Having My Say on Healthcare Inequality: Editor’s Notes
by Virgil H. Simons

There is a prevailing situation today in American healthcare systems collectively called disparity, which suggests that minority populations experience a higher rate of disease incidence and mortality of prostate cancer simply because they are “minorities”. However reality is not so easily “black and white”; many Americans today work for companies that don’t provide a health insurance plan to their employees. While this in and of itself is a contributing factor to the condition of health disparity, even those who have insurance often are faced with the conundrum of getting health care versus other priorities in their lives. For example, I know of one family that currently has health coverage under the husband’s group plan. However, the monthly premium is $300 with a $4,000 deductible on a plan that covers 80% of medical costs. What this really means is that the family pays $3,600 per year so that they can pay another $4,000 out of their own pockets before insurance actually kicks in and they’re still left with 20% of the total bill to pay. No wonder many families are forgoing basic preventive care or not opting to have “insurance coverage” because they can’t afford to be sick, or to check to see if they are sick! As Hippocrates stated centuries ago, “Poor health in one sector of society is threat to the public health of the whole society.”

African-American and Latinos have disproportionately been particularly impacted negatively in many health situations and disease states, from diabetes to cardiovascular disease to just about every form of cancer.

(continued)
Prostate Cancer Roundtable Announces Collaborative Prostate Cancer Advocacy Web Site

WASHINGTON, Apr. 18, 2011 — The Prostate Cancer Roundtable is pleased to announce the availability of its new web site www.ProstateCancerRoundtable.net.

“This new Roundtable web site will make it easier for America’s prostate cancer advocates, patients, researchers, and clinicians to keep track of the shared priorities and policy initiatives of the 12 members of the Prostate Cancer Roundtable,” said Scott Williams, Vice President of the Washington-based Men’s Health Network.

“Membership of the Roundtable is comprised of national, not-for-profit organizations whose primary goal is the health and wellness of all men at risk for or diagnosed with prostate cancer,” Williams continued. “However, we strongly encourage all other interested parties — from local prostate support groups to large national organizations which have prostate cancer as a focus area — to join us in supporting our national policy agenda.”

A key strategic objective of the Prostate Cancer Roundtable has been to facilitate collaboration and cooperation between the many members of the prostate cancer community that have a shared interest in optimizing the prevention, early diagnosis, appropriate treatment, and long-term care of men at risk for or diagnosed with prostate cancer. By working closely together, we can increase the power of our individual voices on Capitol Hill and in state capitols around the country.

Prostate cancer risk is also significantly affected by issues of ethnicity and economics.

According to Thomas Farrington, Founder and President of the Prostate Health Education Network, “African-American men have one of the very highest rates of incidence and death from prostate cancer anywhere in the world. They are 1.6 times as likely to be diagnosed with prostate cancer and 2.4 times as likely to die of this disease as Caucasian Americans. Furthermore, in nearly every state in America, men who are uninsured or under-insured are at very high risk for diagnosis of advanced or late-stage prostate cancer.”

About the Prostate Cancer Roundtable

The Prostate Cancer Roundtable, representing America’s prostate cancer community, is a group of independent, patient-centric, not-for-profit organizations that cooperate to foster the development of policies supporting high quality prostate cancer research, the prevention and early detection of clinically significant prostate cancer, the appropriate care and effective treatment of men with prostate cancer, and the appropriate education of all men at risk for this disease. For more information, please visit www.ProstateCancerRoundtable.net.

The members of the Prostate Cancer Roundtable are: Ed Randall’s Fans for the Cure; Malecare Prostate Cancer Support; Men’s Health Network; National Alliance of State Prostate Cancer Coalitions; Prostate Cancer Foundation; Prostate Cancer International; Prostate Conditions Education Council; Prostate Health Education Network; The Prostate Net; US TOO International Prostate Cancer Education and Support Network; Women Against Prostate Cancer; ZERO — The Project to End Prostate Cancer.

Having My Say…

The causes and cures are open to research and debate, but we know that early detection is key to positive outcomes. Yet, in spite of the overwhelming evidence, most men, regardless of race or ethnicity, fail to act upon the facts. We’ve developed a template to help them understand the risk they face from prostate cancer and their odds against other health risks:

- Of being struck by lightning - 1:835,500
- Of dying in a plane/train/car accident - 1:6,279
- Of having a heart attack - 1:53
- Of dying from prostate cancer - 1:36
- Of getting prostate cancer - 1:6

And, if you’re African-American, the rate of incidence is closer to 1:5 and the risk of dying closer to 1:17. The mandate for personal health responsibility is clear!

