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### SENATE PASSES LAST-MINUTE ‘RESCUE’ FOR DOCTORS FACING BIG MEDICARE CUTS

The Senate has voted to replace a planned 10.1% rate cut in Medicare Part B payments with a 0.5% raise. The pay cut had been scheduled to take effect on January 1, 2008.

The American Medical Association had warned that seniors would be denied access to care and a majority of physicians would have been forced to lay off staff unless Congress acted. But the reprieve is only for 6 months. Physicians will still face the payment reduction by next summer unless Congress acts again with another last-minute fix, or revamps the arcane formula used to calculate physician pay.

The Senate legislation, expected to be approved by the House of Representatives and signed by President Bush, also extends current funding for the State Children’s Health Insurance Program (SCHIP) through March 2009. Bush had twice vetoed expansions of the program that would have cost an additional \$35 billion over 5 years. Efforts to override the first veto failed, but supporters intended to try again in January 2008.

The 0.5% boost in reimbursement rates for doctors is expected to cost about \$6 billion. That will be offset

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PROSTATE CANCER  
EDUCATION & SUPPORT

# HOTSHEET

February 2008

### ASPIRIN THERAPY CAN IMPAIR PROSTATE CANCER TREATMENT

Men who used baby aspirin were significantly more likely to have abnormal liver function test results ( $P=0.02$ ) among men in a study of the antiandrogen flutamide (Eulexin<sup>®</sup>), reported Anthony V. D’Amico, MD, PhD, of the Dana-Farber Cancer Institute here, and colleagues. Abnormal liver function test results led to premature discontinuation of flutamide in 37% of aspirin users but only 16% of non-users, they said in a letter to the editors published in the December 27<sup>th</sup> issue of the *New England Journal of Medicine* (*N Engl J Med*, vol. 357, pp. 2737-8, 2007).

Oncologists, in collaboration with the patient’s cardiologist, need to decide whether he should come off aspirin during hormonal therapy or whether the cardiovascular risk is great enough to forego hormonal therapy if liver function drops, Dr. D’Amico said, especially in view of evidence that antiandrogen therapy may increase heart attack risk. “It’s a trade off,” he said. “It’s going to have to be decided on an individual basis.”

The finding may also have implications for oncologists beyond cautioning about drug-drug interactions, said Philip W. Kantoff, MD, of Dana-

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### MORE ACTION POSSIBLE FOR ERYTHROPOIESIS-STIMULATING AGENTS

US regulators said that they were reviewing two recent studies that provided more evidence of serious risks for some cancer patients treated with erythropoiesis-stimulating agents (ESAs) for anemia. The Food and Drug Administration “is reviewing these data and may take additional action,” FDA Deputy Commissioner Janet Woodcock said in a statement.

In the studies, researchers used Amgen’s Aranesp or J&J’s Procrit to increase patients’ hemoglobin to 12 g/dL or higher, although many patients did not reach that level. Current warnings on the drugs say hemoglobin levels should not rise above 12 for patients with cancer.

The FDA said the studies found patients with breast or advanced cervical cancer who were treated with the medications died sooner, or had more rapid tumor growth, than similar patients who were not given the drugs. The findings will be discussed with a committee of outside advisers at a public meeting in the next few months, an FDA statement said.

The companies had disclosed results from the studies, known as GOG-191 and Prepare, in November and Decem-

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## NEW CANCER TOOL SHOWS PROMISE IN SCOTTSDALE

Ray Simms has prostate cancer, but he fully expects to live at least another 20 years free of the disease. The 78-year-old resident of Tyrone, NM, is undergoing radiation treatment (RT) at the Arizona Cancer Institute in Scottsdale. He's confident the treatment will remove all of the cancer from his prostate, and that he'll know for sure that it's gone. Of course, the RT Simms is receiving is unlike any treatment available in the Southwest. In fact, it's only available at 25 locations worldwide.

The Calypso 4D Localization System is the state-of-the-art tool for treating prostate cancer, said Dr. Scott Tropper, radiation oncologist and the institute's medical director. "If you locate the tumor better, you're better able to direct the radiation at the tumor," he said.

Simms said the one factor that convinced him to go with the Calypso system is it provides proof that the cancer is gone. "My wife had several types of cancer over the years and she finally died as a result of the cancers," he said. "Even though the doctors thought they had eliminated it a couple of times, they hadn't. It had progressed to other areas of the body. So it was very important to me that (Tropper) can prove it."

