



# HAWAII SOCIETY OF CLINICAL ONCOLOGY

*A Chapter Member of the Association of Community Cancer Centers  
and An Affiliate of the American Society of Clinical Oncology*

WINTER 2005

[www.HSCO-HAWAII.com](http://www.HSCO-HAWAII.com)

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## **President's Corner**

*By Charles F. Miller, MD, FACP*

*The President's Message from the HSCO Annual Meeting, November 22, 2004*

Good Morning and welcome to the 9<sup>th</sup> Annual Meeting of HSCO - It is an honor and privilege to have served as President of your Society for the past year. Thank you all for attending our annual meeting – I know how precious weekends are, so the fact that all of you have chosen to be here today, reflects two things – your commitment to HSCO and the value that you see in our local Society.

**History:** Your Society was officially incorporated as the Hawaii Society of Oncology in 1996, and I do remember being at the inaugural annual meeting that was held in the Cancer Research Center Conference Room. From that small beginning of 36 original members, our Society has grown both in numbers and in value – both to the membership and to other leaders in the community as well.

**Membership:** As of this meeting we have 77 active members, 61 who are physicians. As far as prospective members, there are at least 21 MD's statewide with active involvement in treating cancer patients who are not members of the Society. I firmly believe it is important that all MD's involved in treating cancer patients are part of the Society. First, because the more diversity in points of view, the better we can represent and support the needs of our members and their patients, and second, the more representative we are, the stronger our voice in advocating for cancer patients and cancer care at the state level. This will be one of our goals for the coming year.

**Improvements:** If there is one area of weakness in our Society, it is in getting you – the membership – to respond to requests from your Board for information. While there are many decisions that the Board can make unilaterally, there are many issues and concerns that we need membership guidance to pursue. As an example, earlier this year we sent out a short survey to ask members about the impact that Medicare reimbursement would have on their practice and patient care. Unfortunately, the response was so low that it was not useful. In that vein, we have included another survey in your packets for this meeting, and I have asked the staff to lock the doors until everyone completes the survey and hands it in. Seriously, we cannot improve our organization without your ongoing input on critical issues and questions that arise – these can vary from things to make the organization more efficient, to National level policy issues that will affect the care of cancer patients across the country. So my plea for the coming year is – if you get a request from the Board for information, survey, a questionnaire, etc, please do not throw it away – when we send these things out, we really need your help in making decisions

**Past Year:** A number of things have happened over the past year that I want to briefly mention.

**HSCO MEMBERSHIP**

There are 78 members in the HSCO: 62 physician members, 13 associate members and 3 affiliate members.

**WELCOME NEW MEMBERS**

**Mark T. Wakabayashi, M.D.**

*University of Hawaii  
Honolulu*

**Wesley Wong, Pharm. D.**

*Kaiser Permanente  
Waipahu*

**UPCOMING EVENT**

Dinner Meeting  
*April 14, 2005*  
Location: TBD  
Honolulu

2005 Annual Membership Meeting  
*November 19, 2005*  
Shriner's Hospital for Children  
Honolulu

**2005 SPONSORS**

The Society gratefully acknowledges the following companies who have contributed to the advancement of our Society. We would like to recognize and thank them for their help and support.

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State Affiliate Meeting: I had the privilege of attending the first State Affiliate Leadership Conference in October of this year. It was an enlightening experience and I learned much from seeing how other state societies are managed and how they approach many of the same issues and problems that we are dealing with. To put HSCO in perspective, with our 77 members, the ANCO – Association of Northern California Oncologists – has 240 individual physician members. Some of the issues covered in the meeting included:

- **Discussion of Society Management** – there are changes we could make in terms of the Board of Directors that can provide more continuity and achieve broader involvement in the management of the Society.
- **Improving Patient Information & Collaboration** – decision making as a partnership. Specifically making greater use of the PLWC web site that ASCO sponsors for patient information. How many of you have referred patients to the web site or used print outs for patient information?
- **Effective Advocacy for Oncology** - encouragement to be more active participants in state level decisions affecting cancer patients. An example is Hawaii's Comprehensive Cancer Plan, which many members were involved in helping to develop.