A World Health Organization report stated that the U.S. is deficient in being able to deliver equal access to care when compared to other developed nations. We spend more than 1/6 of our Gross Domestic Product on healthcare and more than $650 billion on cancer care alone, totals greater than that of the next five industrialized nations combined. Yet we rank #37 in overall ranking of health system performance, far behind France and Italy that are #1 and #2 respectively.

There are a variety of reasons for the disparities in cancer screening and care, which range from genetic and hereditary factors, insufficiency in access to education and care, socio-economic limitations, as well as cultural perceptions of the system. We have failed to fully encompass the problem of inequality by focusing primarily on those clinical barriers: awareness, access and financial. More critically we have under-assessed the impact of attitudinal barriers in limiting full access to care, as theorized by Dr. Jean Bonhomme at Morehouse Medical School: stoicism in gender and work roles, fatalism in patient perspectives, distrust of the healthcare system and a belief that somehow the individual takes care of their own problems.

Lastly, we have heretofore been unable to grasp the role and impact of societal externalities on the individual and their ability to act responsibly in insure their personal health. How can an individual manage causative stress and health decision making in the face of work expectations for greater productivity and decreased employee populations? How should an individual prioritize preventive health maintenance in the face of increased insurance deductibles, higher co-pays, decreased coverage and family demands for the basics of shelter, food, clothing and education.

We can argue that disparity is all about need and access with professionals needing to insure their awareness of racial differences and patient needs. Yet, we see many incidences of professional “patient profiling” at the bedside wherein minorities, the poor, and the medically underserved often don’t receive the best standard of care based on the doctor’s bias/perspective in assessing the patient. While the Human Genome...
**OPINION:** A Time for Healthcare Reform

*By Blanca Rodriguez*

On March 23, 2010, President Barack Obama signed a comprehensive healthcare reform act into law: The Patient Protection and Affordable Care Act (ACA). This law is the culmination of decades of battles and debate seeking to provide access to quality healthcare. The number of Americans without health insurance has risen steadily over the years to an astounding 47 million. Many Americans also live without coverage of prevention services that are proven to improve health and extend quality of life. Various provisions in the Patient Protection and Affordable Care Act will give an estimated 32 million people access to quality insurance coverage and protect patients from losing coverage due to arbitrary acts of private insurers. Some key points of the legislation include:

**EXPANDING MEDICAID ELIGIBILITY:** Medicaid, the federal program for low income individuals, will be extended to all individuals below the age of 65 who meet specific income requirements. For the first time since its inception, Medicaid will allow childless adults to obtain coverage, if their individual income is up to 133% of the federal poverty level. This Medicaid expansion will also create a minimum threshold across all 50 states, eliminating the major disparities of Medicaid eligibility that currently exist. Furthermore, the Medicaid program will provide a minimum benefit package to all enrollees that includes essential healthcare services and preventive care. In addition to the expansion of the Medicaid eligibility standards, rates of Medicaid payments to primary care physicians will increase to Medicare payment levels. This portion of the program is extremely important due to the number of primary care providers that currently do not accept Medicaid, citing low primary care payment rates.

**HEALTH BENEFIT EXCHANGES:** Every state in the U.S. will develop healthcare benefit exchanges where individuals and small businesses with up to 100 employees are able to purchase health insurance. Any new health insurance plan will be required to offer a minimum level of

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**Getting the Information You Can Trust**

*By Virgil Simons*

More and more, as patients, we are expected to make informed decisions relative to our health care based on our own research and assessment of the situation. The recent Pew Internet study has reported that more than 110 Americans regularly seek health information online; but how do we know that the information we are obtaining is credible and appropriate to our making a correct decision.

One of the most important factors in finding an online source for health information is the Health on the Net Foundation Code of Conduct Certification. The (HONcode) for medical and health Web sites addresses one of the Internet’s main healthcare issues: the trustworthiness and credibility of information.

The Internet has become one of the most widely used communication media. With the availability of Web server software, anyone can set up a Web site and publish any kind of data, which is then accessible to all. The problem is therefore no longer finding information, but assessing the credibility of the publisher as well as the relevance and accuracy of a document retrieved from the Net. In many cases, a given Web site provides no appropriate documentation regarding the scientific design of a medical study, nor are studies made available that support given claims.

The Health On the Net Foundation has elaborated the Code of Conduct to help standardize the medical and health information available on the Internet. The sites are annually audited by HON, and all the websites certified by HON commit to respect the HONcode principles stated below:

1. **Authoritative**
   Any medical or health advice provided and hosted on this site will only be given by medically trained and qualified professionals unless a clear statement is made that a piece of advice offered is from a non-medically qualified individual or organization.

