On December 5, 2000, the Board of Directors of Us Too! International, the World’s Leading Patient Focused Prostate Cancer Support Network changed the age at which it recommends men should be screened for Prostate Cancer. The change was aimed at earlier detection of prostate cancer.

Screening Recommendation
Us Too! International recommends annual prostate specific antigen (PSA) blood tests and digital rectal examinations (DRE) for all men 45 years of age and older. For men at higher risk* they are recommended annually beginning at age 40.

The following supporting medical studies were among those cited by the Us Too! Board in issuing these new recommendations:

- Results from a Mayo Clinic study found that prostate cancer mortality rates in the mid to late 1980’s rose dramatically (to 34/100,000 in 1989 to 1992) but following introduction of PSA testing have dropped significantly (to 19.4/100,000 in 1993 to 1997) - a 22% decline in mortality. ¹

- Results of a mass screening study in Tyrol, Austria found that within a subgroup of men age 40-59 PSA-based screening increased the early detection of prostate-confined tumors which are more potentially curable. ²

- The same “Tyrol Study” found that the DRE in conjunction with PSA value provides a very substantial improvement in ability to detect clinically significant tumors. ²

- A multi-center clinical trial concluded that the use of PSA in conjunction with digital rectal examination enhances early prostate cancer detection. ³

- Prostate cancers found by PSA and/or DRE screening were smaller and at an earlier stage (with less spread to lymph nodes, bones or other organs) than cancers found in men not having an annual PSA and/or DRE. ⁴

Us Too! strongly believes that this recommendation significantly enhances early detection of prostate cancer, improving both the mortality from the disease and the quality of life for patients and their families due to earlier, more effective treatment.

Us Too! also believes that the benefits of early detection and treatment outweigh the impact of occasional false positive results leading to biopsy of non-cancerous abnormalities, as well as the economic cost of these examinations.

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*Men at higher risk include African-American men and those with a family history of prostate cancer.

The prostate cancer awareness stamp image is copywrited by the USPS.

SHOW YOUR SUPPORT! You may still purchase and use the Prostate Cancer Awareness stamp (Item #448240) on-line at:  http://shop.usps.com
CLINICAL TRIALS

A recent search of the Veritas Medicine (www.veritasmedicine.com) clinical trials database found 86 trials in which you might be interested. In order to learn more about the trial locations listed here, including detailed information about the treatments used, and specific contact information for enrollment, you will need to register with Veritas Medicine.

1. Pachlax Plus Estramustine in Treating Patients w/ Metastatic Prostate Cancer
2. Monoclonal Antibody Therapy in Treating Patients With Prostate Cancer
3. Hydrocortisone Plus Aminoglutethimide or Ketoconazole in Treating Patients w/ Localized Stage IV Prostate Cancer
4. External-Beam Radiation Therapy Plus Implanted Radiation Therapy in Treating Patients With Prostate Cancer
5. Androgen Suppression Plus Radiation Therapy in Treating Patients With Prostate Cancer
6. Combination Chemotherapy With or Without Peripheral Stem Cell Transplantation in Treating Patients With Prostate Cancer

