



Newsletter

Prostate Cancer 101, Inc.

January, 2005

The Prostate Cancer Information and Support Group of the Mid-Hudson

A Message from Ron Koster

January Guest Speakers

Dr. Arun Puranik
And
Dr. Yoram Beer



Once again our PC101 group has the pleasure of presenting Dr. Puranik and Dr. Beer at our open meeting on **January 18th, 2005** at 4:30 p.m. in the Hurley Reformed Church, Hurley, NY.

The topic of their talk will be **Brachytherapy and Intensity Modulated Radiation Therapy (IMRT)**. They will also give us insight into the new IMRT equipment recently installed in their medical complex in Latham.

Dr. Beer is Board Certified in Adult and Pediatric Urology. He received his undergraduate education and his Medical Doctorate at Brussels University, Belgium. Upon leaving his birthplace of Tel

Aviv, Israel he became a U.S. Citizen and completed his Internship and Residency in General Surgery and Urology at Jewish Hospital and Medical Center in Brooklyn, NY. After practicing and teaching in Brooklyn, he established a practice in Urology in Troy and Clifton Park, NY whereby he became the Co-Director with Dr. Puranik of the Samaritan Hospital Brachytherapy Program.

In 1996 he and Dr. Puranik were responsible for establishing the 2nd facility in the North East for Radioactive Seed Implantation to the Prostate at Samaritan Hospital, Troy, NY. Together they have done more than 900 implants and Dr. Beer has been a preceptor for many local physicians regarding Brachytherapy and assisted in establishing a Brachytherapy facility in Plattsburg, NY.

Dr. Beer also has expertise in Extracorporeal Shock Wave Lithotripsy and assisted in the establishment of Mobile Lipotripter Service to the Capital District.

Dr. Arun Puranik is a certified Radiation Oncologist with a practice in Latham, NY. Upon completing his residency in Up-

state Medical Center, Syracuse, NY he was an Assistant Professor, Department of Radiation Oncology at Albany Medical College and Albany Regional Oncology Program.

In 1990 and until this past July he was the Co-Chairman of the Prostate Brachytherapy Program at Samaritan Hospital's Cancer Treatment Center in Troy, NY. He was instrumental in getting the regions first intensity modulated radiation therapy (IMRT) machine for external beam radiation therapy. IMRT requires computerized delivery of treatment with multiple segments with better conformality to the target area with minimal dosage to the neighboring structures. At present he is heading up the IMRT program at Community Care Physicians in Latham, NY.

Dr. Puranik has been a frequent speaker at numerous community education conferences on Prostate and Breast Cancer, has published in his field and received "Physician of the Year Award" in 1997 by American Cancer Society of the Capital District, NY.

Please join us for this very informative meeting where your questions will always be welcomed.

Notes from Ron Koster

Department of Defense Prostate Cancer Research Program

The U. S. Department of the Army has again invited me to nominate individuals to participate in the Department of Defense (DOD) Prostate Cancer Research Program (PCRP) scientific peer review committees. Gene Groelle, Ward Miller and Jack Spyker-Oles have previously been nominated, and all three were subsequently invited to participate. Gene has written about his experience in a previous edition of our Newsletter. Both Ward and Jack had to postpone their acceptances because of family or business conflicts.

Nominees must satisfy the following primary eligibility criteria:

- A prostate cancer survivor
- An active participant in a cancer-related organization (support, outreach, advocacy)
- At least a high school education or equivalent
- Ability to read and write English
- Demonstrated interest in extending their personal scientific knowledge

* Willingness and ability to represent the views of Prostate Cancer 101, and not just their own personal perspective

For the Fiscal Year of 2005 Prostate Cancer Research Program, it is anticipated that each peer review committee will meet for two days during early April 2005 in the metropolitan Washington, DC area. Travel, accommodations, meals, and an honorarium of \$1250 will be provided by the PCRP. Expect to invest at least five days studying material in preparation for the actual meeting.

Men interested in being nominated should contact me as soon as possible, but no later than January 15, 2005.

Distinguished Lecture Series 2005

At this time, the 2005 DISTINGUISHED LEC-

TURER program is not quite complete, but it is shaping up to include some of the most important medical professionals in the Prostate Cancer business.