2. **Complementary**
   The information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her existing physician.

3. **Privacy**
   Confidentiality of data relating to individual patients and visitors to a medical/health Web site, including their identity, is respected by this Web site. The Web site owners undertake to honor or exceed the legal requirements of medical/health information privacy that apply in the country and state where the Web site and mirror sites are located.

4. **Attribution**
   Where appropriate, information contained on this site will be supported by clear references to source data and, where possible, have specific HTML links to that data. The date when a clinical page was last modified will be clearly displayed (e.g. at the bottom of the page).
Having My Say… continued from page 3

Project has affirmed that the concept of race is biologically meaningless, skin color can be a determinant in the initial medical work-up by the doctor. While we ask our doctors to be colorblind on the subject of race, have we fully understood the national culture of the doctor in his/her dealings with a patient of another perceived lower status culture? We have a shortage of physicians going into, or remaining in, primary care medicine; there is a shortage of more than 400,000 nurses to fill minimum staffing requirements of our population; and there is a continuing resistance to expand enrollment in U.S. medical schools, all of which have forced a greater reliance on professionals from other countries, many of whom bring with them their cultural biases. But, given that recent studies of healthcare professionals have shown beliefs that: black patients are less intelligent, more likely to abuse drugs, less likely to follow medical advice, and more likely to lack social support than whites, how then can we be certain that disparity is being effectively addressed.

Are we unable to overcome the systemic differences of education, income and insurance among our people to provide equal choice of care? Or, are we merely a society beset by perspectives of racialism that hinder our ability to be fair and balanced in providing healthcare service to our citizens. The answer to all of the above, and more, is “Yes!” Dr. Martin Luther King, Jr. passionately said, “Of all forms of inequality, injustice in health care is the most shocking and inhumane.”

continued on page 11

Getting The Information You Can Trust continued from page 3

5. Justifiability

Any claims relating to the benefits/performance of a specific treatment, commercial product or service will be supported by appropriate, balanced evidence in the manner outlined above in Principle 4.

6. Transparency

The designers of this Web site will seek to provide information in the clearest possible manner and provide contact addresses for visitors that seek further information or support. The Webmaster will display his/her E-mail address clearly throughout the Web site.

7. Financial disclosure

Support for this Web site will be clearly identified, including the identities of commercial and non-commercial organizations that have contributed funding, services or material for the site.

8. Advertising policy

If advertising is a source of funding it will be clearly stated. A brief description of the advertising policy adopted by the Web site owners will be displayed on the site. Advertising and other promotional material will be presented to viewers in a manner and context that facilitates differentiation between it and the original material created by the institution operating the site.

For the past 10 years The Prostate Net® has been certified to post the HON seal on our site and will continue to conform to the principles in bringing you the most credible, leading edge, patient-centered standard of care information enabling you, your caregivers and professionals to make those key decisions relative to treatment and quality of life.
Cixutumumab (IMC-A12)—A New Tool in the Treatment of Advanced Prostate Cancer?

By Diane Johnson

The Southwest Oncology Group (SWOG), a group of investigators from institutions across the U.S. dedicated to “improving the survival of cancer patients through cancer research”, have initiated a new investigational protocol to address the subject of advanced stage prostate cancer. The study is lead by the Principal Investigator, Evan Y. Yu, M.D., Associate Professor, Division of Oncology, University of Washington/Seattle Cancer Care Alliance/Fred Hutchinson Cancer Research Center.

The study is driven by patient care realities based on therapeutic failure and disease progression. The current standard of care for patients with metastatic prostate cancer is androgen deprivation therapy (hormone therapy). This has been the standard for many years and patients respond well to it. However, we have learned over time, that there are subsets of patients who do not respond as well and tend to not do as well in the long-term. The goal with this study is to test whether adding cixutumumab (IMC-A12) to standard hormone therapy will improve overall outcomes for patients. This drug is a monoclonal antibody that targets the growth factor IGF-IR, which is associated with the growth and progression of prostate cancer.

The targeted study population is those men with newly diagnosed metastatic prostate cancer who have either not begun, or are within 30 days of starting, hormone therapy (for example, Lupron, Zoladex, etc.). This is a Phase II trial of 180 patients. Men who qualify for the study will be randomly assigned to one of two groups: combined hormone therapy with or without cixutumumab (IMC-A12). This is a multi-center study with locations in Kansas, Michigan, Nevada, and Washington State. For more specifics on the trial and its criteria for patient participation, go to http://clinicaltrials.gov and search for clinical trial #NCT01120236.