Dr. Jonathan Ashman, a radiation oncologist with Arizona Oncology Services at St. Joseph's Hospital, said improving technology is allowing prostate cancer patients to more safely receive higher doses of radiation, and therefore achieve higher cure rates. "Calypso is but one type of technology that can accomplish that," he said. "There are several types and no one has been shown to be better. This is all relatively new territory."

There's no system in the world that only irradiates cancerous tissue and avoids all normal tissue, but there's been vast improvements in directing radiation at the cancer and avoiding as much normal tissue as possible, Tropper said. In the early 1990s, treatment involved irradiating an area the size of a grapefruit surrounding the prostate, Tropper said. Since then, there has been steady progress in directing the

## JUST FOUR MONTHS OF HORMONE THERAPY CAN DELAY PROSTATE CANCER GROWTH BY UP TO EIGHT YEARS WITH FEWER SIDE EFFECTS

Researchers have found that just four months of hormonal therapy before and with standard external beam radiation therapy (EBRT) slowed cancer growth—especially the development of bone metastases – by as much as eight years, and increased survival in older men with potentially aggressive ("high-risk") prostate cancer. The study was published online January 2nd in the *Journal of Clinical Oncology*.

This "neoadjuvant" hormonal therapy may allow men most at risk of developing bone metastases to avoid long-term hormonal therapy later on. Furthermore, short-term hormonal therapy did not increase the risk of cardiovascular disease – a potential side effect of long-term hormonal therapy.

Hormonal therapy (called androgen deprivation therapy) lowers levels of cancer-fueling testosterone in the blood. It is an important treatment option for men with prostate cancer that continues to grow even after treatment with surgery, EBRT or chemotherapy, but has also been associated with side effects such as bone loss, osteoporosis, depression and an increase in cardiovascular risk factors (including blood lipids, abdominal obesity and a syndrome associated with diabetes).

Starting in 1987, researchers studied 224 men with high-risk prostate cancer who received hormonal therapy (the drugs goserelin and flutamide) before and during EBRT, and 232 men with the disease who received EBRT alone. After 13 years, they found that compared with men who received EBRT alone, fewer men who received hormonal therapy died from prostate cancer (23 percent, versus 36 percent of the EBRT-only group), had cancer that spread to other organs (35 percent versus 47 percent), or experienced a rise in their PSA levels (65 percent versus 80 percent).

Moreover, the percentage of men who

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**DOCTORS FACING BIG MEDICARE CUTS** *(Continued from page 1)*

primarily by freezing payments for inpatient rehabilitation care for stroke, arthritis, and spinal cord or brain injuries, and for prescription drugs delivered by physicians through Medicare Part B, particularly oncologists.

The AMA applauded the Senate for pushing back the reimbursement cuts and for renewing SCHIP. "We are disappointed that the Senate could only agree on a six-month action because it creates great uncertainty for Medicare patients and physicians," said Edward Langston, MD, AMA's board chairman. "We strongly urge Congress to break the tradition of short-term interventions that are not fully funded and fail to chart a course for replacing a flawed payment formula that is a barrier to improving quality and access to care for seniors."

In what has become an annual rite since 2002, the AMA and scores of other medical organizations have been lobbying Congress and Centers for Medicare & Medicaid Services to stop planned cuts, and to scrap the "broken-beyond-repair" formula. The "sustainable growth rate" compares the actual rate of growth in health spending with a target rate, based on such factors as the growth in the number of Medicare beneficiaries, physician practice expenses, and the gross

domestic product. If spending exceeds targets, physician payments are reduced. The 2007 report of Medicare trustees predicts total cuts in physician pay of about 40% by 2016.

"This is a disappointment for many of us," said Sen. Charles Grassley (Iowa). "The purpose of moving forward with a 6-month package now is to provide the opportunity for the Finance Committee to address these priorities next year."

The proposed fee cut had been especially troubling because it was deeper than in previous years and more physicians said they planned to limit their services to Medicare patients, the AMA noted. Although Medicare pays doctors the same as in 2001, average practice costs have risen 18% since then, says the AMA.