7. Testosterone in Treating Patients With Progressive Prostate Cancer That No Longer Responds to Hormone Therapy
8. Capecitabine in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy
9. SU5416 Compared to Dexamethasone in Treating Patients With Progressive Prostate Cancer That Has Not Responded to Hormone Therapy
10. Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy
11. Calcitriol in Treating Patients With Prostate Cancer New York (NY)
12. Monoclonal Antibody Therapy in Treating Patients With Kidney or Prostate Cancer
13. EF5 Prior to Surgery or Biopsy in Patients With Breast, Prostate, or Cervical Cancer or High Grade Soft Tissue
14. Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer
15. Gene Therapy in Treating Patients With Cancer
16. Arsenic Trioxide in Treating Patients With Stage IV Prostate Cancer That Has Not Responded to Previous Hormone Therapy
17. Hormone Therapy With or Without Mitoxantrone and Prednisone in Treating Patients Who Have Undergone Radical Prostatectomy for Prostate Cancer
18. Mitoxantrone and Prednisone With or Without Leflunomide in Treating Patients With Stage IV Prostate Cancer
19. Hormone Therapy Plus Radiation Therapy With or Without Combination Chemotherapy in Treating Patients With Prostate Cancer
20. Leuvectin Followed By Surgery in Treating Patients With Stage II or Stage III Prostate Cancer
21. Chemotherapy in Treating Patients With Prostate Cancer
22. Combination Therapy in Treating Patients With Advanced Prostate Cancer That Has Not Responded to Hormone Therapy
23. Combination Chemotherapy in Treating Patients With Prostate Cancer That Has Not Responded to Hormone Therapy
24. Vaccine Therapy in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy
25. Chemotherapy and Hormone Therapy in Treating Patients w/ Prostate Cancer

Effect of Androgen Suppression on Bone Loss in Patients w/o or w/o Bone Metastases Secondary to Prostate Cancer
Brachytherapy in Treating Patients With Recurrent Prostate Cancer
Peripheral Stem Cell Transplantation and White Blood Cell Transfusions in Treating Patients With Refractory Metastatic Solid Tumors
Broxuridine Plus Surgery in Treating Patients With Stage I or Stage II Prostate Cancer
Vaccine Therapy Plus QS21 in Treating Patients w/ Prostate Cancer
Trastuzumab in Treating Patients With Prostate Cancer
Combination Hormone Therapy Followed by Radiation Therapy in Treating Patients With Prostate Cancer
Paclitaxel Plus Estramustine in Treating Patients w/ Metastatic Prostate Cancer
Standard Therapy With or Without Daltetapin in Treating Patients With Advanced Breast, Lung, Colorectal, or Prostate Cancer
Hormone Therapy in Treating Patients With Rising PSA Levels Following Radiation Therapy for Prostate Cancer
Hormone Therapy in Treating Patients Who Have Stage I or Stage II Prostate Cancer
Combination Chemotherapy in Treating Patients w/ Advanced Prostate Cancer
Vinorelbine Plus Paclitaxel in Treating Patients With Metastatic Prostate Cancer That Is Refractory to Hormone Therapy
Trastuzumab and Docetaxel in Treating Patients Who Have Metastatic Prostate Cancer That Is Refractory to Hormone Therapy
R15777 in Treating Patients With Progressive, Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy
Combination Chemotherapy in Treating Patients w/ Advanced Prostate Cancer Diet and PSA Levels in Patients With Prostate Cancer
Green Tea Extract in Treating Patients With Metastatic Prostate Cancer That Has Not Responded to Hormone Therapy
Genistein in Treating Patients With Stage III or Stage IV Prostate Cancer
Nitrocamptothecin in Treating Patients With Stage IV Prostate Cancer That Has Not Responded to Hormone Therapy
Hormone Therapy in Treating Patients With Prostate Cancer

(continued on Page 8)
PROSTATE CANCER NEWS

News items contained in the US TOO! HotSheet are obtained from various news sources and edited for inclusion. Where available, a point-of-contact and phone number/website address is provided.

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

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CHECKING HUMAN GROWTH FACTOR LEVEL MAY IMPROVE PSA SCREENING

The addition of insulin-like growth factors may improve accuracy of prostate-specific antigen screening and assist in the identification of individuals at increased risk of developing cancer, research suggested. Researchers compared levels of IGF-1, EGFBP-3 and PSA. Since the PSA test is “not particularly sensitive,” the authors suggested that “the additional use of IGF-1 and IGFBP-3 can potentially improve sensitivity of the diagnostic procedures.” The PSA test, “[E]ven with the more strict cut point of less than three ng/mL,” could not detect 25 percent of prostate cancers in the study, the authors warned. The study was published in the December 2000 issue of the Lancet.