**Corporate Sponsorship:** Your board approved the concept of "Corporate Sponsorship" for the Society. This is an effort that has been rewarding for both the Society as well as our new Sponsors and I will talk more about this at the open session later this morning.

**Educational Programs:** HSCO continues to provide many opportunities to bring outstanding educators and researchers in oncology to the islands. Through collaboration with our corporate sponsors, other pharmaceutical companies as well as the Cancer Research Center we will continue to provide these opportunities – primarily based on your feedback – we poll the membership each year to ask what topics and speakers you would like to hear for the coming year.

**HSCO Journal Club:** A new venture that was just started this summer was the Oncology Journal Club; through the efforts of Drs. Bill Loui and Jennifer Fu this has been a great success in a just a short period of time. Once again, we will plan to continue this as an ongoing educational experience for our members

**Comprehensive Cancer Center:** We have maintained an informal liaison with the Cancer Research Center and the University of Hawaii in an effort to serve as an information conduit to and from our membership. I think this relation can be strengthened to the benefit of all parties concerned

**Best of ASCO Regional Meeting:** Finally, as you are all aware, ASCO has been presenting smaller regional meetings after the annual session called the BEST OF ASCO. These meetings have proven very popular, and after discussion with your Board, I sent a letter to ASCO national leadership recommending that they consider holding next year's western regional Best of ASCO meeting here in Honolulu. We will wait to hear about their decision in the near future

**The Future**

**Diversity:** One goal for our future as a society is to expand our membership to include all of those specialties involved in care of the cancer patient. This should include oncology nurses, oncology pharmacists, oncology researchers, oncology program managers and patient educators to name just a few. The more diverse we are the better our perspective in developing programs and supporting policies to improve the care of cancer patients.

**Patient Advocacy:** I believe that the Society can play a much larger and more effective role in supporting cancer patient advocacy. Our voice, representing the leadership for Oncology care in the State of Hawaii can have great impact when added to the voices of

patient's groups campaigning for issues directly supporting patient concerns and cares. One example of this is our focus today on Palliative Care. This is an area where Oncologists can be influential in lobbying for greater State support for this vital aspect of care for our patients during their end of life.

**Collaboration:** As a corollary to this point, I would like for the Society to become more involved with the other organizations in the State supporting cancer care. While we have liaison with Oncology Nursing Society, I believe that our two groups could be far more effective if we joined forces to address many of the common problems that both organizations recognize in trying to improve cancer care. While we have some input into the Cancer Research Center, I believe a greater involvement by HSCO would be beneficial to insure that your views, the opinions of the Society membership are well known to the CRCH leadership.

**Thanks:** In closing, I would like to thank all members for their attendance today, and your support throughout the year. I would like to recognize the other members of your Board who have spent many hours and lots of energy to make this Society a success.

**Dr. Laeton Pang**, Vice President and one of the original board members 9 years ago

**Dr. Carl Higuchi**, Secretary/Treasurer and also on the original Board

**Dr. Paul Morris**, our Immediate Past President

**Dr. Jeffrey Berenberg**, also an original Board member

**Dr. Randall Liu**, in his first term on your Board

**Dr. William Loui**, who heads the Educational Committee

**Dr. Keith Terada**, also serving his first term on the Board

**Special Thanks to our management team: Association of Community Cancer Centers**

**Donna Giffin**, Program Manager who put the nuts and bolts of this meeting together for us

**Mary Lou Bowers**, Director ACCC State Affiliate Program


**Shawna Belcher**, Manager of State Society Administration, who keeps me from going completely insane with the job of President.

## ASCO News

We are very pleased to announce the dates and locations of the two *Best of ASCO* sessions being held this year. The first session, targeting the Western region of the country, will be held June 17-18, 2005, in San Francisco, California. The second session will target the Central region of the country, and will be held June 25-26, 2005, in Dallas, Texas.