Faced with the looming cuts, many physicians are reportedly grappling with whether to participate at all in Medicare in 2008. In a May 2007 AMA survey of 8,955 physicians, 77% said they will limit the number of new Medicare patients -- and 68% said they would limit the number of their established Medicare patients -- if fees are cut by the projected 40% over the next nine years.

*MedPage Today, 19 December 2007*

**NEOADJUVANT THERAPY**

*(Continued from page 2)*

were free of cancer at 10 years was higher for the neoadjuvant hormonal therapy group (11% versus 3%).

Among men who received neoadjuvant hormonal therapy, there was up to an eight-year delay in the time it took 40 percent of patients to develop bone metastases compared with men receiving radiation alone. Men who develop bone metastases often require long-term hormonal therapy, which can increase their risk for side effects.

This study demonstrates that the benefits of early, short-term hormonal therapy for men receiving radiation therapy for high-risk prostate cancer outweigh the risks. While four months of hormonal therapy isn't enough to cause significant side effects, the researchers found that it can significantly delay the development of bone metastases. The findings suggest that by taking a short course of hormonal therapy early on, patients may avoid having to take a longer course of treatment later. Patients with high-risk prostate cancer should discuss these findings with their physicians to determine if this approach is a viable treatment option for them.

*News for Patients from ASCO's Journal of Clinical Oncology, 2 January 2008*

**"LET'S GET READY TO RUMBLE!" FOR SNEAKERS@WORK DAY 2008!**

**Friday, June 13, 2008**



THE DAY FOR NATIONAL PROSTATE CANCER AWARENESS & ACTION

Our goal for June 13th, the 'lucky' Friday before Father's Day, is to have 2,000 companies and a million men and women lace 'em up for SNEAKERS@WORK DAY. With your participation and help we can achieve this goal. Michael Buffer, boxing ring announcer extraordinaire, is the S@W DAY 2008 celebrity spokesman.

The first thing to do is to mark the date on your calendar: **June 13, 2008, S@W DAY!**



**Watch the Us TOO website for more information: <www.ustoo.org/sneakers@work>.**

## RESEARCH YIELDS CLUES TO RECURRENT PROSTATE CANCER

Cancer researchers have identified a link between a cellular signaling protein and the hormone androgen that could play a role in hormone-resistant prostate cancer. According to researchers at Thomas Jefferson University's Kimmel Cancer Center in Philadelphia PA, the protein Stat5 is turned on in almost all recurrent prostate cancers that are resistant to hormone therapy.

Writing in the January issue of *Cancer Research*, the researchers also reported that Stat5 could work with cellular receptors for the hormone androgen in cases of recurrent prostate cancer. "These findings validate Stat5 as a potential drug target in prostate cancer, and in particular, in a form of prostate cancer for which there are no effective therapies," Dr. Marja Nevalainen, associate professor of cancer biology, said in a prepared statement.

Men with prostate cancer are often first treated with either surgery or radiation. Hormone therapy is used for subsequent disease. However, when prostate cancer returns years later, it is often more aggressive and tends to resist hormone treatment. The researchers have previously shown that when Stat5 is turned on, men have a significantly increased risk of recurring cancer.

The research team analyzed prostate cancer cells from 198 patients with prostate cancer recurrence. Stat5 was active in about three out of four (74 percent) of the recurrent prostate cancers, they found, and, of those patients, 127 had been treated with androgen deprivation therapy, a hormone therapy. Stat5 was active in 95 percent of the hormone-resistant tumors. According to the researchers, Stat5 is more likely to be active if patients are treated with androgen deprivation therapy. The protein interacts with the hormone receptors and keeps them active.

The researchers plan to test the dynamic between Stat5 and androgen receptors using animal models to find out if the relationship yields androgen-independent prostate tumor growth.

*HealthDay News, 2 January 2008*

## NONFAT MILK LINKED TO PROSTATE CANCER

The amount of calcium and vitamin D in the diet appears to have little or no impact on the risk of prostate cancer, but the consumption of low-fat or non-fat milk may increase the risk of the malignancy, according to the results of two studies published in the December 2007 issue of the *American Journal of Epidemiology*.

Dietary calcium and dairy products have been thought to increase the risk of prostate cancer by affecting vitamin D metabolism. Data from several prospective studies have supported an association, but many other studies have failed to establish a link.