SCIENTISTS DISCOVER SPECIFIC PROTEIN IN THE BLOOD OF PROSTATE CANCER PATIENTS, NOT PRESENT IN HEALTHY INDIVIDUALS

In a study that tested blood samples from 25 patients with prostate cancer and 20 healthy men, a team of researchers from Maritech Inc. and Johns Hopkins School of Medicine detected a specific protein in the blood of all 25 men with prostate cancer that was not present in the blood samples of the healthy subjects by using a novel mass spectroscopy technique. Moreover, in the study the cancer protein identified five out of the 25 men with prostate cancer who were missed by routine PSA screening.

FREE-TO-TOTAL PSA RATIO CORRELATES WITH TUMOR VOLUME AMONG MEN WITH INCREASED PSA

Free-to-total PSA ratio may be predictive of tumor biology among patients with an increased serum PSA, researchers said. The association between the ratio of free-to-total PSA and prostate pathology, including grade, stage, and tumor volume, were evaluated among 54 patients with prostate cancer who underwent radical prostatectomy and in whom frozen serum was available for assessment. “These preliminary results suggest the need for additional studies among patients with an increased PSA designed to evaluate the potential role of free-to-total PSA ratio in combination with traditional clinical variables in the prediction of prostate cancer pathology,” the researchers concluded. (Grossklaus DJ, et al. J Urol 2001;165:455-8.)

CRYOSURGERY PUTS TUMORS ON ICE, OFFERS HOPE FOR MANY PATIENTS

by Marilynn Marchione Milwaukee Journal Sentinel Feb. 10, 2001 Cryosurgery - turning tumors into ice balls via minimally invasive operations - is growing in popularity and success around the nation for a variety of cancers. It offers hope for many patients whose tumors are inoperable, who are too old or sick for surgery, or whose cancers have recurred after radiation or chemotherapy. For prostate cancer, cryosurgery allows non-surgical destruction of the gland. The prostate is so small - just slightly larger than a walnut - that removing just what appears to be the main tumor isn’t done because that isn’t likely to cure. “Usually prostate cancer is multifocal. Even though it presents with a predominant cancer in one site, you could have microscopic cancers you cannot see, so you have to destroy the entire gland,” explained Fred Lee, a radiologist at Crittenton Hospital in Rochester, Mich., who has performed the most prostate cryosurgeries in the nation - 840. The gold standard for treating prostate cancer that hasn’t spread beyond the prostate to lymph nodes or bone is surgical removal of the gland - prostatectomy. But not all patients are young or healthy enough to withstand the surgery. Some choose radiation, either external beam or radioactive “seed” implants, but radiation only sometimes cures. Cryosurgery is an alternative to prostatectomy as well as an option for patients whose cancer recurred after radiation. “This holds great promise. Here’s a whole new group of patients” who now have a new option, said Robert Donnell, co-director of the prostate center at Froedtert and the medical college. “Newer technology has tremendously lowered the side effects,” said Donnell, the Froedtert. But one side effect - impotence - is nearly universal. When tumor cells escape, it’s often through the neurovascular bundle that controls erections, which is destroyed by cryosurgery. “If they’re not impotent, you haven’t done it right and you need to go back and do it again,” Donnell said. About two-thirds of patients who have standard surgical removal of the prostate also develop impotence, according to published studies. Cryosurgery patients can use a vacuum pump device, surgical implants or a drug injected at the base of the penis to produce an erection, Donnell said. The new cryosurgery technology has improved survival. At an international radiology meeting in 1998, Lee’s group presented five-year follow-up results from nearly 600 patients showing disease-free survival, established by biopsies, of 79 percent. More recent patients should fare even better, because the new technology better destroys the entire gland, Lee said. The cancer also must be confined to the gland, not spread to lymph nodes or other sites. “I think its niche is going to be in older gentlemen whose prostate cancer is locally confined who do not want to go through radiation treatment,” said Richard Babaian of the M.D. Anderson Cancer Center in Houston. His group tried cryosurgery for prostate cancer with mixed success in the early 1990s on patients who had failed previous treatment and has been using the newer technology for about a year and a half.