*Best of ASCO* is an educational initiative that condenses highlights reflecting the most cutting-edge, practice-changing research presented at ASCO's Annual Meeting, and is a joint effort planned collaboratively between ASCO and its State/Regional Affiliates.

The Practice Management Curriculum will be held in conjunction with both *Best of ASCO* sessions. In San Francisco, it will be held on Thursday, June 16th in the afternoon and in Dallas it will be held on Friday, June 24th in the morning.



**REIMBURSEMENT QUESTIONS**

Go to [www.hSCO-hawaii.com](http://www.hSCO-hawaii.com)  
for answers to all your reimbursement and coding questions.



## Reimbursement Issues and Coding Update

Marci Cali, Managing Director, State Society Services  
Consulting

### Expanding Off-label coverage through the Carrier Advisory Committee and State Society Oncology Advisory Panel

In today's environment of shrinking reimbursement and risk of payment denials for effective off-label therapy, difficult decisions have to be made regarding necessary and appropriate treatment for cancer patients. At times it may seem easier to treat a patient with older, less effective treatment *only* because providers know that insurers will pay for these approved therapeutic drugs. There are however, mechanisms in place that provide opportunities to expand treatment options for current, more effective therapies that are approved by the FDA for limited indications. By and large, the physician must be willing to set the process in motion and formally request a payer to medically accept and add additional coverage indications to FDA approved drugs. Unquestionably, support of the expanded use must be based on authoritative medical literature from specific publications and/or evidence that informs the payer that the use is widely accepted clinical practice in the state.

*The vast majority of off-label coverage decisions by Medicare are made at the local level.* This is a significant declaration because change happens more quickly at the local level than it does at the national level. Under general Medicare policy, Medicare contractors, called 'carriers' can cover an off-label use of an FDA-approved drug if the carrier determines that the use is medically accepted. Locally, Medicare carriers have the responsibility and discretion to develop their own payment policies and formal review process in order to consider effective treatments that reflect local practice patterns for the state(s) within its jurisdiction. Once a carrier has determined that there is enough evidence to accept a new indication for an FDA-approved drug, it develops (or revises) a 'local carrier decision' (LCD) which is made available to the physician community and the public at large. Carriers that cover multiple states are encouraged to develop uniform local carrier decisions but are not required to do so.

The one factor that overrides a LCD is a National Coverage Determination (NCD). An NCD describes the extent to which Medicare will cover specific services, procedures, or technologies on a national basis. An NCD is binding on all Medicare carriers, fiscal intermediaries, HMOs, health care prepayment plans, competitive medical plans, and quality improvement organizations. If an LCD is in conflict with an NCD, the carrier must change the LCD to conform to the NCD. Working through the system to get expanded approval for an FDA-approved drug can be a challenging endeavor. But with the support of resources already in place, the burden on individual practices can be greatly reduced. There are two easily accessible mechanisms for practices to use if they want to make an effort to obtain expanded coverage for off-label use.

First, each Medicare carrier has an established Carrier Advisory Committee (CAC). This committee is comprised of selected physician representatives from various medical and specialty societies within each individual state; oncology and hematology have a permanent seat on the CAC. The CAC takes an active role in Medicare policy development and evaluating administrative policies for the carrier in an ongoing effort to make improvements. The CAC acts as a forum for exchanging information between the carrier and community physicians, and provides an opportunity for local physicians to communicate local practice patterns. Physicians should contact the CAC representative to let him/her know the current concerns and need for expanding treatment options. This is vital for the greater good of the community.

Second, every ACCC managed state has an Oncology Advisory Panel in place designated to review off-label requests received from community oncologists. The Panel has evolved into the role of the 'oncology voice and the standard bearer' of clinical care for patients in their community. The Panel is committed to reviewing requests for off-label use from a clinical perspective and advocating for cancer patients within the state. They ensure that compelling requests are presented to Medicare and other payers for coverage consideration.

