



# PUGET SOUND QUARTERLY

Oncology Nursing Society

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## Oncology Nursing - Back to the Basics

### Caring for Cancer Patients During and After Hurricane Katrina

Colleen Lemoine, ARNP, MN, AOCN

Healthcare institutions spend significant time and energy developing comprehensive emergency preparedness plans in anticipation of catastrophic events ranging from natural disasters to bioterrorism. Nursing's role within these plans is paramount given the impact these disasters have on individual and community health. Hurricane Katrina tested the emergency preparedness plans of numerous health care institutions in the metropolitan New Orleans area and the surrounding Gulf Coast. As an oncology nurse who remained at one urban, academic, public hospital in New Orleans during Hurricane Katrina and for four days after,

I was able to witness, first-hand, both the strengths and the shortcomings of my hospital's emergency preparedness plan. It is my hope that by sharing my observations and experience, future emergency preparedness plans can be improved to maximize the quality of care oncology patients receive during and in the wake of a major emergency.

A comprehensive emergency preparedness plan should be well planned,

well communicated, well practiced, and well executed. A dynamic and ongoing planning process, and input



*Hurricane Katrina caused massive destruction and catastrophic flooding in the Gulf Coast areas.*

from all departments, is critical for a successful plan. In addition, the plan should include well defined roles and responsibilities for participants while at the same time building in flexibility and numerous contingencies. The planning process should encourage participants to think outside of the box, consider worst case scenarios, and expect the unexpected.

The plan should be communicated to

everyone and everyone should be fully aware of their role in the plan. Communication of the plan should be formalized (policies and procedures), frequent and routine. Additionally, the plan should be communicated using a variety of formats (written, verbal, electronic) and forums (inservices, unit meetings, town halls, etc.).

Once the plan has been developed and communicated, successful implementation will only be accomplished with frequent practice of the plan in the form of drills, mock events and small scale actual events. Analyzing implementation of the plan during these practices will allow for improvements to the plan.

Finally, a successful plan is well executed. The plan should be applied as developed, communicated and practiced. Built in contingencies should afford the flexibility necessary to accommodate the changing nature of an emergency. Deviations from the plan should be documented so that future analysis can be performed and improvements can be made. I have never more fully appreciated the importance of a comprehensive emergency preparedness plan than in the face of Hurricane Katrina.

I have been the Clinical Nurse Specialist for Oncology and a member of the Emergency Preparedness Committee at my hospital since 1998. Because of the location of New Orleans, our most likely natural disaster is a hur-

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## **PRESIDENT'S MESSAGE**

# **Staying Active Promotes (Professional) Health**

**Barbara Otto NSN, CNRN, OCN  
PSONS President**

Exercise ferments the humors, casts them into their proper channels, throws off redundancies, and helps nature in those secret distributions, without which the body cannot subsist in its vigor, nor the soul act with cheerfulness.

— Joseph Addison,  
*The Spectator, July 12, 1711*  
*English essayist, poet, & politician*  
(1672 - 1719)

**W**e've all heard the many and varied recommendations regarding physical activity and health - is it 30 minutes five times a week or 60 minutes three times a week? As nurses, and especially as oncology nurses, we know the importance of a healthy lifestyle in the promotion of health and prevention of illness. We've also seen the numerous

reports that active engagement of the mind throughout life can aid cognition in later years. Activity promotes one's physical health. Activity can also promote one's professional health. Career building is one component of that, but even more important is one's own professional development.

In many ways, I'm preaching to the choir - you all must believe in professional development since your receiving this newsletter indicates that you are a member of both a national and local professional nursing organization. That's certainly a good start. My question to you then is "what do you do with membership"? Throughout my career, I have seen resumes and curriculum vitas that would list multiple memberships and professional activities, but didn't always see a corresponding knowledge base or practice. Those who listed all the names, but didn't keep their knowledge base or practice standards current were known as "paper members". I never really understood why those paper members didn't



*Barbara Otto*

take advantage of the opportunities afforded them by their professional organizations.

Please let me clarify that I do understand life gets crazy. Finding balance between work and life gets more difficult all the time, even for oncology nurses who know better than most how fragile and tenuous the really important things can be (I hope that none of you take your cell phones, PDAs, and laptops to bed with you as was reported in a recent 60 Minutes segment). So, the next question is "how

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## **EDITORS' NOTES**

**Cathy Goetsch, MSN, ARNP, AOCNP  
Janice Gibson, RN, MSN, OCN**

**T**he subject of fear came to mind recently when I realized that, thanks to Alfred Hitchcock and Psycho, I am not be comfortable in a bathroom unless I can see through the shower curtain. Although this feeling falls into the category of unreasonable fear, its power is unaffected by its lack of rational basis, and I always open the shower curtain.

Fear requires action. Our patients' fear of powerlessness in the face of their cancer diagnoses and treatment can be

mitigated by the support they find in like individuals. Myeloma Fighters! and Cancer Lifeline, two local cancer support organizations, are profiled in this issue, by Janice Gibbons and Nancy Thompson.

All of us fear natural disasters. Colleen Lemoine eloquently shared her story of surviving hurricane Katrina with us at our spring symposium. She has kindly written words of advise for this issue of our newsletter based on her experience of caring for patients during that time.

As nursing professionals we have fears that we deal with on a daily basis. We worry about the rapidly changing

and advancing body of knowledge that we need to assimilate practice safely and to provide the high level of patient care that we demand of ourselves. Ongoing continuing education is one of the best methods of keeping up-to-date. Nancy Thompson has given us a heads up on up coming revisions in the method that credit for contact hours will be figured. The Upcoming Events column provides some places to go for continuing education. Additionally you will find FDA announcements of recent approvals for new drugs and/or new indications.





## ***Back to the Basics:*** Katrina's Timing Shortened Necessary Preparation Time

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ricane and a large focus of our emergency preparedness has been directed at this possibility. I consider our emergency preparedness plan to be very advanced in that we have a specific individual hired for the sole purpose of spearheading and coordinating emergency preparedness efforts. Additionally, we have been honing our plan for the past ten years and our plan now includes ham operator resources and extensive collaboration with local and state agencies.

Code Grey is the term we give to the weather/hurricane related portion of our emergency preparedness plan. Our Code Grey plan has personnel divided into two teams - activation and recovery. There is a very well-defined process of preparation that each department in the hospital takes 96, 72, and 48 hours prior to expected landfall of a hurricane within the area. At 24 hours before expected landfall, activation is called and the activation team reports to the hospital to remain until the hurricane has passed. Once the hurricane has passed, the recovery team is expected to come in to relieve the activation team. Prior to Hurricane Katrina, I have been on the activation team for three other hurricanes, all of which helped me to be better prepared for activation during Katrina. Katrina was especially challenging because it was the weekend (when staffing is lighter and administration is not routinely in the hospital) when New Orleans came into the cone of landfall, and it came so quickly, we didn't have the usual 96 hours to prepare.

Katrina came on shore early Monday morning, August 29th, and although at first it looked like we had once again escaped disaster, as the broken levees continued to pour water into the city and the water continued to rise through Tuesday, it became apparent that the worst of our fears was being realized. Our hospital was surrounded by 6-8 feet of water and we were unable to effectively communicate with rescuers outside.