BONE-TARGETED THERAPY MAY IMPROVE SURVIVAL IN ADVANCED ANDROGEN-INDEPENDENT PROSTATE CARCINOMA

Bone-targeted consolidation therapy after induction chemotherapy improved overall survival in patients with stable or responding advanced androgen-independent prostate carcinoma, a randomized Phase II trial showed. “Our results support the hypothesis that organ-targeted therapy could provide a survival advantage even in the presence of systemic metastasis, and they validate the clinical relevance of time-to-progression as a surrogate endpoint for survival in the clinical investigation of prostate cancer,” the authors wrote. “[These] findings provide a strong rationale for further work on bone-targeted therapy as a viable therapeutic strategy for patients with advanced prostate cancer. However, these results need to be confirmed by further (CONTINUED ON PAGE 6)
**SCIENTIFIC JOURNAL CITATION REVIEW**

The following prostate cancer related articles have appeared in well-known scientific journals. Abstracts only have been posted at the US TOO! website (www.ustoo.org). US TOO! cannot provide copies of the complete article.

**TO OBTAIN A COPY OF THE ARTICLE:** take the citation to your local public or hospital library. The librarian can assist you in obtaining a copy of the article from their collection or from interlibrary loan.

**INCREASED EXPRESSION OF THE INTERLEUKIN-11 RECEPTOR AND EVIDENCE OF STAT3 ACTIVATION IN PROSTATE CARCINOMA.**


Campbell CL, Jiang Z, Savarese DM, Savarese TM

Cytokine/Cytokine Receptor Laboratory, LINK Laboratories, University of Massachusetts Cancer Center, University of Massachusetts Medical School, Worcester, and the Division of Hematology/Oncology, University of Massachusetts/Memorial Health Care, Worcester, Massachusetts.

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Damon SE, Plymate SR, Carroll JM, Sprenger CC, Dechuskhum C, Ware JL, Roberts CT


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Chien J, Shah GV

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**PROSTATE-SPECIFIC ANTIGEN-BASED EARLY DETECTION OF PROSTATE CANCER: VALIDATION OF SCREENING WITHOUT RECTAL EXAMINATION.**
Urology 2001 Jan;57(1):83-90
Schroder FH, Roobol-Bouts M, Vis AN, van der Kwast T, Kranse R
Department of Urology, Erasmus University and Academic Hospital Rotterdam, Rotterdam, The Netherlands
**Prostate Cancer News (Continued from Page 3)**

Clinical studies before they are accepted as a clinically important advance.” (Tu S, et al. The Lancet 2001;357:336-41.)

**Prednisone, a Choice of Treatment for Hormone-Resistant Prostate Cancer**

“Treatment with prednisone or flutamide (Eulexin) leads to similar rates of time to progression [TTP] and overall survival and no difference in subjective or biochemical response” in patients with symptomatic hormone-resistant prostate cancer (HRPC), a Phase III trial indicated. However, prednisone was superior to flutamide with regard to important patient-assessed QL factors. The participants also completed the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C-30 at baseline and 6-week intervals during follow-up. No difference was observed between the 2 groups in median TTP or overall survival. “Monotherapy with low-cost prednisone should be considered as first-line, standard, hormonal manipulation of HRPC, but the combination with tolerable cytotoxic treatment should be explored further,” the authors concluded. (Fossa SD, et al. J Clin Oncol 2001;19:62-71.)