To explore this topic further, Dr. Song-Yi Park, from the University of Hawaii in Honolulu, and colleagues, analyzed data from subjects enrolled in the Multiethnic Cohort Study. This study, conducted between 1993 and 2002, included adults between 45 and 75 years old, were primarily from five different ethnic or racial groups, and lived in California or Hawaii.

A total of 82,483 men from the study completed a quantitative food frequency questionnaire and various factors, such as weight, smoking status, and education levels were also noted, Park's group said.

During an average follow-up period of 8 years, 4,404 men developed prostate cancer. There was no evidence that calcium or vitamin D from any source increased the risk of prostate cancer. This held true across all racial and ethnic groups.

In an overall analysis of food groups, the consumption of dairy products and milk were not associated with prostate cancer risk, the authors found. Further analysis, however, suggested that low-fat or nonfat milk did increase the risk of localized tumors or non-aggressive tumors, while whole milk decreased this risk.

In a similar analysis, Dr. Yikyung Park, from the National Cancer Institute at National Institutes (NIH) of Health in Bethesda, Maryland, and colleagues investigated the relationship of calcium and vitamin D and prostate cancer in 293,888 men enrolled in the NIH-American Association of Retired Persons Diet and

Health Study, conducted between 1995 and 2001. The average follow-up period was 6 years.

No link between total or supplemental dietary calcium and the total number of non-advanced prostate cancer cases was noted. Total calcium intake was tied to advanced and fatal disease, but both associations fell short of statistical significance.

Similar to the first study, skim milk was linked with advanced prostate cancer. Calcium from non-dairy food, by contrast, was tied to a reduced risk of non-advanced prostate cancer.

"Our findings do not provide strong support for the hypothesis that calcium and dairy foods increase the risk of prostate cancer. The results from other large...studies, with adequate numbers of advanced and fatal prostate cancers, may shed further light on this question," Park's team concludes.

*Reuters Health, 2 January 2008*

## CALYPSO SYSTEM

*(Continued from page 2)*

radiation more toward the cancer and away from normal tissue, he said.

The problem is, the prostate constantly moves, even during treatment, and neither the ultrasound nor markers used as landmarks allowed tracking of the prostate's position during treatment.

"Now comes Calypso," Tropper said. "It's actually a series of markers, but ... they're actually beacon transponders. Basically it's a Global Positioning System."

Prostate cancer patients from all over metro Phoenix and Arizona come to the institute for radiation treatment with the Calypso system, and Tropper said he's not limited in the number of patients he can treat. The key to prostate cancer is there are multiple "excellent" treatments during the early stage, Ashman said.

He added "All patients should (consider) both surgery and radiation before deciding. Prostate cancer tends to be a slow-growing disease where there is time to decide the best treatment option."

*(Arizona) East Valley Tribune (AP) 19 December 2007*

## ASPIRIN

(Continued from page 1)

Farber, a co-author of the letter, "From a prostate cancer standpoint," he said, "this finding raises the potential value of more complete androgen blockade being of great importance in treating early prostate cancer."

In previous studies of high-dose aspirin use for arthritis, abnormal liver function tests have been reported in 5% of patients. And an animal study suggested that low testosterone levels contribute to slow metabolism of aspirin. "In men with prostate cancer," they said, this effect "could have clinical importance because the antiandrogen component of hormone therapy is discontinued when liver function tests become abnormal."

So they retrospectively analyzed the impact of low-dose aspirin in a prospective, randomized controlled trial of radiation therapy (RT) with or without at least six months of a luteinizing hormone-releasing hormone agonist (LHRH-A) and flutamide. The study included 206 patients with clinically localized prostate cancer and a PSA of at least 10 ng/mL, a Gleason score of at least seven, or radiographic evidence of extraprostatic disease.

Among other findings of the current report after 7.6 years of follow-up, men completing 6 months on a LHRH-A but stopping flutamide early were at 3.50 times higher relative risk of death (95% confidence interval: 1.03 to 11.80, P=0.04) than those who completed six months of both. RT alone was associated with 6.10-fold risk (95% CI: 2.30 to 16.20, P=0.001) compared with RT plus 6 months of hormone therapy. While men who used baby aspirin were more likely to have abnormal liver function test results (P=0.02), those on another common drug, atorvastatin (Lipitor®) were not (P=0.13).

"Care givers should be aware of drug-drug interactions when treating cancer patients," Dr. Kantoff concluded, "including the interactions of cancer drugs with [other] prescription and non-prescription drugs that could decrease the ability to deliver the cancer drug or diminish its effectiveness."