February 15, 2005	Dr. Hugh Fisher, Albany Medical Center
March 15, 2005	Dr. Howard Scher, Chief of the Genitourinary Service, Memorial Sloan Kettering Cancer Center, NYC
April 19, 2005	TBA
May 17, 2005	Dr. T. Ming Chu, Chair Emeritus, Department of Diagnostic Immunology Research and Biochemistry, created the PSA assay, Roswell Park Cancer Institute, Buffalo, NY
June 21, 2005	Dr. Ashutosh K. Tewari, pioneer in Robotic Prostatectomy, Weil Cornell Medical Center, New York Presbyterian Hospital, Brady Urologic Health Center, NYC
July 19, 2005	TBA
August 16, 2005	Dr. Peter C. Albertsen, Urologist, Researcher, University of Connecticut Health Center
September 20, 2005	Dr. Peter Scardino, Chairman, Dept. of Urology; Florence and Theodore Baumritter/Enid Ancel Chair of Urologic Oncology, Memorial Sloan Kettering Cancer Center, NYC
October 18, 2005	Dr. Michael Dattoli, Pioneer in Radiation Oncology Brachytherapist; Dattoli Cancer Center & Brachytherapy Institute, Sarasota, Florida
November 15, 2005	Dr. Kenneth Chu, Chief of Radiation Dosemetry, Hudson Valley Radiation Oncology Group

Personal Information Update

We have attempted to update the information for our membership, mailing and e-mail lists for several years by recruiting volunteers to make tele-

phone calls to individual members to complete and update the information on our membership list. While this technique has been somewhat successful, we realized that Prostate Cancer 101 is at a point where we need much more information to continue to successfully serve the membership and the community.

As you know, we attempt to provide each newly diagnosed member who attends our PCa 101 seminar with a lot of information and guidance, but one of the most important things we provide each member is an updated membership list. He can study the list, determine who was diagnosed at approximately the same age he was diagnosed and call those individuals and discuss their experience. Others may come to the seminar with a preconceived notion of the treatment they intend to pursue. Some want to know more about the experiences other members have had with particular doctors.

We have enclosed a printed sheet titled "PCa 101 Personal Information – Update" on which you can update the information on the confidential PCa 101 membership list distributed to new members. The form is inserted in a self-addressed envelope which you should use to return it after updating the information. **Please complete the "Personal Information Update" form and return it today!**

One of the questions requests that you include the treatment code(s) that you have experienced, and refers to this listing:

Treatment Code

- A. Radical Prostatectomy
- B. External Beam Radiation
- C. 3-Dimensional Conformal Therapy
- D. Radiated implants, permanent seeds
- E. Radiated implants, temporary wires (HDR)
- F. Hormonal Therapy
- G. Cryosurgery
- H. Proton Beam Radiation
- I. Neutron Radiation
- J. Chemo Therapy
- K. Watchful Waiting
- L. Alternative-Supplemental Treatments

- M. IMRT, Intensity Modulated Radiation Therapy
- N. Orchiectomy
- O. Penile Implant
- P. Artificial Sphincter
- Q. Laparoscopic Prostatectomy
- R. Robotic Laparoscopic Prostatectomy

Please be sure to include all treatments you've experienced, in the order you experienced them.

Updated membership lists are available to the membership. Simply e-mail or call me.

Newsletter Subscription?

We are currently mailing hard copies to the entire membership on a quarterly basis. While we are searching for funding which will allow us to increase the number of hard copies of our monthly Newsletter, we recognize that about 33% of our membership is not on-line, and has no access to most of our Newsletters. Until our treasury allows us to send you twelve "hard" copies a year, we can make them available by subscription. A 12-month subscription costs \$12.00. Newsletter mailings to the entire membership are not deducted from the twelve issue subscription order. If you want to a subscription, write your \$12.00 check, payable to PCa 101, noting that is for a "subscription" and send it in the same envelope with your Personal Information Update.

Howard Adriance

Our long-time "chaplain", octogenarian skier, windsurfer and X-treme sport addict has moved. Howard and Gesa now live at: 132 Grande Meadow Way, Cary NC 27513-3177. We'll miss Howard, and his invocation at the monthly DISTINGUISHED LECTURER presentations.

Dakin Morehouse said a few words at the start of our December meeting. If you are interested in doing an invocation, or simply want to open each meeting with a few words of reflection, please contact me.