**Limited Value of eMRI and TRUS in Clinically Localized Prostate Cancer**

Researchers examined the role of endorectal magnetic resonance imaging (eMRI) and transrectal ultrasonography (TRUS) in 54 patients with biopsy-confirmed prostate cancer who underwent TRUS and eMRI before radical retropubic prostatectomy. “Whereas MRI tended to over-stage, TRUS under-staged prostate cancer. This series shows the current limited value of TRUS and eMRI for planning treatment in patients with clinically localized prostate cancer. Treatment decisions should not be altered based on TRUS or eMRI findings alone,” the researchers concluded. (May F, et al. BJU International 2001;87:66-9.)

**PSA Levels Higher in Young Black Men**

Though young black men have PSA levels greater than that of young white men, PSA velocity is higher in young white men than in young black men, new research revealed. In a study to determine the PSA levels and PSA change over time, investigators performed a retrospective analysis of 588 black and 588 white healthy males. The investigators discovered a significant difference in the baseline serum PSA level between the races. “The median baseline serum PSA levels for black men 20 to 29, 30 to 39 and 40 to 45 [years of age] were 0.38 ng/mL, 0.45 ng/mL and 0.52 ng/mL, respectively,” and for white men, 0.38 ng/mL, 0.45 ng/mL and 0.40 ng/mL, respectively, the research showed. In white men, PSA velocity was significantly higher. Analysis showed mean increases of 2.8 percent per year for white men as compared with 1.6 percent per year for black men. “[T]hese values may prove useful in screening young white and black men known to be at higher risk of prostate cancer.” The study appeared in the February 2001 issue of Urology.

**Erectile Dysfunction Common Among Prostate Cancer Patients Regardless of Type of Therapy Received**

Prostate cancer patients treated with external beam therapy are at the same risk level for erectile dysfunction as those treated with radical prostatectomy, according to a report appearing in the February 2001 issue of the Journal of Urology. “Erectile dysfunction is a common side effect in men treated with for prostate cancer. Previously published studies document the incidence of erectile dysfunction in men treated for prostate cancer to be between 20 percent and 88 percent,” the researchers noted. “In our study erectile dysfunction occurred in greater than 80 percent of patients treated for prostate cancer,” the authors concluded. “[E]rectile dysfunction did not develop based on the type of therapy received, but whether a patient received therapy for prostate cancer,” they pointed out. In an accompanying editorial, Dr. Ian M. Thompson of the University of Texas Health Science Center said, “The only absolute method to determine the actual difference in erectile dysfunction with various treatments will be randomized clinical trials using validated instruments with repetitive measures, which is a goal that is unlikely to be reached.” “Future observational studies should focus on better characterization of patients before treatment ....”

**University of Iowa Researchers Investigate Use of Magnetic Rods to Treat Prostate Cancer**

University of Iowa researchers are developing a new approach to treat prostate cancer. The treatment uses heat generated by implanted magnetic rods to destroy the cancer. The UI scientists hope the new technique will be as successful as surgery and radiation therapy in treating the disease, but will avoid the difficult and unpleasant side effects often associated with those standard treatments. “Our results, and those of our international collaborators, suggest that these rods could be extremely effective in treating the cancer with potentially fewer side effects,” said Robert D. Tucker, M.D., Ph.D., UI associate professor of pathology and adjunct associate professor of biomedical engineering. “The treatment under development at the UI will involve implanting small magnetic alloy rods into the prostate using methods similar to those employed to place radioactive brachytherapy seeds. Each cylindrical rod is 1.4 centimeters long and 1 millimeter in diameter. When the patient with implanted rods is placed in an external alternating magnetic field, the rods heat up and transfer the heat to the surrounding tissue. The heat from the rods does two things: it causes proteins to denature or unravel, which kills cells, and it coagulates the blood supply, which starves the cells and causes them to die. Implanting the rods using a long hollow needle takes about 45 minutes. The patient receives only a spinal anesthetic. The patient undergoes a single treatment in the magnetic field and is able to go home on the same day. “In patients treated so far, the results have been encouraging,” Tucker said. “Another advantage of these permanent rods is that, unlike radiation treatment, thermal therapy can be repeated noninvasively if the patient’s serum PSA values start to rise again.”