CONTACT INFORMATION:
To find out if you qualify for this trial or to get more information, please contact:

SWOG Operations Group at (210) 614-8808. (They will look up the closest location where the study is being administered and refer your information to the appropriate study coordinator.)

More Hope for Advanced Stage Patients

by Virgil Simons

When I was treated for prostate cancer 15 years ago, my doctor counseled me that surgery was my best option for a chance to be “cured”, but if the cancer came back “we can always do something else.” Too often that “something else” was a start on the path to death from the disease with stops along the way for radiation and hormonal therapy.

Today we finally do have true options for long term survival with a good quality of life as seen by many of the drugs recently approved and/or in final clinical investigation. To this point we’ve spoken with Dr. Thomas Flagg, a medical oncologist at the University of Colorado’s Anschutz Medical Campus, about one of the most promising new drugs, Abiraterone Acetate, and a new clinical trial sponsored by the Southwest Oncology Group (SWOG).

Dr. Flagg, please give us some background on the concept for this trial.

TF: SWOG trial 9346 was an important study of men with prostate cancer involving the bone or other distant sites in which these men were given standard hormone therapy. This trial found that men with an initial “good response” to hormonal therapy, as measured by the fall in the prostate specific antigen (PSA) blood test, lived much longer than those with a poor initial PSA response. Specifically, men with a stable or falling PSA, which was still greater than 4 ng/ml after six month of hormone therapy, had a median survival of less than 2 years.

VS: What information did you gain from the study and how did it lead to the development of this new study?

TF: Based on these findings, we began to look for additional therapies for men with advanced prostate cancer who didn’t respond well to the initial hormone therapy — the high-risk group identified by the 9346 study. Abiraterone Acetate is a novel, experimental drug for prostate cancer that is administered orally. It blocks a specific enzyme (CYP17), which is critical for the production of testosterone, a key driver of prostate cancer growth. Standard hormonal therapies such as leuprolide or goserelin (delivered via an injection every 1- 4 months) decrease the level of testosterone by 90% or more; however, low levels of testosterone persist and play a role in the growth of prostate cancer. Notably, Abiraterone Acetate has been shown to eliminate nearly all of the circulating testosterone when combined with standard treatments. The Southwest Oncology Group is now designing a clinical trial for high-risk men with metastatic prostate cancer who have a poor initial response to hormone therapy. In the proposed study, the benefit of adding Abiraterone Acetate to standard hormonal therapies will be tested to see if more men achieve an unmeasurable PSA (< 0.2 ng/ml) with this approach and also assess its effect on survival.

VS: You’ve given us a good chart in identifying the patient criteria for inclusion in this study. Please talk us through the recruitment plan (based on attached S1014 file)
benefits, thus addressing current disparities. Additionally, insurers will offer four different levels of services, taking into account out-of-pocket expenses, premiums and benefits, plus a catastrophic coverage plan. In lieu of a public option, where the federal government acts as an insurer competing with private companies, the federal Office of Personnel and Management will contract with private insurers to develop two plans per state. Subsidies will be available to individuals/families with incomes from 100% to 400% of the federal poverty level to assist in purchasing insurance through the exchanges.

MEDICARE: The health reform legislation eliminates out-of-pocket cost-sharing for most Medicare-covered preventive and screening services. The services with no cost-sharing (copays, coinsurance and/or deductibles) include mammograms, cervical cancer screenings, prostate cancer screenings, flu shots, HIV screening, diabetes screening, medical nutrition therapy and others. In addition to eliminating cost-sharing for such preventive and screening services, the law will substantially reduce the cost of prescriptions for Medicare Part D enrollees. (However, Medicare Part B and Part D premiums will increase for those Medicare enrollees with higher incomes.)

CURRENT COVERAGE: The ACA does not affect those who have existing employee-sponsored healthcare coverage. Young non-disabled adults will be able to remain on their parent’s plan until the age of 26. Health insurance providers are required to eliminate annual and lifetime limits and abolish 90-day waiting periods for coverage. And all health insurance providers will be prohibited from imposing lifetime limits on coverage or canceling coverage, except in the case of fraud.

The Patient Protection and Affordable Care Act of 2010 seeks to address various problems within the current health insurance market:

- The introduction of state health benefit exchanges and subsidies for individuals to purchase health insurance encourages competition and innovation between current and new health insurance companies. For example, because current health insurance coverage in the United States is tied to employment status, there is no reason for health insurance companies to compete with one another for customers—they already have a guaranteed customer base. This lack of competition removes incentives to provide better services to their customers or to increase efficiency and performance. In addition, health insurance companies have been raising premiums steadily for the past 20-30 years.