*A Hurricane Katrina victim stranded on his roof by the ensuing floodwaters.*

In my opinion, the single greatest obstacle encountered during the course of the Katrina emergency was the loss of electrical power. This is also the most universal consequence of an emergency likely to be experienced as it can be associated with blizzards, earthquakes, tornados, floods, and fires. It is imperative that we all think about the problems a prolonged loss of electricity would cause in our particular institutions. Although we had a large backup generator, it ultimately failed and we were forced to rely on several small portable generators. This translated into few precious pieces of equipment able to be powered - primarily ventilators, incubators, monitors in ICU and the pharmacy and blood refrigerators. The loss of power meant no climate control and it was as hot as the hinges of hell. No power also meant no elevator transport which meant that everything and everybody had to move up and down 8 flights of stairs to transport, food, water, medications, and medical supplies. No power meant no ability to perform labs (CBCs, drug levels, electrolyte levels), radiologic exams, dialysis or blood, urine or other biological cultures. No power meant no refrigerated foods/beverages

and no microwaves. Everything we ate or drank was pretty much room temperature. No power meant no computer access, no internet access, no copy machines, no ability to print patient censuses or to mass produce accounting of people in the facility. No power meant no ability to charge cell phones, listen to radios or even see much at night (although flashlights, lanterns and batteries had been widely distributed).

Close behind the loss of power as a formidable problem was the inability to communicate. Communication internally and externally was very difficult, incredibly frustrating and time consuming. There was really no single, reliable means of communication other than person to person. Ham radio communication was slow and land lines, cell phones and two-way radios all proved to be disappointingly unreliable.

We had no running water so hand washing was virtually impossible although we had a more-than-sufficient supply of waterless hand sanitizer. This is obviously a very significant problem for neutropenic patients, although we were fortunate to have had only one neutropenic patient whose counts were on the way back up prior to the storm. Plumbing was also crippled and although the toilets were physically usable, flushing was not possible. Buckets with plastic liners had been widely distributed but weren't widely used until toilets became full.

There were a number of challenges posed by the location of departments within the hospital. Our pharmacy, kitchen, CMS, laundry and sterile supply were all located in the basement which ultimately was completely flooded. Although what could be moved ahead of time had been, stoves, refrigerators, dishwashers and the biological safety cabinet could not be and they were lost.

Food and water was adequate but rationed, and we never lacked necessary medications, medical supplies or staff. Throughout the ordeal, taking care of

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# Coalition for Patients' Rights (CPR) Calls on AMA to Cease Divisive Efforts to Limit Patients' Choice of Providers

25 health care organizations unite to ensure patients a full range of health care provider options and the right to choose among them

**Washington, DC** - In response to divisive efforts by the American Medical Association (AMA) and other physician groups to limit the ability of licensed health care professionals to provide care to millions of patients, the newly formed Coalition for Patients' Rights (CPR) today urged all health care professionals to work together to counter the AMA's actions.

The CPR was formed to ensure that the growing needs of the American health system can be met and that patients have access to quality health care providers of their choice. The coalition represents more than 3 million

licensed professionals who provide a diverse array of safe, effective and affordable health care services.

In a joint statement endorsed by the 25 health care groups that comprise the coalition, the CPR expressed concern about the negative impact on patients if their ability to seek care from advanced practice nurses, psychologists, nurse midwives, chiropractors, and many other licensed, qualified health care providers is limited. The coalition is calling on the AMA and other physician groups aligned with the AMA to cease their divisive efforts to oppose the established practice rights of CPR members. The coalition also seeks an end to legislation at the state level that would reduce provider options for patients.

The CPR is especially concerned about efforts by the AMA and other physician groups that have formed the "Scope of Practice Partnership" to study

the work and qualifications of "allied health professionals" in rural and underserved areas.

"Limiting the ability of health care professionals to practice and provide appropriate care will place an enormous burden on the health care system," remarked Barbara Blakeney, MS, RN, President of the American Nurses Association, which is a member of the coalition. "As leaders of the health community, this coalition seeks to maintain the broadest range of provider choices for everyone," said Blakeney.

The coalition questions the objectives of the AMA and other physician organizations when they seek to advise consumers, regulators, policymakers and insurers on the ability of other health care professionals to offer the services they are allowed by law to provide. Health care providers are a critical source of care for patients throughout the United States, especially those who live in rural areas and medically underserved urban areas. Historically, people who live in rural areas have relied on a strong array of practitioners to meet their health care needs. Advanced practice registered nurses, social workers, and other professions that require rigorous educational preparation and ongoing instruction and certification are the

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## *Back to the Basics*: Finally Rescued on September 2nd

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the patients remained paramount.

Ultimately, we were rescued on Friday, September 2nd. Many of our patients were evacuated via helicopter off of two roofs at our hospital. Some patients left by boat. We had no way of knowing where patients were being taken and had little in the way of medical information to send with the patients. It was a tremendous challenge just to account for all the patients as they left the building. Staff left by boat after all patients had been evacuated and there was no way of knowing where the staff was being taken.

Living through Katrina was a tremendous challenge but for many oncology patients, the full impact of the experi-

ence has yet to be manifested. Continuity of care was significantly disrupted for many patients and dose intensity critically compromised. How this will impact survival remains to be seen. Many patients have yet to resume care and, with so many medical records destroyed in the flood waters, the subtle particulars of diagnosis, workup, and treatment are likely lost forever.

Katrina presented us with an opportunity to rethink how we prepare for emergencies, especially for the oncology patient. Providing for the uninterrupted care of patients over the continuum is a great challenge but one that is critical in maximizing the therapeutic benefit of treatment. Each of us can use this event as a springboard to better

prepare personally and professionally for the emergency situations that we may unfortunately face.

On a personal note, I would like to thank everyone who has offered prayers, words or thoughts of encouragement, or practical assistance for those affected by Katrina. I am especially grateful to the oncology community who so generously accepted and cared for our displaced patients. I am lifted up by the kindnesses shown by my wonderful oncology colleagues - on a daily basis to our patients and their families and to all of us affected by Katrina. I extend to you a very heartfelt and sincere "Thank you".



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backbone of not just the rural health care system, but the entire health care structure in the United States.

“Organizations representing medical doctors (MDs) and doctors of osteopathy (DOs) are not in the best position to conduct a balanced and fair assessment of an issue that directly affects their reimbursement,” said Mitchell H. Tobin, JD, Senior Director of Professional Practice Affairs for the American Association of Nurse Anesthetists, also a member of the coalition.

The coalition asserts that the AMA's actions affect the entire health care community and all current and potential patients.

“Health care professionals other than MDs and DOs have been key to assuring access to care for millions of patients in rural and underserved areas. Given the difficulty that so many people have in getting needed care, now is the time for all health care professions to work together, not to work against each other to meet the need,” said Dr. Russ Newman, PhD, JD, Executive Director for Professional Practice of the American Psychological Association.

The Coalition for Patients' Rights is continuing to expand and invites other health care organizations to join. More information is available at the website [www.patientcoalition.org](http://www.patientcoalition.org).



## ONS Awards, Grants, and Scholarships

Your dedication to providing quality cancer care to each and every patient you encounter is a testament to your commitment to oncology nursing. Why not get recognized by applying for the many awards, research grants, and educational scholarships available through ONS, ONCC, and the ONS Foundation? These opportunities are free for the taking, so don't pass up your chance to receive them!