*MedPage Today, 27 December 2007*

## DOC MOYAD'S WHAT WORKS & WHAT IS WORTHLESS COLUMN ALSO KNOWN AS "NO BOGUS SCIENCE" COLUMN

**"Did you hear that I have a new book coming to bookstores in mid-February that will cover everything you wanted to know about your health from A to Z! Well, that seems a little promotional so let's get on with the column."**

Mark A. Moyad, MD, MPH

University of Michigan Medical Center, Department of Urology

\*To order Dr. Moyad's new "No Bogus Science Diet Book" just call toll-free 1-877-722-2264

**Bottom Line: It is now time to go out and buy an automated blood pressure measuring device in 2008, and to start loving each other right now!**

The US Preventive Services Task Force (USPSTF) is the gold standard group that offers objective advice on preventive screening of all types.

Recently, they reviewed all the medical literature and released a document that received very little attention, because it was a boring story, but in reality it was one of the most important medical papers of 2007. High blood pressure is quickly becoming the number 1 cause of cardiovascular death in the US in men and women. High blood pressure also impacts prostate health by potentially increasing the size of the prostate and causing tremendous damage, which also can reduce erectile function. Anyway, back to the medical paper that received no attention.

The USPSTF stated that the evidence for regular blood pressure screening is so strong that it received a Grade A, or the highest recommendation the group offers in preventive medicine.<sup>1</sup> I also agree with all of their findings! The group also stated that blood pressure screening should start at the age of 18! And, they suggest that several lifestyle changes can reduce blood pressure a lot including:

- Reducing dietary sodium, which is a big problem because most processed foods contain a lot of this stuff, and so it is up to you to compare food and beverage labels, because contrary to popular belief, the salt shaker at the table contributes very little to your overall salt intake.
- Potassium supplements may help.
- More physical activity and weight loss definitely helps most people.
- Stress management, which is why many music-soothing devices are

being sold to consumers now to reduce blood pressure, and I believe many are a rip-off! So, look for other ways to reduce stress.

- Reducing alcohol intake has been shown to have a dramatic blood pressure lowering impact in some people, especially men.

Lately, there has also been some interest in studying coenzyme Q10 supplements, but vitamin D and fish oil is getting a lot of attention as a potential way to reduce blood pressure, but this is all preliminary stuff.

Regardless, what was missed in the latest endorsement of blood pressure screening is that I truly believe everyone reading this column needs to go out and buy an automated blood pressure measuring device at your local pharmacy. The price ranges are generally 50 to 100 dollars, but they are the first step to really understanding how your blood pressure is doing.

In my opinion, it's much better to take your own readings every month or so and bring them to your doctor than having him/her take one reading a year to determine how you are doing. Taking one of the most important numbers for your health once a year is ridiculous, especially if you consider that blood pressure can vary at the doctor's office because of "white coat syndrome" or that it may increase just by being in a doctor's office.

So, for your prostate, kidneys, sexual organs, brain, stomach, lungs, eye and heart health, please think about buying your own home blood pressure monitoring device for your home this year! Hey, if you and your spouse love each other, you can share the device and save some money, and if you do not love each other... well that cannot be good for your blood pressure!

### Reference

1. *Ann Intern Med* 147:783-786, 2007.

## RESULTS OF PROSTATE STUDY AMONG BLACK MEN

A survey of Black American and Nigerian men shows that Black American males are more fatalistic in their cancer beliefs and are less likely to employ religious coping skills when fighting cancer.

The first of its kind study was conducted by researchers from predominantly Black Florida A&M University and the H. Lee Moffitt Cancer Center.

“Men who have fatalistic beliefs about prostate cancer ... may be less likely to take the steps necessary to prevent cancer or undergo cancer screening to detect cancer,” says lead researcher Professor Folakemi Odedina of FAMU’s Economic, Social & Administrative Pharmacy program. She added, “These are cultural beliefs that compound existing health disparities for Black American men.”

Odedina’s team found that Black America men are 60 percent less likely than West African men to possess the religious coping skills which might be able to help sustain them during cancer treatment. Among the study’s findings was Black American men tend to know more about prostate cancer than their African counterparts but cultural and religious beliefs cause them to take less preventive action.