Prostate Cancer 101 Seminar

About 130 Ulster County men are being diagnosed with Prostate Cancer each year. Probably even more Dutchess County men are being diagnosed each year. Even though our members come from a geographic area far larger than these two counties, we are not seeing nearly as many newly diagnosed men at our monthly seminar (first Tuesday of each month, Dutch Room, Hurley Reformed Church Hall) as we should be seeing.

We have expanded the focus of the monthly seminar – men who have been treated and suspect or know that they are experiencing recurrence, or have other concerns are also invited to attend the monthly seminar to share their concerns and talk about appropriate alternatives.

If you are aware of newly diagnosed men, or treated men experiencing problems, please encourage them to attend our seminar. Offer to drive them to the seminar.

Grants

John Breithaupt is going to research the possibilities of obtaining an educational grant from IBM to help us expand our work. If you are currently employed by IBM, or are an IBM retiree, please call John (845-331-2168) and let him know. We suspect that IBM may be more disposed to grants to an organization which includes a large number of IBM employees.

If you work or are the retiree of another firm that is known to award educational grants to worthy causes, please call John. We really need help accomplishing our program Goals and Mission:

Program Goals

Patient education - to provide accurate information about diagnosis, treatment options and related quality-of-life issues for prostate cancer.

Support - to provide support, encouragement, and solutions to common problems associated with prostate cancer.

Awareness - to promote awareness of prostate cancer as a major health care concern for all men.

Mission Statement

To provide information about prostate cancer to the public

To bring together men who have been diagnosed with prostate cancer, physicians, and other health care professionals

To provide forums for men, their partners, friends and family to learn about diagnosis and treatment options through presentations, written materials, and videos

To encourage and empower men who have been diagnosed with prostate cancer to take a proactive role in educating themselves in the options and treatments of their disease

To create a consistent meeting environment that encourages men to discuss their concerns openly and honestly and to share solutions to common problems

To provide opportunities to promote a greater public understanding of prostate cancer, particularly the need for early detection and treatment

To explore the impact of prostate cancer on partners by encouraging them to participate in discussions when possible

Report on prostate cancer frames debates on treatment

The Prostate Cancer Foundation (PCF) has issued a Report to the Nation on Prostate Cancer that addresses the urgent need to improve the management of prostate cancer and accelerate the development of better treatments and a cure.

This year, 230,000 men will be diagnosed with prostate cancer in the United States, and 30,000 are expected to die from the disease. Today, about two million men are battling prostate cancer, and over the next decade, about three million more will be compelled to join the war.

Report executive editor, Peter Carroll, MD, chair of the Department of Urology at the University of California, San Francisco, commented, "It is imperative that continued advances be made in the scientific understanding and optimal treatment of prostate cancer.

"Despite the high profile and high prevalence of the disease, there remains considerable controversy surrounding the benefits and risks of early detection and there continues to be a lack of consensus for the management of many stages of the disease.

"The Report to the Nation on Prostate Cancer identifies the areas of consensus and frames the

debates regarding the treatment of prostate cancer. Most importantly, it helps to establish an agenda for research that must be undertaken to advance the field," he said.

The PCF's Report to the Nation on Prostate Cancer, authored by 24 leading prostate cancer physician-scientists, offers a comprehensive review of the state of the art in prostate cancer prevention, diagnosis, treatment, and research.

One key aim of this report is to present and summarize current and emerging information on treatment strategies for every stage of the disease - establishing a common framework for a dialogue among the various specialists treating patients with prostate cancer.

An underlying theme of the report is the need for multidisciplinary collaboration among urologists, radiation oncologists and medical oncologists at all stages of the disease to optimize therapy and to expedite the development of new therapies.

Source: Prostate Cancer Foundation

January Birthdays

Name	DOB
Philip E. Kyritz	4-Jan
Walter A. Lastig	6-Jan
Bruce G. Schoonmaker	6-Jan
Sinclair Blake	9-Jan
Robert Gorsline	9-Jan
Clinton Bubb, II	10-Jan
Myles Carton	10-Jan
Peter Grasse	10-Jan
Louis Smith	10-Jan
Anthony Quinn	11-Jan
Guy V. Goldsmith	14-Jan
David Marell	14-Jan
Charles Farcher	17-Jan
John W. Dixon	20-Jan
Chris Pappas	21-Jan
Calvin Brueckner	22-Jan
Ferrell F. McElrath	22-Jan
Raymond St. Rose	23-Jan
Leonard Botto	25-Jan
Gene Gormley	28-Jan
Sam Kates	28-Jan
Donald C. Markle	29-Jan

Birthdays are announced on Kingston radio station WKNY (1490 am) between 7:15 and 7:25 a.m. and between 7:40 and 7:50 a.m. on WGHQ (920 am) each day on the early morning shows. Listen for Birthday Greetings from "The Gang".