- Get recognized for your dedication and commitment to oncology nursing and patients with cancer.
- Recognize your peers for their achievements in oncology nursing.
- More than 70 opportunities and \$500,000 are available in awards, scholarships, and research grants.

### Nominate Yourself or Your Colleagues and Win an ONS Membership\*!

For every nomination we receive from you, whether for yourself or your colleagues, you will automatically be entered into a drawing to receive one of four free ONS one-year memberships! So what are you waiting for?

Nominations can be submitted by Chapters or Special Interest Groups but are not eligible for the free membership drawing. Complete information, including applications, is available at the ONS website [www.ons.org](http://www.ons.org)

## President's Message: Many Opportunities to Promote Professional Health

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do I maintain that balance while still staying active in promoting my professional health?"

For me, I find it energizing and calming at the same time to broaden my knowledge. There is so much happening in our field that we never lack opportunities for evidence-based information to incorporate into our practices. The Oncology Nursing Society (ONS) and the Puget Sound chapter (PSONS) make it pretty easy to access. Have you taken a few minutes to look at all those great CE monographs and CD-ROMs you receive in the mail, or check out their websites? How about all those other great websites you find while searching for patient information? Have you thought about giving yourself a night out, attending one of the many informational dinners

about which you receive mailings? Does your organization have a journal club, in person or virtual? For those of you who are certified, these provide lots of opportunities for those CEs needed for recertification (often free of charge). Have you been to community event benefiting one of the many worthwhile patient and advocacy organizations recently? It doesn't have to take up a big chunk of time. Sometimes, it's only 10-15 minutes to read an article or participate in an activity.

The more we know and do, the bigger the difference we can make. Please take advantage of the professional opportunities that present themselves to you. The balance is challenging, but rewards are energizing. Promote your professional health as part of your healthy lifestyle.



## PSONS Members Honored

On April 27th, Cancer Lifeline held its sixth Annual Faces of Caregiving Awards Ceremony at the Washington State Convention & Trade Center. Two PSONS members were recognized as Caregiver at Work Honorees: Karen Brandstrom, RN, MS who works at Northwest Hospital & Medical Center and Nancy Thompson, RN, MS, AOCN who works at the Swedish Cancer Institute. Congratulations to our PSONS members for their caregiving work!



# Personalized Treatment Trial for Breast Cancer Launched

*National Cancer Institute,  
Bethesda, Maryland*

The Trial Assigning Individualized Options for Treatment (Rx), or TAILORx, was launched to examine whether genes that are frequently associated with risk of recurrence for women with early-stage breast cancer can be used to assign patients to the most appropriate and effective treatment. TAILORx is sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), and is coordinated by the Eastern Cooperative Oncology Group (ECOG). All of the NCI-sponsored clinical trials groups that perform breast cancer research studies have collaborated in the trial's development and are participating in this study.

"This trial is important because it is one of the first to examine a methodology for personalizing cancer treatment," said NIH Director Elias A. Zerhouni, M.D.

The majority of women with early-stage breast cancer are advised to receive chemotherapy in addition to radiation and hormonal therapy, yet research has not demonstrated that chemotherapy benefits all of them equally. TAILORx seeks to incorporate a molecular profiling test (a technique that examines many genes simultaneously) into clinical decision making, and thus spare women unnecessary treatment if chemotherapy is not likely to be of substantial benefit to them. The study will enroll over 10,000 women at 900 sites in the United States and Canada. Women recently diagnosed with estrogen receptor and/or progesterone

receptor positive, Her2/neu negative breast cancer, which has not yet spread to the lymph nodes, are eligible for the study. Overexpression of the Her2/neu gene carries poorer prognosis for patients.

TAILORx will determine the most effective current approach to cancer



treatment, with the fewest side effects, for women with early-stage breast cancer by using Oncotype DX™, a validated diagnostic test developed by Genomic Health, Inc., Redwood City, Calif., in collaboration with the National Surgical Adjuvant Breast and Bowel Project (NSABP), a network of cancer research professionals. TAILORx is the first trial to be launched as part of a new NCI program, the Program for the Assessment of Clinical Cancer Tests (PACCT), which seeks to individualize cancer treatment by using, evaluating and improving the latest diagnostic tests.

Research appearing online today in the *Journal of Clinical Oncology* provides strong evidence for the value of

using Oncotype DX™ to help women with this form of breast cancer determine whether they will benefit by adding chemotherapy to hormonal therapy. This study, as well as several other similar studies in recent years, provided the basis for the launch of TAILORx.

Breast cancer is the most frequently diagnosed cancer in women, with an estimated 212,920 new cases of invasive breast cancer expected in the United States in 2006. Over one-half of these women will have estrogen receptor positive, lymph node negative breast cancer. For 80 percent to 85 percent of those women, the current standard treatment practice is surgical excision of the tumor, followed by radiation and hormonal therapy. Chemotherapy is also recommended for most women, but the proportion of women who actually benefit substantially from chemotherapy is fairly small.

"A large number of these women are receiving toxic chemotherapy unnecessarily, and we need a means of identifying them," said Jo Anne Zujewski, M.D., senior investigator in the Clinical Investigation Branch of NCI's Cancer Therapy Evaluation Program. "TAILORx could help change the way we treat breast cancer and improve the quality of patients' lives, helping to better identify women who are likely to benefit from chemotherapy from those who are not."

Oncotype DX™ measures the levels of expression of 21 genes (whether they are transcribed into messenger RNA) in breast tumors. This assessment can more precisely estimate a person's risk of recurrence than standard characteristics, such as tumor size and grade. Based on the Oncotype DX™ gene expression analysis, a recurrence score from 0 to 100 is generated; the higher the score, the greater a woman's chance of having a recurrence if treated with hormonal therapy alone.

Women will be studied for 10 years, with an additional follow-up of up to 20 years after initial therapies. Based on their recurrence score, women will be assigned to three different treatment groups in the TAILORx study:

- Women with a recurrence score

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# FDA Approves of the HPV Vaccine to Prevent Cervical Cancer

## *Cancer Information Service - Northwest Region*

After nearly two decades of research have led to the recent the Food and Drug Administration (FDA) approval by of the vaccine Gardasil™, which protects against infection from the two types of human papillomavirus (HPV) that cause the majority of cervical cancers worldwide.

Population studies helped to establish the link between HPV infections and the disease, revealing that while most HPV infections do not lead to cancer, virtually all cases of cervical cancer were caused by HPV infection. NCI scientists Douglas Lowy, M.D., and John Schiller, Ph.D., pioneers in HPV research, then examined ways to boost the body's immune response to prevent the cancer-causing infection. This work led to the development of the technology on which the HPV vaccine is based.

"Genetic engineering - technology involving the manipulation of genetic material - was used to create this vac-

cine, which is made up of non-infectious virus-like particles (VLPs)," explained Lowy, chief of the Laboratory of Cellular Oncology in NCI's Center for Cancer Research (CCR). "These hollow spheres, formed by a single protein from the virus (L1 protein), trigger an antibody response that is capable of protecting the body against infection by the targeted virus types."

"Gardasil is similar to other immunizations that guard against other infection," said Schiller, deputy chief of the Laboratory of Cellular Oncology in CCR. "By preventing infection with two of the HPV types that can cause cervical cancer, this vaccine, if given prior to exposure to these sexually transmitted viruses, can protect women from ultimately developing cervical cancer." For this reason the recommended administration is to girls before they become sexually active, ages 9-26 yrs.