**New Marker for Malignancy in Prostate Discovered**

Previous research has linked fat intake and metabolism with prostate cancer, and the presence of high amounts of certain fatty acids in the blood has also been associated with increased risk. Altered levels of arachidonic acid metabolism, controlled by LAT activity and the deacylation-reacylation cycle that incorporates it into the lipid membrane, are also thought to convey greater risk. Writing in the Journal of Urology, Dr Fred Faas and colleagues said, “Since the benign and malignant tissues were obtained from different portions of the same prostate in the radical prostatectomy specimens, the increased LAT activity must be specific for malignant tissues and not simply a general increase in enzymatic activity related to the presence of malignancy.” If a sensitive assay can be developed to detect activity of LAT in a needle biopsy, it may be possible to predict which patients will develop aggressive disease. The Journal of Urology, February 2001, Vol. 165, 463-468.
The impact of prostate biopsy on patient well-being begins while waiting for the scheduled procedure, the authors wrote. "Shortening the anticipation period before results are disclosed and administering pre-biopsy anxiety decreasing measures may benefit patients. Analgesic therapy is recommended in younger patients, those reporting moderate to severe intraoperative pain and those with known prostatic inflammatory infiltrate. The risk of acute erectile dysfunction should be discussed cautiously with patients who are potent before biopsy." (Zisman A, et al. J Urol 2001;165:445-54.)

**NEW HYPERTHERMIA THERAPY PUTS THE HEAT ON CANCER**

by Jon Van , Chicago Tribune Feb. 19, 2001 — A cancer therapy that was tried with much enthusiasm in the mid-1980s, and then discarded by most physicians, may be on the verge of getting a second chance. Heating tumors to make them more vulnerable to radiation or chemotherapy is a fairly straightforward idea that has been proven to work in lab experiments. But many physicians were disappointed when they tried adding heat to their treatments and patient outcomes didn't seem much better. After a few years of disappointing results, hyperthermia, as the tumor-heating strategy is known, mostly fell into disuse in this country, although some centers in Europe and Asia continued using it. Now, positive results at European hospitals recently published in medical journals are causing American cancer therapists to take another look at the technology. In Chicago, Dr. John Kalapurakal, an assistant professor of clinical radiology at Northwestern University, said he has been amazed at how well some patients have done after being treated with radiation and hyperthermia. Kalapurakal has treated a handful of patients whose prostate cancers had recurred after their original treatment. The revived tumors had robbed patients of hope, leaving them at the end of the line with conventional cancer therapies. "We had no other option for patients who had failed radiation therapy," said Kalapurakal. "They faced the possibility of living for years with pain and disability." A study published last year in a British medical journal, The Luncet, by Dutch researchers demonstrated significant benefits of hyperthermia for patients with advanced pelvic tumors. Northwestern is one of only a few medical centers in the U.S. with a machine that uses microwaves to heat tumors deep inside the body. If large studies could show a clear benefit to the therapy, problems of insurance reimbursement and a lack of champions among medical specialties likely would be overcome. Initial indications are that hyperthermia can enhance the tumor-fighting power of radiation and chemotherapy twofold, said Dr. Steven Stroup, director of radiation oncology at Centennial Medical Center in Nashville. "Hyperthermia works," said Stroup. "But it's very labor-intensive, and it's as much art as science. I think there will be a resurgence in it as people look for new ways to enhance their treatments."