Each station also draws a name from all the men, women, and children celebrating birthdays each day for the award of "special gifts" Many of our members have been selected as winners but not all have picked up their prizes.

Six-Month Androgen Suppression Plus Radiation Therapy Vs Radiation Therapy Alone for Patients With Clinically Localized Prostate Cancer: A Randomized Controlled Trial

D'Amico AV, Manola J, Lofredo M, Renshaw AA, De-laCroce A, Kantoff PW
JAMA. 2004;292(7):821-827

Patients with clinically localized prostate cancer who choose to undergo radiotherapy for definitive treatment can be divided into low-, intermediate-, and high-risk categories on the basis of clinical stage, Gleason grade, and prostate-specific antigen (PSA) value.

Patients with low-risk disease have only a 10% biochemical recurrence rate within 5 years of treatment. It is thus difficult for any adjunctive treatment to improve outcome and survival in this group.

Randomized trials in patients with high-risk disease have shown that long-term (ie, greater than 3 years) androgen ablation improves survival in this group of patients, whose biochemical disease-free survival rate at 5 years is about 20% to 30%.

The majority of patients, however, belong to an intermediate-risk group, and the role of adjunctive androgen ablation with radiation therapy is more controversial. Other randomized studies

have shown that concomitant androgen ablation improves biochemical disease-free survival, but an effect on survival has not yet been demonstrated.

This trial thus makes a major contribution and validates a common clinical practice. A total of 206 patients were randomized to 70 Gy 3-dimensional conformal radiotherapy alone or with the addition of luteinizing hormone-releasing hormone agonist injections starting 2 months prior to initiation of radiotherapy and continuing through 2 months following radiotherapy. Patients had a PSA of at least 10 ng/mL or a Gleason score of at least 7, thus effectively excluding low-risk patients.

The Kaplan-Meier 5-year survival estimate in the combined therapy group was 88% vs 78% in the radiotherapy alone group ($P = .04$). Other secondary efficacy end points also favored the combined therapy group. There was no increase in local or long-term toxicity.

This is now the second randomized trial to show a survival advantage with combined androgen

ablation and radiotherapy.

Of note, in this trial, and in direct contrast to the other trial, the duration of androgen ablation was much shorter, and included patients with a somewhat lower risk for recurrence.

Nevertheless, a number of important questions remain unanswered. Specifically, it is unclear whether concomitant androgen ablation also plays a role when higher radiotherapy doses using intensity-modulated radiation therapy or pelvic lymph node irradiation are utilized. In addition, the minimal duration of concomitant androgen ablation that is equivalent to long-term adjuvant androgen ablation is also unknown.

Perhaps most important, especially for high-risk patients, is whether prostate radiotherapy provides any survival advantage over androgen ablation alone. Ongoing trials should help address these important questions. (WS)

Source: Medscape

[Please complete the "Personal Information Update" form and return it today!](#)

How drug's rebirth as treatment for cancer fueled price rises

by GEETA ANAND, The Wall Street Journal

WARREN, N.J. -- When Celgene Corp. got its first drug approved, it priced a 50-milligram capsule at \$6. Today, it sells the same white capsule for nearly five times the original price, or \$29.

Little has changed to affect the cost of making the drug since it was first sold in 1998 as a treatment for leprosy and severe weight loss, or wasting, caused by AIDS. But today, it is primarily prescribed for cancer, a disease whose patients and advocacy groups have shown little interest in fighting for lower U.S. prices.

"When we launched it, it was going to be an AIDS-wasting drug," says Celgene's chief executive, John Jackson. "We couldn't charge more or there would have been demonstrations outside the company."

Celgene's drug is thalidomide, which earned world-wide notoriety in the 1960s for causing birth defects. The story of its reincarnation as an AIDS and cancer treatment shows how the political environment and drug companies' perception of what the market will bear drive decisions on drug prices in the U.S. For some serious diseases such as cancer, the sky is virtually the limit -- although it may not stay that way.

The ability to price medicines ever higher has helped fund the pharmaceutical industry's research and development programs, which bring new medicines to patients. It also fills the coffers of some com-

panies and their executives. Meanwhile employers, insurers and sometimes patients must pay the tab.