"This vaccine opens a new era in cancer prevention," said NCI Acting

Director John E. Niederhuber, M.D. "It has the potential to save women's lives, as well as to reduce health disparities in the United States and around the world." Niederhuber added, "NCI's immunology and vaccine research regarding HPV infection is far from finished. We continue to work on improved vaccines and immunization technology, to make these prevention strategies even more effective and accessible to women worldwide."

HPVs not targeted by the current vaccines also can cause cervical cancer; women should continue to be screened with a Pap test or an approved alternative screening method. Look for further improvements in the technology, but this is a major step forward in cancer prevention.

Additional information about HPV, vaccines, and cervical cancer is available at [www.cancer.gov/cancertopics/hpv-vaccines](http://www.cancer.gov/cancertopics/hpv-vaccines).



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## **TAILORx:** Trial Focuses on Effectiveness of Chemotherapy

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higher than 25 will receive chemotherapy plus hormonal therapy (the standard of care)

- Women with a recurrence score lower than 11 will receive hormonal therapy alone
- Women with a recurrence score of 11 to 25 will be randomly assigned to receive adjuvant hormonal therapy, with or without chemotherapy.

TAILORx is designed primarily to evaluate the effect of chemotherapy on those with a recurrence score of 11 to 25. Women in this last group will comprise 4,390 women, or about 44 percent of the study population. Because the degree of benefit of chemotherapy for women with recurrence scores between 11 and 25 is uncertain, TAILORx seeks to determine if the Oncotype DX™ test will be helpful in future treatment planning for this group.

Hormonal therapies in the trial are assigned based on menopausal status

and include tamoxifen and the aromatase inhibitors anastrozole, letrozole and exemestane. Women on the chemotherapy arm of the trial will receive one of several standard combination chemotherapy regimens considered to be the best available standard care today. It will also be possible for women participating in TAILORx to participate in other NCI-sponsored clinical trials, provided the therapy prescribed in the clinical trial is consistent with their assigned therapy in TAILORx.

Additional goals of this clinical study are to create a tissue and specimen repository for patients enrolled in the trial and to collect follow-up information regarding the health status of those who participate in the study. Tissue collected in this study will be stored for use in future studies to learn more about breast cancer and to evaluate, and potentially refine, diagnostic tests for treatment decisions to an even greater degree than in TAILORx.

"With TAILORx, we are taking a big step toward personalized medicine. By

using cutting-edge diagnostic tests, we'll be able to customize an individual's cancer treatment," said Joseph Sparano, M.D., Montefiore Medical Center, Bronx, NY, and Eastern Cooperative Oncology Group protocol chair.

Women in the study will have a physical exam performed by their doctor every three to six months for the first five years, then once a year after that for up to 20 years. An annual mammogram will check for signs of recurrence.

For eligibility and registration information regarding TAILORx, go to [www.ctsu.org](http://www.ctsu.org) and enter "TAILORx" in the search box.

To view the PDQ summary of the TAILORx protocol, including contact information for sites currently enrolling participants, go to [www.cancer.gov/clinicaltrials/ECOG-PACCT-1](http://www.cancer.gov/clinicaltrials/ECOG-PACCT-1)

For a complete set of links and other information related to TAILORx, go to [www.cancer.gov/clinicaltrials/digest-page/TAILORx](http://www.cancer.gov/clinicaltrials/digest-page/TAILORx)



# Recent FDA Drug Approvals

## Dr. Richard Pazdur

Director, Division of Oncology Drug Products  
Center for Drug Evaluation and Research, FDA

### REVLIMID®, lenalidomide for Multiple Myeloma

On June 29, 2006, the U.S. Food and Drug Administration granted approval to lenalidomide oral capsules (REVLIMID®, Celgene Corporation) for use in combination with dexamethasone in patients with multiple myeloma who have received one prior therapy. REVLIMID® is available under a special restricted distribution program, called RevAssistSM (described below).

Efficacy and safety were demonstrated in two randomized, double-blind, multi-center, multi-national, placebo-controlled studies comparing the combination of lenalidomide plus oral pulse dexamethasone versus dexamethasone alone in patients with multiple myeloma who had received at least one prior therapy. REVLIMID® (lenalidomide) was administered at a starting dose of 25 mg/day orally as a single 25 mg capsule on days 1-21 of repeated 28-day cycles. Dexamethasone was administered orally at a dose of 40 mg/day on days 1, 4, 9, 12, and 17-20 of each 28 day cycle for the first 4 cycles and then 40 mg/day orally on days 1-4 every 28 days in both treatment arms of both studies.

Data were evaluated from 692 patients in the two studies, 341 patients in Study 1 and 351 patients in Study 2. The primary endpoint of time-to-progression (TTP) was evaluated in a pre-specified interim analysis in each study. In Study 1, median TTP was 37.1 weeks in the lenalidomide/dexamethasone arm compared to 19.9 weeks with dexamethasone alone (HR=0.356; 95% CI [0.257, 0.494];  $p < 0.0001$ ). In Study 2, median TTP was not reached in the

lenalidomide/dexamethasone arm compared to 20 weeks in the dexamethasone alone arm (HR=0.392; 95% CI [0.274, 0.562];  $p < 0.0001$ ).

Safety data were evaluated from 691 patients in the two studies. Grade 3 and 4 neutropenia, thrombocytopenia, leukopenia, lymphopenia, febrile neu-

troponia, deep vein thrombosis, pulmonary embolism, atrial fibrillation, constipation, diarrhea, fatigue, pneumonia, hypokalemia, hypocalcemia, muscle weakness, neuropathy and depression were reported in a greater proportion of patients treated with the combination of lenalidomide and dexamethasone compared to dexamethasone alone.

Thrombotic or thromboembolic events, including deep vein thrombosis, pulmonary embolism, thrombosis, and intracranial venous sinus thrombosis were reported more frequently in patients treated with the combination of lenalidomide plus dexamethasone (12%) compared to dexamethasone alone (4%) in the pooled analyses. Patients and physicians are advised to

be observant for the signs and symptoms of thromboembolism. It is unknown whether prophylactic anticoagulation or antiplatelet therapy prescribed in conjunction with lenalidomide may reduce the potential for venous thromboembolic events. The decision to prescribe prophylactic measures should be considered carefully after an assessment of an individual patient's underlying risk factors.

Patients with renal impairment were excluded from the studies. Because lenalidomide is primarily excreted by the kidney, renal function should be carefully monitored. Females should be advised to avoid pregnancy while taking lenalidomide. Lenalidomide is an analogue of thalidomide, a known human teratogen that causes severe life-threatening human birth defects.

Reproductive toxicity studies are ongoing to assess lenalidomide's potential teratogenicity. To avoid fetal exposure, lenalidomide is only available under a special restricted distribution program called RevAssistSM. Under this program, only prescribers and pharmacists registered with the program can prescribe and dispense the product. Patients enrolled in the program to receive the drug must agree to comply with the requirements of the RevAssistSM program.

Full prescribing information including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at [www.fda.gov/cder/foi/label/2005/021880lbl.pdf](http://www.fda.gov/cder/foi/label/2005/021880lbl.pdf).