- The Medicaid expansion standardizes programs across the states and still maintains income eligibility requirements. For those individuals who are not employed or who work at a job that does not offer health insurance, this is a major safety net for their healthcare needs. A lack of health insurance by one individual can affect us all. For example, many individuals often seek emergency care services at hospitals only when they are very ill. Because hospitals are expected to absorb these costs, there have been several hospitals that have had to close their ER facilities.

- The Medicaid expansion also guarantees that communities of color will have access to comprehensive preventive and ongoing medical services. This will help address existing severe disparities in medical care within this population.

- Lastly, the new rules will help protect all of us. The ACA will prevent health insurance providers from discriminating against potential customers with “pre-existing conditions” or dropping coverage if you become disabled, leaving you potentially bankrupt and unable to care for yourself. If your child is born with a severe developmental disability, the ACA will prevent your insurance provider from denying life-saving services because of a cap on lifetime care.

The ACA is an extensive and complicated piece of legislation and strong opposition has been voiced, particularly about the expected substantial increase in federal spending.

However, for too many years, working Americans have been at the mercy of their health insurance providers. There is still much to work out, but The Patient Protection and Affordable Care Act is a step in the right direction for healthcare reform in this country. Many say this law goes too far and others say it does not go far enough; however, it builds a foundation for accessible quality healthcare and provides real choices and support for American citizens.

Editor’s Note: The current debate within Congress as to continuing and sustainable provisions of the Act will ultimately compromise the broad sweeping changes originally enacted. We must make our voices heard with our legislators if we are to get the healthcare that we all desire, and deserve.
More Hope for Advanced Stage Patients  continued from page 5

TF: This study will be open to all SWOG centers, which are located around the country. We will specifically be offering this study to those men with advanced, metastatic prostate cancer, who have a PSA of > 4 ng/ml after 6 months of standard hormonal therapy.

VS: We’ve seen recent FDA approval of several new drugs; how does Abiraterone work in treating advanced stage disease versus some of the other agents approved or in trial, specifically MDV 3100 or Provenge?

TF: This is a much more optimistic time in prostate cancer, with several new medical treatments recently identified. Sipuleucel-T (Provenge) is a novel autologous cellular immunotherapy treatment. It is a first-in-class agent only approved for use in prostate cancer at this point. It is for men with metastatic and minimally symptomatic prostate cancer that is progressing despite hormone therapy. Each treatment is customized to each patient and involves leukapheresis (removal of some of the white blood cells), shipment of the patient’s blood to the production facility and the re-infusion of the patient’s treated blood several days later.

MDV3100, like Abiraterone Acetate, is also an oral hormonal agent, but it works in a different way. MDV3100 doesn’t reduce the level of testosterone, but rather blocks the androgen receptor, so that it cannot be activated by testosterone. This is similar to the mechanism of our current anti-androgens (e.g. bicalutamide), but it appears that MDV3100 may be more effective than the older anti-androgens, with several late-stage trials now being done or completed with MDV3100. In contrast, Abiraterone Acetate works to directly lower circulating testosterone levels. While our current hormonal treatments (leuprolide, goserelin, etc.) reduce the testosterone levels by 90% or more, the addition of Abiraterone Acetate reduces testosterone to unmeasurable levels. We believe that the complete or near complete elimination of testosterone with the addition of Abiraterone Acetate in these patients may improve their outcomes.

VS: Lastly, Dr. Flagg, if any of our readers want additional information or want to participate in your trial, how can they do this?

TF: SWOG trial 1014 is currently in the late stages of development and we expect it to be activated very soon. It will then be available to all SWOG sites nationally. Once opened, information about the trials and the locations in which it is open may be found at either the SWOG site or the ClinicalTrials.gov site, linked below. The search terms “1014” or “prostate abiraterone” may be used to search for the study — looking under studies currently open to accrual.

http://www.swog.org/Visitors/SearchProtocols.asp?Type=Open

Editor’s Note For Patients in Need:

Preliminary investigational results reported to date suggest that Abiraterone has clinical benefit for some patients with advanced stage disease. In order to offer therapeutic benefit on a compassionate care basis, the manufacturers of the drug are offering an expanded access program (EAP) to provide patients with the opportunity for treatment with the investigational drug, Abiraterone Acetate, before government approval.

Abiraterone acetate is an investigational drug and is not currently approved by the Food and Drug Administration (FDA). The safety and efficacy of abiraterone acetate has not been fully established or thoroughly evaluated by regulatory agencies. In accordance with local regulations, the EAP is either run as a clinical trial or on a named patient basis in a particular country.