"For patients, the side effect of taking this drug is penury," says Raymond Comenzo, a hematologist at Memorial Sloan-Kettering Cancer Center in New York City.

Thalidomide is inexpensive to make. Fundacao Ezequiel Dias, a government laboratory in Brazil, sells 100-milligram capsules to the Brazilian government health system for seven cents. The pills are given to leprosy and cancer patients free of charge. A Netherlands pharmacy sells the same dose for about \$2.60.

Celgene began as the biotechnology department inside a big chemical firm, Celanese Corp., in the late 1970s. In 1987, after Celanese merged with another company, it decided to spin off the biotechnology division. The new company, named Celgene, at first focused on using biological processes to make industrial chemicals. But in the early 1990s it decided to move into pharmaceuticals because the old focus was "a lousy business," says Sol J. Barer, a founder of Celgene who is now chief operating officer. "Chemicals are priced on the cost of ingredients," he says, while pharmaceuticals are "priced on value."

In the 1990s, Dr. Barer, a chemist, was wandering the halls of Rockefeller University in Man-

hattan in search of products when he bumped into a scientist who was studying why thalidomide helped treat leprosy. She theorized that the drug acted to inhibit a protein associated with inflammatory diseases from asthma to rheumatoid arthritis.

Dr. Barer grew excited about thalidomide's potential but was wary of its history. In the early 1960s, the drug was found to cause horrific birth defects in the babies of mothers who had taken the drug for morning sickness. Most of the babies were born in Europe because the drug was never approved by the U.S. Food and Drug Administration. Some babies had no arms or legs, while others had deformed limbs.

Thalidomide was still being used in poorer countries because it was cheap and effective in treating leprosy and wasting in tuberculosis patients. U.S. AIDS patients were importing thalidomide illegally to treat wasting. Dr. Barer concluded that Celgene could get the FDA to approve thalidomide, despite its notoriety, if the company sought to sell the drug for AIDS.

Celgene began clinical trials to show thalidomide could reduce wasting in AIDS patients but unexpectedly found the amount of AIDS virus in patients' blood seemed to rise temporarily on thalidomide. That meant more testing would be needed. Dr. Barer says he decided on a quicker route: getting the drug approved for treating leprosy, for which substantial data existed in public health databases around the world. Once the drug was on

(Continued on page 8)

(Continued from page 7)

the market for leprosy, doctors could prescribe it for AIDS or any other disease, a practice known as "off label" prescribing.

The company devised a system for dispensing the drug that requires, among other things, regular pregnancy tests for patients of childbearing age. Since thalidomide had been around for decades and the composition couldn't be patented, Celgene would eventually patent this system of controlling distribution.

The FDA faced pressure from AIDS activists who wanted access to thalidomide. In July 1998, the FDA granted Celgene approval to market thalidomide for leprosy under the brand name Thalomid, giving the green light to those who wanted to prescribe the drug off-label for AIDS wasting.

The next challenge was setting the price. Mr. Jackson, a lanky former Marine who had held executive positions at Merck & Co. and American Cyanamid, took over as Celgene's chief executive in 1996. Mr. Jackson and Dr. Barer wanted to avoid antagonizing AIDS activists. "Our pricing people said if you charge more than \$3,000 (per year), they'll show up at the door," Mr. Jackson says.

Only after the price had been set at \$6 for each 50-milligram capsule did the two men fully realize thalidomide's potential to treat cancer. In 1997, Bart Barlogie, a cancer specialist in Little Rock, Ark., tried thalidomide on an elderly man with multiple myeloma, a cancer of the plasma cells in

bone marrow that afflicts 50,000 Americans. Dr. Barlogie was acting on the suggestion of Judah Folkman, a researcher at Children's Hospital Boston who studied substances that can deprive cancer cells of new blood vessels for growth. Dr. Barlogie's patient had a nearly complete remission.

On Dec. 6, 1999, Dr. Barlogie reported the results of a clinical trial: About 30 percent of 169 patients who had relapsed after other treatments saw levels of a protein associated with myeloma decrease by 50 percent or more after taking thalidomide.

Thalidomide was reborn as a cancer medicine just as the drug was eclipsed by new AIDS medicines that made wasting virtually a thing of the past in the U.S. Again it was being prescribed off-label since Celgene hadn't received FDA approval to sell the drug for cancer.