### Decitabine (Dacogen®) for MDS

On May 2, 2006, the U.S. Food and Drug Administration (FDA) approved decitabine for injection (Dacogen®, MGI Pharma, Inc.) for the treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed siderob-



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## COMMUNITY CROSSINGS

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# Cancer Groups Provide Resources and Support for Patients and Their Families

### Cancer Lifeline

*Nancy Thompson, RN, MS, AOCNS*

**C**ancer Lifeline was founded in 1973 by a cancer patient who could not find the community resources and support she needed to help her "life with it." The mission of Cancer Lifeline: "Optimizing the quality of life for all people living with cancer" guides its services to more than 9,000 people a year in the greater Seattle area. They offer all their services free of charge due to funding from the United Way and generous gifts and grants.

### Cancer Lifeline Services

**Family Support Program** - A family consultant meets in the home to open lines of communication, clarify concerns and help families deal with the impact of cancer.

**Kids'/ Parents' Group** - Kids have fun and make friends while identifying feelings and learning coping skills. Parents group held concurrently.

**Healing Arts Program** - A wide variety of creative experiences are presented from gardening to painting and poetry in a supportive community that encourages emotional healing.

**Health Promotion Program** - Education and physical activities are offered for people in all stages of treatment, recovery and survivorship. Class topics include nutrition, lymphedema management and exercise programs such as Stretch & Strength and Gentle Yoga.

**Lymphedema Education and Support Program** - Education and support for people with lymphedema.

**Lymphoma Specific Networking Group** - formed by lymphoma patients and survivors to offer information, education, support and connection.

**Colorectal Group** - Formed by colorectal cancer patients and survivors to provide information and support.

**Workplace Consultation** - Small group seminars held on-site in the workplace help managers and co-workers address issues that cancer creates on the job (there is a fee for this service).

**24-Hour Lifeline** - Staffed by Cancer Lifeline volunteers, this phone line provides supportive, caring listeners who can offer emotional support and information. Phone number is 206-297-2500.

### Contact Information

The Cancer Lifeline Centers are known for their warm and nurturing environment that avoid a clinical or office ambiance and are open Monday through Friday. Classes and programs are held at each site listed below.

**Cancer Lifeline Seattle**  
Dorothy S. O'Brien Center  
6522 Fremont Ave. N  
Seattle, WA 98103  
206-297-2100

**Cancer Lifeline Eastside**  
15255 SE 30th Place  
Bellevue, WA 98007  
425-747-4367

**Cancer Lifeline at Northwest Hospital**  
Professional Building  
1570 North 115th Street, Suite 3  
Seattle, WA 98133  
206-297-2100, ext. 114

**Website:** [www.cancerlifeline.org](http://www.cancerlifeline.org)  
**24-hour Lifeline** - 206-297-2500

### Northwest Multiple Myeloma FIGHTERS!

*Janice Gibson RN, MSN, OCN*

**T**he American Cancer Society estimates that this year there will be 16,570 new cases of Multiple

Myeloma (MM) and that 11,310 persons will die of their disease. With chemotherapy the median survival increased from 7 months to 24 - 30 months and the 10 year survival to 3%. Today many patients have more of a fighting chance because of newer therapies such as pulse corticosteroids, thalidomide, bortezomib, and autologous and allogeneic stem cell transplants.

The Northwest Multiple Myeloma (NWMM) FIGHTERS! are the Seattle area support/information source for patients and their families living with MM.

This group was founded in 1998 by Ray Larson who observed the need for support and information. The first five families met in Ray's home and the name MM FIGHTERS! was born. Ray died two months after this group was started. Today 15-20 families meet generally (but not always) on the fourth Saturday of every month between 10 am and Noon at the Aldersgate United Methodist Church in Bellevue Washington. The mission of the MM FIGHTERS! is to provide information, education, and hope to patients and their families by providing a discussion and question and answer group for persons newly diagnosed with MM.

Tom Blakney joined the team of Northwest Multiple Myeloma (NWMM) Fighters support group in February 1998. Tom's interest is a personal one. His first wife was diagnosed with multiple Myeloma in 1997 and died in 1999. He keeps the support groups running and runs the NWMM fighters website. Guest speakers at the meetings have included the Leukemia and lymphoma Society, Hospice, and nurses from PSONS. The web site provides links to recent publications. There are also links to the International Myeloma Foundation, and the Multiple Myeloma Research Foundation. Patients can also

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## Community Crossings: Northwest Multiple Myeloma FIGHTERS!

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access a tool kit which includes blood and bone marrow transplant resources and also addresses health and comfort concerns.

I asked Tom what changes he has seen in the last eight years. When Tom's wife died the survival was 2-3 years and patients may have been told to put their affairs in order. He has seen increases up to 6-8 years. I asked what nurses can do as advocates of patients with MM. He told me that information is the main thing. He would encourage patients to go to physicians who see more than 1-2 patients with MM per week, have up to date clinical and treatment information and have access to clinical trials. He also told me that things are going great right now and we are making progress in the treatment of MM.

Since the founding, the MM FIGHTERS! have met on a regular monthly basis on the 4th Saturday of each month at Aldersgate United Methodist Church in Bellevue, Washington. Monthly meeting attendance generally totals about 30 to 45 patients and

caregivers. The format of the two-hour meetings is not complicated: Every person present is given a chance to update the group on their status and concerns. In particular, new members are encouraged to participate and ask questions of anyone present. Several times a year, a speaker will present information of interest or the group will view a video tape. Refreshments are generally served with all encouraged to bring cookies or fruit!

One important aspect of the MM FIGHTERS! meetings is the Book Exchange and information table with the latest information from the front-line organizations in the fight to conquer multiple myeloma. Members are also encouraged to contribute as well as borrow books or other information which will provide medical or emotional support during their battle against MM.

At this time, there are about 140 families on the rolls of the MM FIGHTERS! throughout the Pacific Northwest including Alaska and Canada. About 95% have e-mail accounts and most communication occurs using the Internet. Newsletters

from other support groups and other news of interest are regularly forwarded to members. For members without e-mail, conventional snail-mail is used.

The MM FIGHTERS! charge no dues but maintain a Contribution Jar where funds donated are forwarded to the International Myeloma Foundation to help support MM programs.

### Websites

- American Cancer Society  
[www.cancer.org](http://www.cancer.org)
- International Myeloma Foundation  
[www.myeloma.org](http://www.myeloma.org)
- The Leukemia & Lymphoma Society  
[www.leukemia-lymphoma.org](http://www.leukemia-lymphoma.org)
- The Multiple Myeloma Research Foundation  
[www.multiplemyeloma.org](http://www.multiplemyeloma.org)
- NWMM FIGHTERS!  
[mmfighters.home.comcast.net](http://mmfighters.home.comcast.net)
- Cancer Lifeline  
[www.cancerlifeline.org](http://www.cancerlifeline.org)
- Gilda's Club  
[www.Gildasclub.org](http://www.Gildasclub.org)



### Looking for a unique opportunity to work outside of the clinical arena, yet still utilize your oncology nursing clinical skills and knowledge?

Consider working part-time hours (+/- 10 hours per month) for NexCura, Inc., a Seattle-based health care education and information company that develops proprietary, Web-based, clinical decision-support applications called NexCura® NexProfilers® Treatment Option Tools for patients, caregivers and providers to facilitate communication and promote better informed decisions about treatment options and care.

Oncology clinical specialist positions available for advanced practice RNs involve researching and writing material for online education tools. Hours are flexible, work at home or our office.