Patients with metastatic, castration-resistant prostate cancer (mCRPC) who have progressed after treatment with taxane-based chemotherapy may be eligible to receive investigational drug based on certain criteria. For details on the program, visit the Website listed here:

http://www.prostatecancerearlyaccess.com/

To learn more about a study center, please contact the Customer Communications Center at (800) 457 6399 or MedInfo@CentocorOrthoBiotech.com.
Castration By Any Other Name!!

By Virgil Simons

In dealing with prostate cancer, as patients we have had to accept many terms and definitions applied to us and our treatment that need to be re-addressed. For examples, as patients and survivors we have somehow become “consumers”, as if we somehow went out shopping for a pound of prostate cancer! Equally, if not more distasteful, is that state of advanced stage disease wherein hormonal therapies are no longer effective and we become “Castration Resistant”! Well, Hell yeah! If I can resist castration, you bet I will.

Fortunately, two of our leading clinical practitioners as well as advocates for patient-centered care, have come forward to speak on our behalf. Drs. David Crawford and Daniel Petrylak wrote recently on the subject. Their commentary from the Journal of Clinical Oncology (Vol. 28, Nbr. 23, August 10, 2010) is reprinted as follows.

Castration-Resistant Prostate Cancer: Descriptive Yet Pejorative?

TO THE EDITOR: The euphemistic term castration-resistant prostate cancer (CRPC) has slowly entered the everyday lexicon of those who study and treat prostate cancer. Ahmann and Crawford1 utilized this term in 1987. Emanating from what used to be called hormone refractory prostate cancer and/or androgen-independent prostate cancer, this CRPC consensual definition was first formally reintroduced at a 2005 ODAC discussion on prostate cancer trial end points. Subsequently, in 2008, it was specifically defined in a Prostate Cancer Working Group Guidelines report, published in Journal of Clinical Oncology.2

At that time, Scher et al2 recognized that despite medical or surgical castration, prostate cancers were still sensitive to subcastrate levels of androgens, either emanating from the adrenal cortex or from prostate cancer cells themselves (with direct intracrine activation of the androgen receptor cascade).

However, there have been some concerns expressed by clinicians, and more importantly by patients themselves, that the term castration implies some sort of testicular removal, which has a negative connotation for many men who have this disease.

Hormone-refractory prostate cancer and androgen-independent prostate cancer did not have this perceived stigma, but in contrast, they have proven to be considerably inaccurate, as second generation androgen deprivation therapy clinical trials are beginning to demonstrate.3,4

Therefore, we would like to propose that a term such as endocrine-resistant prostate cancer may be a better description to utilize with our colleagues and patients. It is both accurate and less emotionally charged. Seen in this fashion, it gives us in the field, as well as our patients, a clearer way to view therapeutic options (which will increase significantly in the years to come).

Therapeutically, if patients knew their disease was either endocrine sensitive or endocrine resistant, potentially approvable agents like Abiraterone, MDV-3100, and even estrogenic compounds could be clearly delineated from the evolving non-hormonal options that are also coming down the pike, like immunotherapy, targeted agents, and newer chemotherapies.

E. David Crawford
University of Colorado Health Science Center, Denver, CO

Daniel Petrylak
Columbia University Medical Center, New York, NY

REFERENCES
Premature Death Among Men = Poverty for Aging Women

The poverty rate of older women is too often a function of their marital status. The 2000 Census offers insight into the problem. In each state, with two exceptions, there are significantly fewer men alive at retirement age than women, meaning that many women enter retirement as widows. For women who marry men approximately their own age, a national average of over 14% may be widows as they retire age 65-69), including over 15% in Massachusetts, Alabama, Missouri Rhode Island, many other states, and over 17% in states like New York, Mississippi, and New Jersey.

The gap in life expectancy between males and females is leaving more women in poverty than ever before. The problem is even more striking if you look at the age group 65-74. While males outnumber females at birth 105 to 100, in 2000 there were fewer than 80 men for every 100 women by the time they reach age 65 - 74.

The onset of poverty is most commonly attributed to factors directly related to the death of a spouse including the loss of income (the mean income for women drops from $23,284 to $11,121 after the death of her husband) and other expenses caused by the death. About 12% of elderly women and 7% of elderly men currently fall below the poverty line, with widowed women being 3 to 4 times as likely to live in poverty compared to married women of the same age. This is reflected in the U.S. Administration on Aging finding that over-one-half of elderly widows now living poverty were not poor before the deaths of their husband.