Celgene, like many small biotech companies, had lost money every year since its founding. In 1998, it reported a loss of \$32 million on revenue of \$3.8 million. Now it could begin to tackle those losses. Mr. Jackson says he knew he could charge a lot more for thalidomide as a cancer drug. The question, he says, was whether to double or triple the price immediately or make more gradual increases. He decided on the latter. In 1999, he raised the price by 21 percent to \$7.23 from \$6 for the 50-milligram thalidomide capsule. The cost for consumers at pharmacies is typically between 20 percent and 25 percent higher than what Celgene charges to drug distributors.

Celgene's revenue soared to \$38 million in 1999 and \$85 million in 2000. It became a star on the stock market, even though it continued to post losses. In February 2000, Mr. Jackson did a secondary offering, raising \$298 million at \$101 a share. Mr. Jackson and Dr. Barer, who had dreamed of turning Celgene into a major pharmaceutical company, acquired a San Diego cancer research firm in June 2000 for \$200 million in stock.

As the use of thalidomide spread, some cancer doctors noticed that they could get the same results with a lower dose. That was significant because thalidomide can cause a nerve disorder and sleepiness, especially at higher doses. At the end of 2000, the company says it found the average daily dose per patient had fallen by about 25 percent to 225 milligrams, from 300 milligrams a day per patient at the start of the year. That meant the average patient was spending less per day on thalidomide -- \$35.70 compared with \$43.38 at the start of 1999. Mr. Jackson believed Celgene could raise the price.

Over 2001 and 2002, he did so several times. The medicine remained cheaper than many cancer drugs and Mr. Jackson says he received few, if any, complaints. By the end of 2002, Celgene was selling the 50-milligram capsule for \$11.03. "By bringing it up every year, it was heading toward where it should be as a cancer drug," says Mr. Jackson.

It was a time in which

(Continued on page 9)

(Continued from page 8)

"companies just raised the price and somebody paid the bill and nobody objected," says Margaret Tempero, a cancer specialist who is the immediate past president of the American Society of Clinical Oncology.

In December 2002, Mr. Jackson made another acquisition, a New Jersey company that harvested stem cells from human placentas after pregnancy, for \$45 million in stock. At the end of 2002, Celgene reported a loss of \$100 million on revenue of \$136 million, as it continued to significantly boost its research and development spending.

The next year brought another reason for raising the price. A biotechnology firm in Cambridge, Mass., Millennium Pharmaceuticals Inc., brought the drug Velcade to market in May 2003 for multiple myeloma, priced about twice as high as thalidomide. Velcade, delivered in an infusion in the hospital, cost about \$4,400 per month for the average patient, compared with around \$1,800 per month for a typical thalidomide user.

In June, one month after Velcade came to market, Mr. Jackson raised thalidomide's price by 10 percent to \$15.76 from \$14.33. "We felt certainly from a competitive perspective that would be justifiable," he says. By the end of 2003, the 50-milligram capsule of thalidomide cost \$22.32. In 2003, thalidomide sales nearly doubled to \$244 million. Celgene declared its first profit, of \$13.5 million.

Mr. Jackson says the price increase wasn't as rapid as it seems

because in 2003 Celgene also introduced 100-milligram and 200-milligram doses of thalidomide and didn't raise the prices of those higher doses as frequently. More than 60 percent of patients take 200 milligrams per day or more of the drug, according to Celgene. Previously they had to take four 50-milligram pills; now they could take a single 200-milligram pill and save some money.

Each year, as thalidomide revenue grew, Mr. Jackson plowed more money into research and development of new medicines. By 2003, the R&D budget at Celgene had reached \$123 million, which amounted to nearly half of the company's revenue of \$271 million. Part of the research budget funded three clinical trials of Revlimid, a drug the company believes could be more effective than thalidomide in certain cancers without the potential to cause birth defects.

As revenue grew, the company raised pay for top officers. In 2003, Mr. Jackson earned \$1.8 million in salary and bonus, compared with \$365,000 in 1998. He says he took a pay cut to take the job in 1996 because of the potential upside, particularly the stock options. By the end of 2003, he held 1.5 million stock options valued at \$31 million, according to the company's proxy statement. Other senior executives also received big increases in their salaries, bonuses and options.