**LAWMAKERS PROPOSE OFFICE OF MEN'S HEALTH**

Dying at astonishing rates from many preventable and treatable diseases, many men don't care about their health enough to go to a doctor, experts say. In fact, men are 25 percent less likely to visit a doctor than women and are also less likely to have health insurance. On average, men die seven years earlier than women and are more likely to suffer from the 10 leading causes of death, which include heart disease, cancer, stroke and AIDS. Statistics like these have sparked many health advocates and lawmakers, such as Rep. Randy "Duke" Cunningham (R-Calif.) and Rep. Jim McDermott (D-Wash.), to do something about this perceived crisis. This past Valentine's Day, the two men submitted a bill to Congress that proposed an Office of Men's Health through the Department of Health and Human Services, which supporters say will help save the lives of thousands of men across the country. If approved, the Office of Men's Health would seek to raise awareness about men's health issues as well as emphasize the need for screening and early detection. Harmony Allen, a spokeswoman for Cunningham said "Men are dying needlessly across the country when they could've just gone to the doctors to get treatment. We want to stress the importance of going out and getting tested. A lot of men don't care about their health in this country, and this bill is designed to change that. We need people who think it's not a big deal to start caring." Cunningham's particular focus lies in prostate cancer. And dedication to the cause stems from personal experience — he was diagnosed with prostate cancer three years ago and is now in remission. The Office of Men's Health was first proposed last June but failed to garner support due to the hectic election year. With over 50 sponsors so far, many are confident it will make it through Congress this year.