Must have experience and interest in providing/writing patient education and excellent computer skills.

Contact Judy Petersen, RN MN AOCN, Director of Clinical Development by email [judy.petersen@thomson.com](mailto:judy.petersen@thomson.com), or phone 206-272-1134 to learn more or submit your resume.





## **FDA Approvals:** Dacogen® Approved for MDS Injection Treatments

Continued from page 8

lasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

Safety and efficacy were demonstrated in an open-label, multi-center, randomized, controlled trial in 170 adult patients with all five French-American-British (FAB) subtypes of MDS and with International Prognostic Scoring System scores of High-Risk, Intermediate-2 and Intermediate-1. Eighty-nine patients were randomized to decitabine plus supportive care and 81 were randomized to supportive care. Patients randomized to the decitabine arm received the drug intravenously at a dose of 15 mg/m<sup>2</sup> over a 3-hour period every 8 hours for 3 consecutive days. This treatment cycle was repeated every 6 weeks, depending on the patient's clinical response and toxicity. Supportive care consisted of blood and blood product transfusions, prophylactic antibiotics, and hematopoietic growth factors.

Responses were classified using the MDS International Working Group criteria. Patients were required to be red blood cell and platelet transfusion independent during the period of response. The overall response rate (CR+PR) in the intent-to-treat population was 17% in the decitabine-treated group and 0% in the supportive care group ( $p < 0.001$ ). In the decitabine-treated group the median duration of response was 288 days and the median time to response was 93 days. All but one of the decitabine-treated patients who responded did so by the fourth cycle. Decitabine treatment did not significantly delay the median time to acute myelogenous leukemia or death.

A total of 164 patients were accrued to two additional open-label, single-arm, multi-center studies of decitabine in patients with any of the FAB subtypes of MDS. The overall response rates in these two studies were 26% (N=66) and 24% (N=98).

The major toxicity of decitabine was myelosuppression as manifested by neu-

troponia, thrombocytopenia, anemia, and febrile neutropenia. Other common adverse events included nausea, vomiting, diarrhea, constipation, fever, edema, hyperglycemia, hypomagnesemia, hypokalemia, arthralgias, back pain, cough, headache, insomnia, rash, petechiae, and pallor. No age- or gender-related differences in safety were detected. Patients with hepatic or renal dysfunction were not studied. Insufficient numbers of non-white patients were enrolled in these clinical trials to draw any conclusions.

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at [www.fda.gov/cder/foi/label/2006/021790lbl.pdf](http://www.fda.gov/cder/foi/label/2006/021790lbl.pdf).

### **Bevacizumab (Avastin®) for second line treatment of metastatic colon cancer**

On June 20, 2006, the FDA granted approval for a labeling extension for

bevacizumab (Avastin®, Genentech), administered in combination with intravenous 5-fluorouracil-based chemotherapy, for the second-line treatment of metastatic carcinoma of the colon or rectum. This recommendation is based on the demonstration of a statistically significant improvement in overall survival (OS) in patients receiving Avastin® plus FOLFOX4 (5-fluorouracil, leucovorin, and oxaliplatin) when compared to those receiving FOLFOX4 alone.

The trial (E3200) supporting this approval was an open label, randomized, 3-arm, active-controlled, multi-center clinical trial evaluating AVASTIN® alone (n=244), AVASTIN® plus FOLFOX4 (n=293), and FOLFOX4 alone (n=292). Following a planned interim analysis, the AVASTIN® monotherapy arm was closed to accrual based on evidence of decreased survival in patients treated with AVASTIN® alone compared with FOLFOX4 alone. Patients entered

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## **HIGHLINE CANCER CENTER**

Highline Medical Center's comprehensive system of care includes two health care campuses, a state of the art cancer center and more than 19 clinics across Southwest King County. Our acute care campus is located in Burien. The Highline Specialty Campus is in nearby Tukwila. Highline embraces the Planetree philosophy and utilizes the Baldrige National Quality Award criteria to achieve excellence. We are looking for a Registered Nurse to join our beautiful new **Outpatient Oncology Clinic**. Qualified candidates will have one-year recent acute care experience with Oncology experience strongly preferred. OCN preferred. One year Charge experience required. This is a full-time, days, 8:00a to 4:30p position with no weekends or holidays. Highline offers competitive salaries and benefits. In addition, we offer a community setting, free parking, and a convenient location, within 20 minutes of downtown Seattle.

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### **Please submit resume to:**

Highline Medical Center  
Attn: Miriam McDonald  
12844 Military Road South  
Tukwila, WA 98168  
Ph 206-248-4609 Fax 206-439-1035  
Email [mmcdonald@HighlineMedical.org](mailto:mmcdonald@HighlineMedical.org)

For more information visit our website <http://www.HighlineMedicalCenter.org>

## **FDA Approvals:** Underestimation of Avastin® Adverse Event Rates Likely

**Continued from page 11**

on the trial had progressive or recurrent disease following prior 5-FU and irinotecan-based therapy. Patients (99%) received irinotecan with or without 5-FU as initial therapy for metastatic disease; those who received adjuvant irinotecan-based chemotherapy were required to have recurred within 6 months of completing therapy.

In both the combination and monotherapy arms, AVASTIN® was administered at a dose of 10 mg/kg every 2 weeks. The FOLFOX4 regimen, administered every 2 weeks, consisted of oxaliplatin 85 mg/m<sup>2</sup> and leucovorin 200 mg/m<sup>2</sup> administered concurrently as an intravenous infusion, then 5 FU 400 mg/m<sup>2</sup> IV bolus followed by 5 FU 600 mg/m<sup>2</sup> continuous intravenous infusion on day 1. On day 2, patients received leucovorin 200 mg/m<sup>2</sup> IV, then 5 FU 400 mg/m<sup>2</sup> IV bolus followed by 5 FU 600 mg/m<sup>2</sup> continuous intravenous infusion. When given in combination with FOLFOX4, AVASTIN® was administered on day 1 prior to oxaliplatin and leucovorin.

Among the 829 randomized patients,

the median age was 61 years and 49% had an ECOG performance status of 0. Twenty-six percent had received prior radiation therapy, 80% received prior adjuvant chemotherapy, and all received prior irinotecan therapy.

Overall survival, the trial's primary endpoint, was significantly longer in patients receiving AVASTIN® in combination with FOLFOX 4 as compared to those receiving FOLFOX4 alone (median OS 13.0 mos vs. 10.8 mos; hazard ratio 0.75, p=0.001 stratified log rank test). The survival benefit was also observed in subgroups defined by age (65 yrs) and gender. Patients treated with the AVASTIN® combination were reported by investigator assessment to have significantly longer progression-free survival and higher overall response rate.

**The most serious, and sometimes fatal, AVASTIN® toxicities are** gastrointestinal perforation, wound healing complications, hemorrhage, arterial thromboembolic events, hypertensive crisis, nephrotic syndrome and congestive heart failure. The most common adverse events in patients receiving

AVASTIN® are asthenia, pain, abdominal pain, headache, hypertension, diarrhea, nausea, vomiting, anorexia, stomatitis, constipation, upper respiratory infection, epistaxis, dyspnea, exfoliative dermatitis, and proteinuria.

In Trial E3200, data were collected only for National Cancer Institute-Common Toxicity Criteria (NCI-CTC) grade 3-5 adverse events (grade 5 being death). Therefore, these data are likely to underestimate the true adverse event rates (since mild grade 1-2 toxicities were not recorded). In addition, neither the time of onset nor the time to resolution of adverse events were collected.