Also last year, Celgene raised \$400 million in a convertible debt offering. The money helped it buy a Welsh manufacturer of

thalidomide for \$110 million this year. The company still sits on about \$800 million in cash and marketable securities. Celgene's shares, which have split twice since 2000, stood at \$30.41 in 4 p.m. Nasdaq Stock Market trading Friday, giving the company a market capitalization of about \$5 billion.

In theory a generic-drug company could sell thalidomide in the U.S., since the patent on the drug's composition expired long ago. However, it would need to get the FDA's approval for a distribution system to keep the drug out of the hands of pregnant women. Such a system would be difficult to devise without violating Celgene's five patents on its own system. And the FDA might hesitate to approve an alternative system because Celgene's system has worked well to prevent birth defects from thalidomide. Celgene says no other company has attempted to bring thalidomide to market in the U.S.

Celgene is seeking FDA approval to market thalidomide for multiple myeloma; currently, since the drug is only approved for leprosy, Celgene sales representatives aren't allowed to directly promote it for other uses.

This year, Mr. Jackson has raised the price of the 50-milligram capsule twice, by a total of 32 percent, to take it to \$29.44 from \$22.32. The current price of the 200-milligram capsule is \$75.60, or about 36 percent cheaper than the 50-milligram capsule on a per-milligram basis. Patients who take 200 milligrams a day are now paying about three times as much as they did in 1998, while

those with a 50-milligram daily dose are paying nearly five times as much.

Still, Mr. Jackson says a month of thalidomide for a typical patient costs only about 60 percent as much as a month of Velcade, meaning there's room for more price increases. He says if he brought his drug to market today he'd sell it for the same price as Velcade. In fact, he told investors during a recent presentation at an industry conference to expect Celgene's next product, Revlimid, to be priced at twice the cost of thalidomide "unless the political environment changes."

Some on Wall Street believe such a change is looming. Oncologists have begun to complain that prices are out of hand. And the Centers for Medicare and Medicaid Services, the federal agency that covers health-care costs for seniors and the indigent, has proposed cutting federal reimbursements for the infused biotechnology medicines covered at present. Analyst Eric Schmidt at SG Cowen & Co. says he expects the federal agency to exert more pressure on drug prices when it begins covering most prescription medicines for seniors in January 2006.

Mr. Jackson argues the high prices don't hurt patients. "Either people are wealthy enough to pay or health insurance pays or our company gives the medicine away for free," he says. Don Baylor, the New York Mets' hitting coach last season, takes thalidomide to treat his multiple myeloma and says in an interview the cost of the drug is covered under Major League Baseball's health-insurance plan.

But other patients bear much of the cost themselves. Mary Lou Wright,

a retired insurance agent in Harrisonburg, Va., says she has paid a portion of the cost of thalidomide under her insurance plan, although she has enough income to make the expense manageable. Until Ms. Wright went off the drug recently, she paid \$289 a month for her prescription of 50 milligrams a day. "The price of the drug is outrageous," says Dr. Comenzo, the Sloan-Kettering oncologist who treats Ms. Wright and Mr. Baylor.

Celgene's free drug program, generous by industry standards, helps patients who earn less than \$38,000 a year and also have assets of less than \$10,000. It doesn't apply to people whose insurance is paying part of the bill. Dr. Comenzo's nurse, Alice Ford, says she sees many patients who struggle to pay for thalidomide and don't qualify for Celgene's free drug program. For that reason, she says, "I discourage the doctor from putting people on it." Velcade, though more expensive, has been covered by Medicare.

The two biggest advocacy groups for multiple myeloma haven't made lower drug prices a priority. "I try to focus on the positive rather than coming after them on price," says Kathy Giusti, president of the Multiple Myeloma Research Foundation.

Susie Novis, president of the International Myeloma Foundation, says taking on drug companies over pricing is a losing battle. "They won't even discuss it. They say, 'It is what it is,' " she says.

Dr. Comenzo, while praising the advocacy groups' work, accuses them of shying away from the pricing issue because they receive

substantial donations from Celgene and Millennium, among other drug companies. Ms. Giusti says drug-company donations don't influence her views on pricing. Ms. Novis says she surveyed her group and found only a minority of U.S. members worried about price. But she may take up the price issue in Europe, where patient groups and doctors have raised an outcry.

Celgene licensed the right to market thalidomide in Europe to Pharmion Corp. of Boulder, Colo. Pharmion sells the drug under a program for making life-saving medicines available before they've been officially approved by regulators. A patient in Europe on a daily dose of 100 milligrams would pay about \$30 a day to get thalidomide from Pharmion.