It is advantageous to have the CAC representative serve as a member on the State Society Oncology Advisory Panel in order to communicate with the membership about actual experiences in the community. Furthermore, a CAC representative/Oncology Advisory Panel member can ensure that information about valid off-label uses are shared among the oncology community. The representative helps establish goals for approaching payers on behalf of the entire State Society.

In many cases Medical Directors in different states recognize the value in working together to resolve coverage decisions for a broader range of constituents. It then becomes advantageous for the CAC representatives in those states to work together in pursuing uniform standards of coverage.

Obtaining expanded coverage for FDA-approved drugs starts with the physicians. Using the processes already in place supports information exchange and provides a well developed platform for communicating needs and being heard.

The contact information for your CAC representative can be found on the Medicare carrier's website. For more information about your State Society Oncology Advisory Panel and the process for requesting expanded coverage for FDA-approved drugs through this process, you may contact Marci Cali at [mcali@acc-cancer.org](mailto:mcali@acc-cancer.org).

## Drugs in the News

- Schering AG (Berlin, German) has announced that the FDA has issued an approval letter for **Bonefos**<sup>®</sup> (clodronate), an oral non-amino bisphosphonate intended to reduce the occurrence of bone metastases in the post-surgical (adjuvant) treatment of breast cancer patients.
- The FDA has given fast track designation to **HuMax**<sup>™</sup>-**CD20** (Genmab A/S, Copenhagen, Denmark) for chronic lymphocytic leukemia (CLL) for patients who have failed fludarabine therapy. This patient group includes those who are refractory to available treatment. HuMax-CD20 is currently in two phase I/II studies to treat CLL and non-Hodgkin's Lymphoma.
- Myriad Genetics, Inc. (Salt Lake City, Utah) has submitted an Investigational New Drug (IND) application to the FDA to begin a Phase I clinical study with its pro-apoptotic cancer drug candidate, **MPC-6827**. The study is designed to evaluate the safety and pharmacokinetic profile of MPC-6827 in patients with advanced solid tumors, in an escalating dose regimen. Myriad Genetics has also submitted an IND application to the FDA to begin a Phase I human clinical trial with **MPC-2130** (previously referred to as MPI-176716), a broad-acting inducer of apoptosis in cancer cells. The Phase I clinical trial is designed to evaluate the safety and pharmacokinetic profile of MPC-2130 in patients with advanced metastatic tumors or blood cancers, as well as refractory cancer that has progressed despite previous chemotherapy. In preclinical studies MPC-2130 demonstrated significant cancer cell killing activity in ovarian cancer, prostate cancer, and two lymphoma cell lines, Burkitt's lymphoma, and T-cell lymphoma.
- Procyon Biopharma, Inc. (Montreal, Canada) has filed an IND application with the FDA in order to initiate a pilot trial followed by a North American Phase IIb clinical trial, with **PCK3145**, its anti-metastatic prostate cancer drug.
- The FDA has given fast track designation to **Phenoxodiol** (Novogen, Sydney, Australia). The anti-cancer, investigational drug is intended for use in patients with hormone-refractory prostate cancer. Phenoxodiol in intravenous form was granted fast track status by the FDA in November 2004 for its intended use in patients with ovarian cancer.
- Tapestry Pharmaceuticals, Inc. (Boulder, Colo.) has submitted an IND application to the FDA for its novel taxane, **TPI 287**. In preclinical testing TPI 287 demonstrated the ability to inhibit tumor cell growth in a number of in vitro cell lines and has shown superior inhibition to tumor burden in certain animal xenograft models when tested against standard comparative agents. The Phase I study of TPI 287 is designed to evaluate the safety and pharmacokinetic profile of the compound in patients with recurrent and/or refractory cancer in a carefully controlled dose-escalating regimen.
- The FDA has accepted Millennium Pharmaceuticals, Inc.'s (Cambridge, Mass.) supplemental new drug (sNDA) application for **Velcade**<sup>®</sup> (bortezomib) and also granted Velcade priority review designation for the treatment of patients with multiple myeloma who have received at least one prior therapy. The sNDA submission was based primarily on the results of the Phase III APEX confirmatory study that compared Velcade to high-dose dexamethasone. The APEX trial was halted one year early after an independent data monitoring committee concluded the findings of a pre-specified interim analysis showed a statistically significant improvement in time-to-disease progression in favor of Velcade.
- Abbott (Abbott Park, Ill.) has submitted an NDA for its oral agent **Xinlay**<sup>™</sup> (atrasentan). The company is seeking approval of Xinlay for the treatment of metastatic hormone-refractory prostate cancer. Xinlay is an investigational, oral, once-daily, non-hormonal, non-chemotherapy, anticancer agent that belongs to a class of compounds known as selective endothelin-A receptor antagonists (SERA<sup>™</sup>). Xinlay is currently being studied in several stages of prostate cancer, and is being evaluated in combination trials with approved treatments for prostate cancer.
- Exelixis, Inc. (South San Francisco, Calif.) has submitted an IND for **XL880**, a novel, orally administered small molecule for the treatment of cancer. In pre-clinical studies, XL880 demonstrated potent inhibition of the Met and VEGFR2 (KDR) receptor tyrosine kinases which play synergistic roles in promoting tumor growth and angiogenesis. Pending FDA clearance, Exelixis intends to initiate a phase I clinical trial in the first quarter of 2005.