NCI-CTC grade 3-5 adverse events that were more common in patients receiving the AVASTIN® compared to FOLFOX4 alone were fatigue (19% vs. 13%), diarrhea (18% vs. 13%), sensory neuropathy (17% vs. 9%), nausea (12% vs. 5%), vomiting (11% vs. 4%), dehydration (10% vs. 5%), hypertension (9% vs. 2%), abdominal pain (8% vs. 5%), hemorrhage (5% vs. 1%), other neurologic toxicities (5% vs. 3%), ileus (4% vs. 1%), and headache (3% vs. 0%).

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MINOR & JAMES MEDICAL, PLLC



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**Minor & James Medical, PLLC**



## FDA Approvals

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related adverse events in patients receiving AVASTIN® in this study included CNS hemorrhage, gastrointestinal hemorrhage, and gastrointestinal perforation with sepsis.

Full prescribing information including clinical trial information, safety, dosing, drug-drug interaction and contraindications is available at [www.fda.gov/cder/foi/label/2006/0125085s074lbl.pdf](http://www.fda.gov/cder/foi/label/2006/0125085s074lbl.pdf)

### Thalidomide in Combination with Dexamethasone for the Treatment of Newly Diagnosed Multiple Myeloma Patients

On May 26, 2006, the U.S. Food and Drug Administration granted accelerated approval for thalidomide (THALOMID®, Celgene Corporation) in combination with dexamethasone for the treatment of newly diagnosed multiple myeloma (MM) patients. Because of thalidomide's known teratogenicity, the FDA is controlling Thalidomide's marketing in the United States via the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.®) program. This mandatory registry includes authorized patients, prescribers and pharmacies, extensive patient education regarding thalidomide's safety, and is designed to prevent fetal exposure to thalidomide during pregnancy.

Thalidomide was evaluated in 207 patients with newly diagnosed MM in one open-label, multi-center, cooperative group trial. Patients were randomized to 4 cycles of thalidomide 200 mg daily plus dexamethasone (Thal/Dex) or to dexamethasone (Dex) alone. Response rates based on serum or urine paraprotein measurements were significantly higher in the combination arm than Dex alone (51.5% vs. 35.6%, respectively,  $p = 0.025$ ). After completing treatment, patients were encouraged to undergo stem cell transplantation.

The incidence of grade 3 or 4 adverse events was 84.3% on the Thal/Dex arm and 73.5% on the Dex alone arm. The most common toxicities associated with thalidomide were somnolence, constipation, neuropathy,

venous thromboembolism (VTE), and rash.

The incidence of VTE was significantly higher in the Thal/Dex arm than with Dex alone (22.5% vs. 4.9%, respectively,  $p = 0.002$ ). Prophylactic antithrombotic therapy prescribed with thalidomide may reduce VTE; however, the decision to prescribe antithrombotic therapy should be made after a careful assessment of the patient's underlying risk factors.

This approval is based on objective response rates and is approved under accelerated approval regulations (Subpart H) requiring further clinical trials to demonstrate thalidomide's clinical benefit in the treatment of multiple myeloma.

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at [www.fda.gov/cder/foi/label/2006/021430lbl.pdf](http://www.fda.gov/cder/foi/label/2006/021430lbl.pdf).

### Hycamtin®, Topotecan Hydrochloride for Cervical Cancer

On June 14, 2006, the U.S. Food and Drug Administration approved topotecan hydrochloride (Hycamtin®, GlaxoSmithKline) in combination with cisplatin for the treatment of Stage IVB recurrent or persistent carcinoma of the cervix that is not amenable to curative treatment with surgery and/or radiation therapy.

Topotecan was evaluated in women with stage IVB recurrent or persistent cervical cancer in one open-label, multi-center, cooperative group trial. Two hundred ninety-three patients were randomized to six cycles of topotecan 0.75 mg/m<sup>2</sup> IV over 30 minutes for three consecutive days (Days 1-3) plus cisplatin 50 mg/m<sup>2</sup> IV over 1 hour on Day 1 every 21 days or to cisplatin alone at the same dose and schedule. The primary endpoint was overall survival. The median survival was 9.4 months in the topotecan plus cisplatin group and 6.5 months in the cisplatin group (log-rank  $p = 0.033$ ). The unadjusted hazard ratio was 0.76 (95% CI: 0.59, 0.98).

The most common toxicity on the combination arm was myelosuppres-

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### Puget Sound Chapter of the Oncology Nursing Society

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#### PSONS Newsletter

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Letters, articles and announcements are requested from all PSONS members and other readers on topics of interest. Submissions and questions should be sent in electronic format to [Cathleen.Goetsch@vmmc.org](mailto:Cathleen.Goetsch@vmmc.org). Neither the Puget Sound Chapter of the Oncology Nursing Society, the Oncology Nursing Society, the editorial board of the Quarterly, nor the American Cancer Society assume responsibility for the opinions expressed by authors. Acceptance of advertising does not indicate or imply endorsement by any of the above-stated parties. Published four times a year by the Puget Sound Chapter of the Oncology Nursing Society with the support of the American Cancer Society.

Call PSONS @ 206-283-9292  
between 9 a.m. and 5 p.m.

## UPCOMING EVENTS FOR PATIENTS

### Tools for the Journey: Living with Cancer One-day Workshop

Sponsored by Harmony Hill Retreat Center  
September 18, 10:00 - 4:00 pm.  
Harmony Hill Retreat Center, Union Washington Provides practical resources and strategies for those facing the challenge of cancer. No charge includes lunch.  
For more information contact Anna at (360) 898-2363 or visit [www.harmonyhill.org](http://www.harmonyhill.org).

### 3-day Residential Cancer Retreat

Sponsored by Harmony Hill Retreat Center  
September 22-24, 2006  
Experience and education to help individuals explore the issues, choices, feelings and concerns associated with a cancer diagnosis. No charge.  
For more information. Contact Cindy or Anna at (360) 898-2363 or visit [www.harmonyhill.org](http://www.harmonyhill.org)

## Advertise Job Openings or Educational Events in The Quarterly

Your Hospital or Organization can place employment ads or educational event notices in the Puget Sound Quarterly and reach their target audience - nurses - like no other trade publication!

Contact Judy Petersen at [judy.petersen@thomson.com](mailto:judy.petersen@thomson.com)



## FDA Approvals

### Continued from page 13

sion. Grade 3-4 hematologic adverse events occurring more commonly in the combination arm included neutropenia (74% vs. 2%), anemia (40% vs. 22%), thrombocytopenia (33% vs. 3%), and febrile neutropenia (18% vs. 8%). Grade 3-4 non-hematologic adverse events reported more commonly in the combination treatment arm included pain, nausea and vomiting, metabolic-laboratory, and hepatic.

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at [www.fda.gov/cder/foi/label/2006/020671s014lbl.pdf](http://www.fda.gov/cder/foi/label/2006/020671s014lbl.pdf).