*Presented at the American Association for Cancer Research Conference on “The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved, Atlanta, GA.”*

*EURweb.com, 7 December 2007*

## SORAFENIB ACTIVE AGAINST HORMONE-REFRACTORY PROSTATE CANCER (HRPC)

Sorafenib, an agent with both antiangiogenic and antiproliferative activity, may represent a useful treatment for progressive HRPC, new research suggests in a phase II study reported in the British Journal of Cancer (*Br J Cancer*, vol. 97, pp. 1480-5, 2007).

Dr. K. Mross, from Albert-Ludwigs-University in Freiburg, Germany, and colleagues assessed the outcomes of 57 patients with HRPC who were treated

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## PELVIC NODE IRRADIATION DOES NOT IMPROVE SURVIVAL IN LOCALIZED PROSTATE CANCER

There is no survival benefit in adding pelvic node irradiation to prostate irradiation in the treatment of localized adenocarcinoma of the prostate, French researchers report in the December 1<sup>st</sup> issue of the Journal of Clinical Oncology (*J Clin Oncol*, vol. 25, pp 5366-73, 2007).

In the GETUG-01 study, a multicenter team led by Dr. Pascal Pommier of the Centre Leon Berard in Lyon, France, assessed the benefit and the effect on quality of life of pelvic node irradiation in 444 patients with nonmetastatic prostate cancer. Patients were randomized to prostate-only irradiation or to both prostate and pelvic node irradiation. Patients were also stratified according to prognosis based on pelvic node involvement. The study design allowed for only 6 months of concomitant hormone therapy or neoadjuvant chemotherapy. The radiation dose to the prostate was 66 Gy early in the study and increased to 70 Gy toward the end of the study. The pelvic dose delivered was 46 Gy. Progression-free survival (PFS) was defined as biologic PSA recurrence or the development of local or metastatic disease.

Both overall survival and PFS rates were similar in the two treatment arms after 42.1 months of follow-up. The exception was in the group with a low risk of nodal involvement who also received concomitant hormone therapy. This group showed a statistical improvement in progression-free survival. Quality of life was also similar in the two arms, except for a “significant unexpected increase of grade 2 or greater urinary acute toxicities in the prostate-only group ... possibly explained by the more frequent use of 2 or greater Gy per fraction in the prostate only-group and 1.80 Gy per fraction in the pelvis-plus-prostate group.”

One of the major contributions of the GETUG-01 study, Dr. Pommier and colleagues conclude, “was to demonstrate that the pelvic irradiation with the radiotherapy modalities used in this study did not impair patients’ quality of life.”

*Reuters Health, 20 December 2007*

## HIGHLY ELEVATED PSA AND DIETARY PHIP INTAKE IN A PROSPECTIVE CLINIC-BASED STUDY AMONG AFRICAN AMERICANS

Bogen K, Keating II G, Chan J, et al

**Prostate Cancer Prostatic Dis**  
**Vol. 10, issue 3, pp. 261-9, 2007**

African-American men die from prostate cancer (PC) nearly twice as often as white US men and consume about twice as much of the predominant US dietary heterocyclic amine, 2-amino-1-methyl-6-phenylimidazo[4,5-b]pyridine (PhIP), a genotoxic rat-prostate carcinogen found primarily in well-cooked chicken and beef.

To investigate the hypothesis that PhIP exposure increases PC risk, an ongoing prospective clinic-based study compared PC screening outcomes with survey-based estimates of dietary PhIP intake among 40-70-year-old African-American men with no prior PC in Oakland, CA. They completed food-frequency and meat-cooking/consumption questionnaires and had a PSA test and digital-rectal exam. Results for 392 men indicated a 17 ( $\pm 17$ ) ng/kg day mean ( $\pm 1$  SD) daily intake of PhIP, about twice that of white US men of similar age.

PhIP intake was attributable mostly to chicken (61%) and positively associated ( $R^2=0.32$ ,  $P<0.0001$ ) with saturated fat intake. An odds ratio (95% confidence interval) of 31 (3.1–690) for highly elevated PSA  $\geq 20$  ng/ml was observed in the highest 15% vs. lowest 50% of estimated daily PhIP intake ( $\geq 30$  vs.  $\leq 10$  ng/kg day) among men 50+ years old ( $P=0.0002$  for trend) and remained significant after adjustment for self-reported family history of (brother or father) PC, saturated fat intake and total energy intake. PSA measures were higher in African-American men with positive family history ( $P=0.007$  for all men,  $P<0.0001$  for highest PSA quartile).