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ZYTIGA™ (abiraterone acetate) Receives FDA Approval For Treatment Of Metastatic Prostate Cancer After Priority Review

First Once-Daily, Oral Treatment for Metastatic Prostate Cancer Inhibits Androgen Production at All Three Sources

Horsham, Pa., April 28, 2011—Centocor Ortho Biotech Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved ZYTIGA™ (abiraterone acetate), an oral, once-daily medication for use in combination with prednisone for the treatment of men with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel.

Androgens are hormones that promote the development and maintenance of male sex characteristics. However, in prostate cancer, androgens can help fuel the tumor’s growth. Androgen production primarily occurs in the testes and adrenal glands; in men with prostate cancer, the tumor tissue is an additional source of androgens. ZYTIGA is an oral androgen biosynthesis inhibitor that works by inhibiting the CYP17 enzyme complex, which is required for the production of androgens at these three sources.

“This FDA approval represents a welcome new option in the treatment of metastatic prostate cancer,” said Howard Scher, MD, Chief of the Genitourinary Oncology Service, Sidney Kimmel Center for Urologic and Prostate Cancers at Memorial Sloan-Kettering, and one of the co-lead investigators for the Phase 3 clinical study. “As a clinician, I believe the efficacy and safety profile of abiraterone acetate, as well as its oral, once-daily formulation, will help address the important need for additional therapeutic choices for men living with this serious disease.”

“In a Phase 3 study, treatment with ZYTIGA plus prednisone showed a significant increase in median survival compared with placebo plus prednisone,” said Professor Johann S. de Bono, MD, FRCP, MSc, PhD, The Institute of Cancer Research, The Royal Marsden NHS Foundation Trust, and one of the co-lead investigators for the Phase 3 clinical study. “It’s an exciting time for men with prostate cancer, and I believe that ZYTIGA will play an essential role in clinical practice.”

Results of the pivotal Phase 3, randomized, placebo-controlled, multicenter study showed that at pre-specified interim analysis, treatment with ZYTIGA in combination with prednisone resulted in a 35 percent reduction in the risk of death (14.8 months vs. 10.9 months (hazard ratio (HR) = 0.646; 95 percent CI: 0.543, 0.768; p<0.0001)) and a 3.9 month difference in median survival compared to placebo plus prednisone. In an updated analysis, results were consistent with those from the interim analysis with a 4.6 month difference between the two arms in median survival (15.8 months vs. 11.2 months (HR = 0.74)).

At a predetermined number of events in the study, an interim analysis was conducted and it was determined that efficacy had been demonstrated. At that time, the study was unblinded at the recommendation of the Independent Data Monitoring Committee. Information regarding these results can be found at: http://www.centocororthobiotech.com/cobi/viewDocumentByTitleAlias.html?title=PR_101110.

The most common adverse reactions (greater than or equal to 5 percent) reported in the clinical study joint swelling or discomfort, hypokalemia, edema, muscle discomfort, hot flush, diarrhea, urinary tract infection, cough, hypertension, arrhythmia, urinary frequency, nocturia, dyspepsia and upper respiratory tract infection. Additional information is included in the Important Safety Information below.

“Prostate cancer is a significant public health threat in the United States,” said Wendy L. Poage, MHA, President, Prostate Conditions Education Council, a national organization committed to men’s health. “ZYTIGA is an important new option and a welcome addition to the armamentarium we have to fight this deadly disease.”
Having My Say  

continued from page 3

That therefore is the conundrum of disparity and health inequality we face in America: how are all members of our society not equally and equitably sharing the world’s best healthcare? We have seen many theories, initiatives and research targeted on disparity with minimal impact in changing the paradigm; but the essential equation is found in seeing that “Health” is not just having access to care, but in looking at those social conditions regarding it formed by the individual’s experience. We must look to improve the societal conditions - education, work, political imperatives, personal satisfaction – all of which will determine the health of our society today and in the future. Rudolf Virchow, a physician and an early proponent of public health, clearly provided the mandate for our legislators and public health administrators: “Health is an indirect measure of a society’s collective democracy.”
For immediate release (April 21, 2011)

Addition of atrasantan to standard chemotherapy for advanced prostate cancer shows no benefit in phase III clinical trial

NCI-supported SWOG trial S0421 closes early based on interim finding that atrasantan added to docetaxel and prednisone did not confer additional survival benefit to patients with hormone-refractory prostate cancer.

ANN ARBOR, MICH. – A Data and Safety Monitoring Committee (DSMC) has determined that patients in a phase III clinical trial given atrasantan in addition to a standard chemotherapy regimen for advanced prostate cancer did not have longer survival or longer progression-free survival than patients on the same chemotherapy regimen who got a placebo rather than atrasantan.