### iPledge Program for Isotretinoin

Isotretinoin, a potent human teratogen, is indicated for the treatment of severe, recalcitrant acne, and is also used off-label for the treatment of certain types of cancer. iPLEDGE is a technology-based risk management program that was designed to reduce the risk of fetal exposure in patients who are prescribed Accutane (isotretinoin) or one of its generics (Amnesteem, Claravis, or Sotret). As of March 1, 2006, all pharma-

cies dispensing isotretinoin must register with iPLEDGE, all isotretinoin prescribers, including oncologists, must register and activate with iPLEDGE in order to prescribe isotretinoin, and all patients, including oncology patients, must be registered and qualified within iPLEDGE in order to receive isotretinoin. Prescribers can register at [www.ipledgeprogram.com](http://www.ipledgeprogram.com) or by calling 1-866-495-0654.

Since the iPledge program came into effect, oncologists have brought to the FDA's attention difficulties in prescribing isotretinoin for their patients. To accommodate these unique oncology uses, iPledge has created an exception form. A registered prescriber whose registered oncology patient is unable to fill his or her prescription due to some of the automated iPLEDGE restrictions (e.g., an oncology patient misses the 7 day dispensing window or for some other reason is "locked out" by iPLEDGE) should complete the "Request for Exception Authorization for Oncology Patient" form and fax the form to iPLEDGE. The form and instructions are available on the New Approaches to Neuroblastoma Therapy (NANT) website at <http://www.nant.org/13cis.shtml>. This form is intended to request an exception to the iPLEDGE requirements, it is not intended to

replace the requirements of iPLEDGE.

By submitting the exception form, the prescriber confirms that he/she is prescribing isotretinoin to treat cancer and that if the patient is a female of child-bearing potential, that she is not pregnant as of the date of the request. The prescriber should fax the completed form to iPLEDGE at 888-887-8097. In addition, the prescriber should contact the patient's pharmacy to alert them to access the iPLEDGE system for authorization. To use the form the prescriber and patient must be registered with iPLEDGE.

Oncologists who experience difficulties in using the exception form can call iPLEDGE at 877-475-3345 (not staffed with a live operator) and leave a message with contact information. The call will be returned within one business day. Such calls are limited to oncology exception questions only.

Additional information about isotretinoin and iPLEDGE is available at: [www.fda.gov/cder/drug/infopage/accutane/default](http://www.fda.gov/cder/drug/infopage/accutane/default)

For further information related to oncology drug approvals, regulatory information, and other oncology resources, please refer to the FDA "Oncology Tools" website at [www.fda.gov/cder/cancer](http://www.fda.gov/cder/cancer).





# UPCOMING EVENTS

## 6th Biennial Ovarian Cancer Research Symposium - From Prevention to Cure

Sponsored by *Marsba Rivkin Center and Swedish Medical Center*  
September 7-8, 9:00 - 5:00 pm,  
Swedish Medical Center, Seattle

This two day conference is a CME activity. While there is no charge for the conference, a suggested donation of \$50 to the Rivkin Center is greatly appreciated. For more information contact Jocelyn Moore at (206) 215-6200 or [jocelyn.moore@swedish.org](mailto:jocelyn.moore@swedish.org).

## 14th International Conference on Cancer Nursing

September 27 - October 1, 2006  
The Sheraton Centre, Toronto, Canada  
For more information:  
[www.isncc.org/conference/2nd%20Announcement.pdf](http://www.isncc.org/conference/2nd%20Announcement.pdf)

## Genomic Health Care: The Future is Now

*International Society of Nurses in Genetics*  
October 7-10, 2006  
Bourbon Orleans Hotel, New Orleans, Louisiana  
Contact information: e-mail: [ionghq@msn.com](mailto:ionghq@msn.com);  
Phone: 412/344/1414

## 3rd Biennial Cancer Survivorship Research Conference- Cancer Survivorship: Embracing the Future

Sponsored by the *NCI's Office of Cancer Survivorship, the American Cancer Society, and the Lance Armstrong Foundation*  
October 4-5, 2006  
Bethesda North Marriott Hotel & Conference Center, Bethesda, MD  
Information and Registration:  
[www.blsmeeing.net/survivorship06/gen](http://www.blsmeeing.net/survivorship06/gen)

## LIVESTRONG Summit

Sponsored by *The Lance Armstrong Foundation (LAF)*  
October 27-29, Austin, Texas  
Through an application process, the LAF will identify approximately 1,000 current and potential leaders who are willing to champion the cancer cause in their local communities. \$115 conference fee, some financial assistance may be available. For more information and to apply visit [www.livestrong.org/summit](http://www.livestrong.org/summit).

## 5th National Conference on Quality Health Care for Culturally Diverse Populations

Sponsors: *Drexel University Center for Health Equality; Resources for Cross Cultural Health Care; US Dept. of Health and Human Services*  
October 17-20, 2006  
Renaissance Seattle Hotel, 515 Madison St., Seattle, WA  
For more information: e-mail [ccconf@drexel.edu](mailto:ccconf@drexel.edu), or call 215-762-7638, or on the web at [www.diversityrx.org/ccconf](http://www.diversityrx.org/ccconf)

## ONS Seventh Annual Institutes of Learning

November 10-12, 2006  
AND

## ONS Advanced Practice Nursing Conference

November 9-11

both Pittsburgh, PA.  
For information:  
[www.ons.org/ccCentral/conferences/IOL](http://www.ons.org/ccCentral/conferences/IOL)

## 9th National Conference on Cancer Nursing Research

February 8-10, 2007 o Hollywood, CA  
[www.ons.org/meetings/research07/index](http://www.ons.org/meetings/research07/index)  
For information: Phone: 412-859-6100;  
Toll free: 866-257-4ONS  
E-mail: [customer.service@ons.org](mailto:customer.service@ons.org); Web site: [www.ons.org](http://www.ons.org)

## ONS Annual Congress

April 24-27, 2007 · Las Vegas, NV  
The call for abstracts for Congress 2007 will be available via the ONS website in October 2006. The deadline for abstracts is January 3, 2007 at 5pm EST.

## Future Institutes of Learning Meetings

November 9-11, 2007: Chicago, IL

## TREASURER'S REPORT

### Second Quarter 2006

Balance..... \$109,897.90  
Uncleared checks last quarter . . . . . 9,807.59

**A. BEGINNING BALANCE . . . . . \$100,090.31**

### REVENUE

Dues . . . . . 237.50  
Program Fees . . . . . 0  
Interest Checking . . . . . 15.34  
Interest Savings . . . . . 0.79  
Gains . . . . . -2,387.82  
Exhibit Fees . . . . . 3,350.00  
Ads . . . . . 250.00  
Office Support . . . . . 19,232.70

**B. TOTAL REVENUE . . . . . \$4,304.81**

### EXPENSES

Printing (Typing, xeroxing, etc.) . . . . . 1763.59  
Postage . . . . . 291.59  
Supplies . . . . . 0.00  
Symposium/Meetings . . . . . 6,564.94  
Travel . . . . . 0.00  
Honorariums/Speakers . . . . . 1,092.90  
Scholarships/Grants . . . . . 2,500.00  
Website . . . . . 459.00  
Office Support . . . . . 2,634.65  
Chapter Insurance/Dues . . . . . 558.00

**C. TOTAL EXPENSES . . . . . \$6,799.72**

**D. ENDING BALANCE THIS QUARTER . . . . . \$97,631.40**

**E. Outstanding Checks . . . . . 9,807.59**

**F. TOTAL (Balance + Checks + Deposits) . . . . . \$107,438.99**

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*Puget Sound Chapter of the Oncology Nursing Society*  
and all those who



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