These preliminary results are consistent with a positive association between PhIP intake and highly elevated PSA, supporting the hypothesis that dietary intervention may help reduce PC risk.

*Medscape Urology, 18 December 2007*

## SORAFENIB

(Continued from page 6)

with sorafenib 400 mg twice daily. Four of the 55 patients had stable disease based on Response Evaluation Criteria in Solid Tumors (RECIST), a standard gauge of therapeutic efficacy. Eleven patients had PSA values indicating stable disease and two patients were classified as responders at 12 weeks. Two patients were excluded from the study.

A total of 257 adverse events were logged, of which 15 were of maximum Common Toxicity Criteria grade 3 and were thought to be drug related. Twenty-four serious adverse events were recorded in 14 patients. No treatment-related fatalities occurred.

“Sorafenib has antitumor activity in HRCP when evaluated for RECIST- and PSA-based response. Further investigation as a component of combination regimens is necessary to evaluate its definite or overall clinical benefit for HRCP,” Dr. Moss concludes.

*Reuters Health, 24 December 2007*

## MORE ACTION FOR ESAS

(Continued from page 1)

ber. The FDA had approved stronger warnings on ESAs earlier in November.

The Prepare study enrolled women who received chemotherapy before breast-cancer surgery. The FDA said that after 3 years, 14% of patients treated with Aranesp had died, compared with 9.8% who did not get the drug. In GOG-191, researchers studied women receiving chemotherapy and radiation for advanced cervical cancer. After three years, 66% of patients who did not take Procrit were alive and free of cancer growth, compared to 58% who had received the drug, the FDA said.

Ortho-Biotech, the J&J unit that sells Procrit, said in a statement that the studies showed a numerical trend toward shorter survival in patients treated with the anemia drugs, but neither showed a statistically significant difference in survival or tumor growth. Amgen is working with the FDA on updates to the anemia drug labels because the company is “concerned about patient safety.”

*Reuters, 4 January 2008*

## THE DOCTOR’S NOTE: COMMENTARY ON SELECTED ARTICLES IN THIS MONTH’S HOTSHEET

By Gerald W. Chodak, MD

This month we have several articles that are likely to stir some controversy, so here are some things to be aware of when reading them.

First up is an analysis of an ongoing prospective randomized study investigating radiation therapy with or without combined androgen blockade in men with intermediate risk localized prostate cancer. The study has been showing a statistically significant improvement in survival for the group receiving 6 months of an LHRH agonist and anti-androgen. Any man who selects radiation for this stage should make sure they are made aware of this treatment option.

In this issue, however, is further analysis from that study which showed that men who only received three months of their anti-androgen did much worse and the ongoing use of low dose aspirin resulted in a greater chance that the anti-androgen would have to be discontinued due to changes in liver function. This is a most interesting finding which does need further study to confirm. But men who are scheduled to receive this therapy and are on aspirin may want to discuss it carefully with their doctor.

Another radiation therapy article provides less clear information. A long-term study looked at a short course (four months) of hormone therapy had significant benefit in men receiving EBRT. This study unfortunately lacks the necessary study design to make it clear if four months significantly improves survival. Other randomized studies have not clearly shown four months is enough but longer therapy does improve survival. Here again, patients scheduled for EBRT should make sure they understand their op-

tions as fully as possible.

A third radiation therapy article provides some interesting but not yet definitive data about the value of pelvic radiation in men treated for prostate cancer. Though the study design is appropriate, the study is too immature to determine if the added radiation is beneficial although it did find the side effects acceptable. Much longer follow-up is needed as well as an assessment if enough high-risk patients were included in both treatment arms.

Two dietary studies are included. In one, which was not sufficiently designed to determine if its conclusions are valid, looked at the impact of Calcium and vitamin D in the development of prostate cancer, finding no association. It did find, however, that low-fat or non-fat milk did increase the risk of non-aggressive tumors while whole milk reduced the risk.

Before you throw out your non-fat milk, be aware that the study design does not permit any valid conclusions one way or another about the good or bad effects of low fat milk. These cohort analyses, even when large (82,000+ men) are just not adequate to make any recommendations. So, for now, if you drink low fat milk because of its health benefits, I would not change based on this information.