## Approved Drugs

- American Pharmaceutical Partners, Inc., and American Bioscience, Inc., (Schaumburg, Ill.) announced that the U.S. Food and Drug Administration (FDA) has approved **Abraxane**<sup>™</sup> for **Injectable Suspension** (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) in metastatic breast cancer. Abraxane is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should

have included an anthracycline unless clinically contraindicated. Abraxane is first in a new class of “protein-bound particle” drugs made possible by ABI’s nanoparticle albumin-bound (nab™) technology.

- GlaxoSmithKline (Philadelphia, Penna.) announced that the FDA has approved a supplemental Biologics License Application (sBLA) for expanded use of **Bexxar® Therapeutic Regimen** (Tositumomab and Iodine I 131 Tositumomab). The expanded indication will make Bexxar an earlier option for patients with relapsed low-grade or follicular non-Hodgkin’s lymphoma. The Bexxar Therapeutic Regimen is now indicated for the treatment of patients with CD 20 antigen expressing relapsed or refractory, low-grade, follicular, or transformed non-Hodgkin’s lymphoma, including patients with Rituximab-refractory non-Hodgkin’s lymphoma.

- **Clolar™** (clofarabine) (Genzyme Corp., Cambridge, Mass.) has been granted orphan drug designation by the FDA for adult and pediatric acute lymphoblastic leukemia. The drug is indicated for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens.

- The FDA has approved CANADA-QLT, Inc.’s (Vancouver, Canada) **Eligard®** 45 mg. (leuprolide acetate for injectable suspension) six-month formulation, for the palliative treatment of advanced prostate cancer. Eligard depot is a member of a class of drugs known as luteinizing hormone-releasing hormone agonists. The drug works by lowering the levels of testosterone in the body, which may result in a reduction of symptoms related to the disease.

- Amgen Inc., (Thousand Oaks, Calif.) announced FDA approval for **Kepivance™** (palifermin) for severe oral mucositis in cancer patients undergoing bone marrow transplants. Kepivance is a recombinant human keratinocyte growth factor that works at the cellular level to help protect patients with hematologic malignancies undergoing high-dose chemotherapy and/or radiation followed by bone marrow transplant from severe oral mucositis.

- **TheraCIM hR3**, the EGF receptor monoclonal antibody, (YM BioSciences, Inc., Mississauga, Ontario) has received FDA orphan drug designation for the treatment of glioma. TheraCIM hR3 (nimotuzumab) is a humanized monoclonal antibody that targets the epidermal growth factor receptor (EGFr).

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