Almost 1,000 patients who had advanced, hormone-refractory prostate cancer were given up to 36 weeks of chemotherapy with docetaxel and prednisone. These patients were randomized so that one half got an additional pill with a dose of atrasantan while the other half got a placebo pill. Patients who completed their chemotherapy and showed no progression of the disease were given the option of continuing the additional blinded pill (atrasantan or placebo).

The study’s DSMC evaluated a planned interim analysis of trial data and determined the evidence indicating no benefit from the drug was strong enough to close the study early rather than waiting another 18 months as was originally planned. The DSMC did not find evidence that the drug was harming patients.

New patient enrollment to the study stopped in April 2010 and few patients continue to take the study pill. Patients still taking study medication should speak to their doctor about stopping safely and what to do with their remaining pills. Treatment assignment is being unblinded, so patients can learn from their study doctor whether they took atrasantan or a placebo.

The study ("S0421: Phase III Study of Docetaxel and Atrasantan Versus Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer") was supported by the National Cancer Institute (NCI) and was conducted by SWOG (formerly the Southwest Oncology Group) with the participation of several other NCI cooperative groups.

Atrasantan for the trial was provided under an agreement with Abbott Laboratories and was distributed by the Department of Veterans Affairs Cooperative Studies Program Clinical Research Pharmacy Coordinating Center.
Symposium Registration Information
(Please print this page, complete and mail to address found at the bottom of the page)

Name (Please list name as you wish it to appear)

______________________________________________________________________________

Address ________________________________________________________________________

City, State and Zip __________________________________________________________________

Contact Telephone # (Required) __________________________________________________________________

Contact Email (Required) __________________________________________________________________

Category:  
PATIENT  /  SURVIVOR  /  SPOUSE  /  PARTNER  /  CAREGIVER  /  PATIENT ADVOCATE  
UROLOGIST  /  MEDICAL ONCOLOGIST  /  RADIATION ONCOLOGIST  
NURSE PRACTITIONER  /  NURSE  /  HEALTH SERVICE PROFESSIONAL  /  STUDENT  /  FACULTY  

Registration for the Symposium is Free! Please indicate the location for which you are registering
(NOTE – a separate registration form is required for each person attending):

- May 21 – New Orleans, LA; Tulane University Cancer Center  
- July 23 – Jacksonville, FL; Mayo Clinic Medical Center  
- August 27 – Ann Arbor, MI; University of Michigan Cancer Center  
- September 17 – Chicago, IL; Northwestern University Lurie Cancer Center  
- October 29 – New York, NY; New York University Kimmel Center  

Specific details will be provided with registration confirmation.

Please return completed forms to:
The Prostate Net - P.O. Box 2192 – Secaucus, NJ 07096-2192
Email: support@prostatenet.org
Fax: 270-294-1565
For more information or to register by Phone: 1.888.477.6763
2011 Symposium Series

Prostate cancer is the 2nd leading cause of male cancer death globally and the most commonly diagnosed cancer in American men. As the baby boom generation matures and other factors of socio-economic impact, more and more men will be diagnosed with this cancer. While there has been some progress in reducing disease mortality over the past decade, there still remain many significant disease specific issues relative to risk awareness, advanced stage disease management, treatment options, reduction and/or elimination of pain and suffering attendant to a diagnosis.

Contributing to the impediments against this goal are the following factors:

1. The media tends to focus on the issue of screening versus the overriding concerns for risk awareness, appropriate diagnostics, informed decisions on treatment and on-going management of advanced stage disease

2. Physicians, engaged in the treatment and/or management of prostate and breast cancer, often are not able to implement the latest, evidence-based, information in their practices because of lack of awareness or access to the detail

3. Patients need to have awareness of, and access to, that information which will enable them to engage with their doctors to make the appropriate informed decisions as to their treatment

Individual presentations from all of the previous Symposia can be viewed at: http://prostatenet.com/page/

Building on the strength of this educational initiative over the past two years, we will continue this awareness/educational effort, targeted to both patients/spouses and healthcare professionals engaged in the care and treatment of patients. 2011 events will be presented as follows:

May 21 – New Orleans, LA; Tulane University Cancer Center
July 23 – Jacksonville, FL; Mayo Clinic Medical Center
August 27 – Ann Arbor, MI; University of Michigan Cancer Center
September 17 – Chicago, IL; Northwestern University Lurie Cancer Center
October 29 – New York, NY; New York University Kimmel Center

Registration for the Symposium is Free!
Click Here to download the registration form
For more information or to register by Phone: 1.888.477.6763