREE at all Us TOO Support Group Chapter meetings, and on www.ustoo.org. But what if
   you are unable to regularly attend chapter meetings, or don’t have access to the Internet? Don’t miss an issue—we can
   deliver it right to your home or office!

5) “What You Need To Know For Better Bone Health” – FREE Us TOO brochure

6) 100 Questions & Answers About Prostate Cancer – $14.95 includes S+H
   By Pamela Ellsworth, MD, John Heaney, MD, Cliff Gill

7) Prostate Cancer Resource Kit – $18.95 includes S+H
   Included in this handy boxed kit:
   - A Primer on Prostate Cancer - by Dr. Stephen Strum and Donna Pogliano
   - Know Your Options – from Us TOO and the National Cancer Institute (NCI)
   - Prostate Cancer Treatment Guidelines for Patients – from National Comprehensive Cancer Network (NCCN)
   - and the American Cancer Society
   - What You Should Know About Prostate Cancer - from Prostate Cancer Research Institute (PCRI)
   - Prostate Cancer Resource Guide - from the American Foundation for Urologic Disease (AFUD)
   - Us TOO / Phoenix 5 CD-ROM - developed by Robert Young

8) Understanding Prostate Cancer: A Patient's Resource Kit – $7.50 includes S+H
   Included in this handy boxed kit:
   - Humanizing Prostate Cancer: A Physician-Patient Perspective by Roger E. Schultz, MD (Physician), and Alex
     W. Oliver (Patient)
   - Living With Prostate Cancer – booklet
   - Know Your Options – from Us TOO and the National Cancer Institute (NCI)
   - Living With Advanced Prostate Cancer video - patient testimonials on Viadur


10) Us TOO Prostate Cancer NEWS You Can Use – FREE e-News

Proceeds from all items benefit Us TOO’s FREE programs, support services and
educational materials for prostate cancer patients and their families
DENDREON ANNOUNCES PROVENGE STUDY RESULTS

Dendreon announced that final results of its second Phase III study of Provenge, the company’s investigational active immunotherapy for the treatment of advanced prostate cancer, would be presented at the ECCO 13 Congress, Europe’s preeminent cancer research conference, which begins October 30, 2005 in Paris, France.

Provenge is designed to stimulate a patient’s immune system against prostate cancer. It is developed through Dendreon’s proprietary Antigen Delivery Cassette technology, which utilizes a recombinant form of an antigen found in 95 percent of prostate cancers, prostatic acid phosphatase.

Provenge is being further evaluated in an ongoing Phase III study in asymptomatic, metastatic androgen-independent prostate cancer under a special protocol assessment agreement with the FDA. The double blind, placebo-controlled trial is enrolling men with advanced-stage prostate cancer at leading cancer centers around the country.

FDA News, 4 October 2005

SOLVING ONE OF THE BIGGEST CHALLENGES IN TREATING PROSTATE CANCER

With support from B.C. residents and the Canadian Cancer Society, Dr. Kim Chi is trying to solve one of the biggest challenges in treating prostate cancer today. Dr. Chi is about to open a clinical trial on a targeted "smart" drug he hopes will overcome the problem of prostate cancer treatment resistance.

Although prostate cancer is more treatable than ever before, about 25% of men diagnosed with the disease will die of it. "Initially, treatment works really well," says Dr. Chi. "But for some men, the cancer recurs and becomes more difficult to treat."

Dr. Chi is targeting one of the culprits behind this treatment resistance - a protein called clusterin. Cancer cells use clusterin as a defense mechanism to fight off anti-cancer therapies. The protein has been found not only in prostate cancer but also in other cancers including breast, colorectal and lung cancers, and is associated with poorer prognosis.

Dr. Chi is overseeing clinical development of a drug called OGX-011, which turns off the gene that produces clusterin. Results of 2 small, Phase I trials have been promising. "Phase I trials are all about finding the optimal dose, looking at side effects and seeing if the drug biologically does what we want it to do," Dr. Chi explains. "And this drug succeeded on all 3 of those things."

The next step is a randomized Phase II trial of 90 patients with treatment-resistant prostate cancer. Half of the men will receive standard chemotherapy treatment; the other half will also receive OGX-011. Patient enrollment will begin this fall in Vancouver, Victoria and Kelowna, as well as across Canada.

"I’m hoping to get as many people in B.C. as we can," says Dr. Chi, a medical oncologist with the BC Cancer Agency and the Prostate Centre at Vancouver General Hospital.

The trial is coordinated by the National Cancer Institute of Canada Clinical Trials Group (CTG), which is funded by the Canadian Cancer Society. Dr. Chi has also received a 4-year research grant from the Society for his clusterin research. Clinical benefits could be huge.

For further information, call (604) 675-7340 or hlochner@bc.cancer.ca

Newswire, 23 September 2005