Pieter Sonneveld, a hematologist at the University of Rotterdam in the Netherlands, says his patients complained so much about Pharmion's price that he helped set up a pharmacy to make thalidomide and sell it at cost in the Netherlands through hospital pharmacies. It costs about \$2.60 for 100 milligrams, he says. However, if Pharmion gets marketing approval from European regulators it would have exclusive rights to sell the drug for multiple myeloma, making it more difficult for low-cost alternatives such as Dr. Sonneveld's to survive.

Miriam Jordan contributed to this article.

Source: GEETA ANAND, The Wall Street Journal

Living Longer With Prostate Cancer

If You Want to Help:

Prostate Cancer 101 Seminar

Fred Bell

Phone 845-338-1161
E-Mail: FWBell@aol.com

David Marell

Phone: 845-657-2969
E-Mail: dmarell@hvc.rr.com

Newsletter

Walter Sutkowski

Phone: 845-331-7241
E-Mail: wsutkowski@hvc.rr.com

Greeters

Bob Miggins

Phone: 845-382-1305
E-Mail:
gd7m37@verizon.net

2005 Program Committee

Arlene Ryan

Phone: 845-338-9229
E-Mail: Aryan@ulster.net

Dakin Morehouse

Phone: 845-688-5773
E-Mail: DakinWM@juno.com

Audio/Visual Master

Yavuz Birturk

Phone: 845-687-9403
E-Mail: WYEBEE@aol.com

Other PCa101 Activities

Ron Koster

Phone: 845-338-8005
E-Mail: RKoster@hvc.rr.com

NEW YORK (Ivanhoe Broadcast News) -- Patients with advanced prostate cancer usually must undergo standard chemotherapy, but there's a new combination of drugs that's giving some patients a whole new outlook on life.

Fourteen years ago, Carl Visoky received the grim diagnosis of prostate cancer. He says, "The doctor told me, 'Go home,' cause there's nothing he can do for me. It's too late, and it'll be over."

But today, Visoky is doing just fine -- thanks to a combination of two drugs -- Taxotere and estramustine. He says, "There was nothing else available at the time. I heard this drug was doing good, so I said, 'Why not?'"

Taxotere inhibits tubulin, a protein essential to cell division. Basically, it prevents cells from dividing and growing. It's used in patients who have hormone refractory prostate cancer, which means standard treatment has failed and the cancer is progressing.

Daniel Petrylak, M.D., an oncologist at NewYork-Presbyterian Hospital/Columbia, says, "Our study demonstrated that when you treated patients with the combination of Taxotere plus another drug called estramustine that there was a 20-percent improvement in overall survival. We've had patients who lived three, four, five

years with this treatment, where in the past they've only lived about 12 to 15 months."

But a prolonged life with this drug mixture has its share of side effects. Doctors say some patients suffer from nausea, fatigue, hair loss, infections from lowered blood counts, and blood clots.

Yet many patients tolerate the drugs just fine. Visoky is one of them. He says his quality of life is great.

This drug combination has not yet been approved by the FDA, although each drug is approved when used alone. If you're interested in learning more about the study or how to participate, talk to your doctor.

This article was reported by Ivanhoe.com, who offers Medical Alerts by e-mail every day of the week. To subscribe, go to: <http://www.ivanhoe.com/newsalrt/>.

If you would like more information, please contact:

Linda Betharte
Public Affairs
NewYork-Presbyterian Hospital
627 West 165th St., Suite 621
New York, New York 10032

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Atrasentan: targeting the endothelin axis in prostate cancer. Jimeno A, Carducci M.

Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University, Bunting-Blaustein Cancer Research Building, Room 1M89, 1650 Orleans Street, Baltimore, MD 21231-1000, U S A .

Endothelin axis deregulation triggers a series of events that lead to a profound deregulation in cancer cells, including key tumorigenic cellular events such as proliferation, invasion, escape from programmed cell death, new vessel formation, abnormal osteogenesis and the alteration of nociceptive stimuli. Atrasentan is a novel agent that effectively targets this pathway and is able to inhibit and/or reverse several of those events.

Biological and clinical activity in patients with prostate cancer has been demonstrated in a Phase III clinical setting by the suppression of markers of biochemical and clinical prostate cancer progression, and by a delay in time to disease progression, especially in patients with bone disease.

Source: PMID: 15566319 [PubMed - in process]

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