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<table>
<thead>
<tr>
<th>Page</th>
<th>Clinical Trials (Continued from Page 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>47</td>
<td>Radiation Therapy Plus Amifostine in Treating Patients With Primary Prostate Cancer</td>
</tr>
<tr>
<td>48</td>
<td>Combination Chemotherapy Plus Filgrastim in Treating Patients With Stage IV Prostate Cancer That Has Not Responded to Hormone</td>
</tr>
<tr>
<td>49</td>
<td>Radiation Therapy in Treating Patients With Prostate Cancer</td>
</tr>
<tr>
<td>50</td>
<td>Combination Chemotherapy in Treating Pain in Patients With Hormone Refractory Metastatic Prostate Cancer</td>
</tr>
<tr>
<td>51</td>
<td>Mitoxantrone and G-CSF in Treating Patients With Metastatic Prostate Cancer</td>
</tr>
<tr>
<td>52</td>
<td>Radiation Therapy in Treating Patients With Bone Metastases From Breast or Prostate Cancer</td>
</tr>
<tr>
<td>53</td>
<td>Hormone Therapy Plus Radiation Therapy in Treating Patients With Prostate Cancer</td>
</tr>
<tr>
<td>54</td>
<td>Computer Planned Radiation Therapy in Treating Patients With Stage I or Stage II Prostate Cancer</td>
</tr>
<tr>
<td>55</td>
<td>Combination Chemotherapy With Ketoconazole in Treating Patients With Prostate Cancer</td>
</tr>
<tr>
<td>56</td>
<td>Estramustine, Docetaxel, and Carboplatin in Treating Patients With Prostate Cancer That Has Not Responded to Hormone Therapy</td>
</tr>
<tr>
<td>57</td>
<td>Cyproterone Acetate in Treating Hot Flashes Following Surgical or Chemical Castration for Prostate Cancer</td>
</tr>
<tr>
<td>58</td>
<td>Hyperthermia Plus Radiation Therapy in Treating Patients With Nonmetastatic Advanced Prostate Cancer</td>
</tr>
<tr>
<td>59</td>
<td>Advanced Prostate Cancer</td>
</tr>
<tr>
<td>60</td>
<td>PET Scan in Treating Patients With Metastatic Prostate Cancer</td>
</tr>
<tr>
<td>61</td>
<td>Surgery in Treating Patients With Prostate Cancer</td>
</tr>
<tr>
<td>62</td>
<td>Radiation Therapy With Androgen Suppression in Treating Patients With Prostate Cancer</td>
</tr>
<tr>
<td>63</td>
<td>Radiation Therapy With or Without Bicalutamide in Treating Patients With Stage II, Stage III, or Recurrent Prostate Cancer</td>
</tr>
<tr>
<td>64</td>
<td>Chemotherapy Plus Hormone Therapy Versus Androgen Suppression in Treating Patients With Metastatic or Unresectable Prostate Cancer</td>
</tr>
<tr>
<td>65</td>
<td>Docetaxel in Treating Patients With Stage II or Stage III Prostate Cancer</td>
</tr>
<tr>
<td>66</td>
<td>Ultrasound in Treating Patients With Recurrent Stage I or Stage II Prostate Cancer</td>
</tr>
<tr>
<td>67</td>
<td>Leuvetin in Treating Patients With Locally Recurrent Prostate Cancer</td>
</tr>
<tr>
<td>68</td>
<td>Low, Intermediate, or High Dose Suramin in Treating Patients With Hormone-Refractory Prostate Cancer</td>
</tr>
<tr>
<td>69</td>
<td>Doxorubicin Plus Estramustine in Treating Patients With Metastatic Prostate Cancer</td>
</tr>
<tr>
<td>70</td>
<td>Photodynamic Therapy With Lutetium Texaphyrin in Treating Patients With Locally Recurrent Prostate Cancer</td>
</tr>
<tr>
<td>71</td>
<td>Pain Control in Patients With Recurrent or Metastatic Breast or Prostate Cancer</td>
</tr>
<tr>
<td>72</td>
<td>Hormone Therapy in Treating Men With Stage IV Prostate Cancer</td>
</tr>
<tr>
<td>73</td>
<td>Hormone Therapy and Radiation Therapy in Treating Patients With Prostate Cancer</td>
</tr>
<tr>
<td>74</td>
<td>Prostatectomy Compared With Watchful Waiting in Treating Patients With Stage I or Stage II Prostate Cancer</td>
</tr>
<tr>
<td>75</td>
<td>Radiation Therapy in Treating Patients With Stage I, Stage II, or Stage III Prostate Cancer</td>
</tr>
<tr>
<td>76</td>
<td>Radiation Therapy With or Without Antiandrogen Therapy in Treating Patients With Prostate Cancer</td>
</tr>
<tr>
<td>77</td>
<td>Vaccine Therapy in Treating Patients With Advanced Prostate Cancer</td>
</tr>
<tr>
<td>78</td>
<td>Paclitaxel and Bypostatin I in Treating Patients With Metastatic Prostate Cancer</td>
</tr>
<tr>
<td>79</td>
<td>Radiation Therapy in Treating Patients With Prostate Cancer</td>
</tr>
<tr>
<td>80</td>
<td>Thalidomide for the Treatment of Hormone-Dependent Prostate Cancer</td>
</tr>
<tr>
<td>81</td>
<td>PSA-Based Vaccine and Radiotherapy to Treat Localized Prostate Cancer</td>
</tr>
<tr>
<td>82</td>
<td>PSA Vaccine or Nilutamide to Treat Advanced Prostate Cancer</td>
</tr>
<tr>
<td>83</td>
<td>A Safety and Feasibility Study of Active Immunotherapy in Patients with Metastatic Prostate Carcinoma Using Autologous Dendritic Cells Pulsed with Antigen Encoded in Amplified Autologous Tumor RNA</td>
</tr>
<tr>
<td>84</td>
<td>Trastuzumab Plus R115777 in Treating Patients with Advanced or Metastatic Prostate Cancer</td>
</tr>
<tr>
<td>85</td>
<td>Bicalutamide in Treating Patients With Stage I, Stage II, or Stage III Prostate Cancer</td>
</tr>
<tr>
<td>86</td>
<td>Hormone Therapy in Treating Patients With Metastatic Prostate Cancer</td>
</tr>
<tr>
<td>87</td>
<td>A Pharmacokinetic Study of Genistein, a Tyrosine Kinase Inhibitor</td>
</tr>
</tbody>
</table>

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