Similarly, a study in African Americans suggested that saturated fat and total energy intake predicted a much higher PSA level. Unfortunately, the cause and effect relationship is completely unproven. Other factors unrelated to the fat and energy could explain these results so without performing a prospective study, it is not quite sufficient to make changes in your cooking habits based on this report.

### NEW AUDIO AND TRANSCRIPT AVAILABLE

Audio & transcript from the Us TOO *Intimacy & Prostate Cancer Teleconference* held Tuesday, 30 October 2007 is now available on the Us TOO website. The teleconference features frank, open dialog about this challenging issue by speakers Lawrence S. Hakim, MD, Head, Section of Sexual Dysfunction, Male Infertility and Prosthetics, Cleveland Clinic Florida, Weston, FL, and a married couple who has dealt with prostate cancer and its after-effects on their intimate relationship.

For more details, please go to the Us TOO website:  
<[www.ustoo.org/Inti\\_Prostate\\_OCT30.asp](http://www.ustoo.org/Inti_Prostate_OCT30.asp)>

**BISPHOSPHONATES POSSIBLE CAUSE OF SEVERE BONE, JOINT, AND/OR MUSCLE PAIN**

FDA informed healthcare professionals and patients of the possibility of severe and sometimes incapacitating bone, joint, and/or muscle (musculoskeletal) pain in patients taking bisphosphonates.

Although severe musculoskeletal pain is included in the prescribing information for all bisphosphonates, the association between bisphosphonates and severe musculoskeletal pain may be overlooked by healthcare professionals, delaying diagnosis, prolonging pain and/or impairment, and necessitating the use of analgesics.

Severe musculoskeletal pain may occur within days, months, or years after starting a bisphosphonate. Some patients have reported complete relief of symptoms after discontinuing the bisphosphonate, whereas others have reported slow or incomplete resolution. The risk factors for and incidence of severe musculoskeletal pain associated with bisphosphonates are unknown.

Healthcare professionals should consider whether bisphosphonate use might be responsible for severe musculoskeletal pain in patients who pre-

sent with these symptoms and consider temporary or permanent discontinuation of the drug.

Read the complete 2007 and 2008 MedWatch Safety Summary including

a link to the FDA Drug Information Page regarding this issue at <[www.fda.gov/medwatch/safety/2008/safety08.htm#Bisphosphonates](http://www.fda.gov/medwatch/safety/2008/safety08.htm#Bisphosphonates)>.

*FDA MedWatch, 8 January 2008*

**SPECIAL THANK YOU TO REX ZEIGER**

In the December edition of the Hot-Sheet, we highlighted the release of the Us TOO Annual Report on 2006 activities. We are always pleased to be able to mention our supporters in this document and not to overlook someone special we want to highlight Rex M. Zeiger from Arizona.

*"I want to publicly thank Rex for not only his outstanding work on behalf of Us TOO but I also want to extend my personal apologies to him for the major misspelling of his name in our recently released Annual Report. Rex presented a gift to Us TOO in memory of his daughter Lynn Zeiger Carey during 2007 and I do not want to overlook him," said Us TOO President and CEO Tom Kirk.*

Rex has been an outstanding and active Us TOO volunteer since 1992, having started an Us TOO support

group, agreed to serve as a District Director and then also agreed to serve on the Us TOO Board of Directors for eight years.

As we closed out 2007, Rex decided that his health challenges would force him to find another volunteer to step into his role as an Us TOO Regional Director for Arizona. We thank him for his ongoing support as he manages his own health challenges. He does assure us he will remain involved in Us TOO activities into 2008 and beyond. Thank you, Rex, and we apologize for the error in the Annual Report!!

If you'd like to read Us TOO's 2006 Annual Report, either call the office for a copy, or read it on the Us TOO website at: <[http://www.ustoo.org/About\\_UsTOO.asp](http://www.ustoo.org/About_UsTOO.asp)> (look under the RELATED LINKS column on the right, 7th item down the list).

**US TOO INTERNATIONAL:  
OUR MISSION**

Communicate timely, personalized and reliable information enabling informed choices regarding detection and treatment of prostate cancer.



**US TOO INTERNATIONAL**

has received Charity Navigator's highest rating for the third year in a row for sound fiscal management. Less than 9% of the charities in the US receive this exceptional rating.

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