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

SUMMER 2005

www.HSCO-HAWAII.com

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President's Corner

By Charles F. Miller, MD, FACP

The summer months go by all too quickly as I struggle to write another President's letter for the Society. First, let me review with you some of the actions that your Board of Directors took this summer. We made some significant changes in the by-laws to allow for greater participation on the Board, and more continuity by staggering the election of Board members over a two-year period. In addition, we defined a new category of membership for those physicians and other health care providers working in the Pacific Islands; these oncologists have no organized structure to provide on going assistance and education in areas such as Guam, the Marshall Islands and various other Pacific Island nations. The Hawaii Society of Clinical Oncology will encourage this group to join hopefully allowing them to benefit from both the educational and administrative support that our Society can provide.

Another decision that the Board made was to offer the Society's support to a planned meeting in 2006 on Cancer Genetics, with one of the experts in the area, Dr. Henry Lynch. HSCO will co-sponsor the meeting and assist in getting educational grants to support bringing this outstanding program to Hawaii.

As many of you are aware, 2006 will mark some significant changes in Medicare coverage for some cancer drugs. We are planning to review some of these changes with Medicare "D" drugs at the annual meeting.

The Board also made final plans for the annual meeting and hopefully all of you have already received information by fax or e-mail regarding the program. We will focus this year on the current status of defining "Quality in Cancer Care" and are planning to have some outstanding speakers for the day. The meeting will be held November 12, 2005, and I am looking forward to seeing all of you there.

I wish all of you the very best for the rest of the summer. While we are all very busy with our practice and our patients, it is so important not to lose sight of our priorities. Please take time for yourselves, your families and your friends.

Aloha

HSCO MEMBERSHIP

There are 81 members in the HSCO: 62 physician members,15 associate members and 3 affiliate members.

WELCOME NEW MEMBERS

Eleanor R. Hastings, M.D.
Tripler Army Medical Center
Honolulu, HI

Danielle Scelfo, MHSA
Sanofi-Aventis Oncology
San Diego, CA

UPCOMING EVENT

Membership Meeting
November 12, 2005
Pacific Club
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.

CORPORATE SPONSORS

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Action by Congress Needed to Preserve Patient Access to Physicians

By Marci Cali, RHIT, Managing Director, State Society Services
Association of Community Cancer Centers

The year 2005 will no doubt be as tumultuous going out as it was coming in with regard to physician payment issues. Practices that are heavily dependent on Medicare patients have been especially struck by the deep reductions in reimbursement in spite of the fact that costs to operate a practice continue to increase. With declining revenue and more cuts on the horizon, many physicians are caught in the predicament of having to limit the number of Medicare patients treated in their practice; or end participation in Medicare entirely if cuts on the care of these patients continue. The damaging result for the 41 million Medicare recipients is that access to medical services would suffer significantly.

One of the expected cuts to physicians' payments is a consequence of the sustainable growth rate (SGR) formula that is used annually to increase payments for practice cost inflation. Under MMA, physician payments in 2004 and 2005 increased by 1.5 percent. But a flaw in the methodology cuts physician payments if Medicare spending on their services exceeds the SGR. This means that Medicare payments will decrease by 4.3 percent next year and will be reduced further in following years such that by 2012 physician reimbursement will decline by approximately 26 percent. This is a key impetus for the devastating financial decision to discontinue care to Medicare beneficiaries.

In order to prevent the reduction that will go into effect on January 1, 2006, a temporary bill has been presented to Congress that will require the SGR formula to be replaced; and takes into consideration the current cost of providing healthcare to seniors. The bill, called the Preserving Patient Access to Physicians Act of 2005 (H.R. 2356 and S 1081), proposes to keep pace with the rate of inflation in practice costs. This will affect a payment increase of no less than 2.7 percent in 2006 and projects a 2.6 percent increase in 2007. This increase was recommended by the Medicare Payment Advisory Commission in their March report and continues to gain bipartisan support in the Congress.

Congress must act before the end of this year to stop the cuts in Medicare reimbursement. Let your state legislators know that you are counting on their support to change the SGR with a new formula to provide some stability in Medicare payment rates and your ability to continue to accept and treat Medicare patients.

REIMBURSEMENT QUESTIONS

Go to *www.hsco-hawaii.com* for answers to all your reimbursement and coding questions.

Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B - Medicare Final Rule

CMS announced on August 3, 2005 that the vendor bidding process for the Competitive Acquisition Program (CAP) has been suspended until further notice. The suspension will allow CMS to address concerns by proposed vendors and other stakeholder groups. However, the agency restated its intentions to issue a final rule by the end of the year and begin the physician election process shortly after that. Please go to *www.hsco-hawaii.com* to read an ACCC summary of the interim final rule.

Also, please go to *www.accc-cancer.org/media/newsletters/media_ACCC_July25_05.htm*. It links to information on the extension of the Demonstration Project as well as a summary of the HOPD proposed rule.

New Sessions Added to ACCC Fall Economics Conference

Special Nightcap Sessions!

Significant Medicare Payment Changes Affecting HOPD
Wednesday, September 14, 2005, 8:30 PM - 9:30 PM

- Payment rates for drugs, biologicals, and radiopharmaceutical agents
- Pharmacy handling and overhead
- Hospital coding & billing for evaluation and management services
- Multiple diagnostic imaging procedures

Strategic Business Decisions for Physician Practices
Thursday, September 15, 2005, 8:30 PM – 9:30 PM
Consolidation

- What is consolidation?
- Should you consolidate?
- How to approach consolidation and pay the lawyers less!

Log on to www.accc-cancer.org for updates and to register online or call 301.984.9496

Drugs in the News

■EntreMed (Rockville, Md.) announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for **2-methoxyestradiol (2ME2 or Panzem®)** for the treatment of ovarian cancer. The FDA's decision was based on a review of data from preclinical experiments and a Phase I clinical study, together with in vitro data demonstrating that 2ME2 has activity against a variety of ovarian carcinoma cell lines including those resistant to other chemotherapeutic agents. EntreMed received orphan drug designation previously for 2ME2 in the treatment of multiple myeloma.

■The USP DI has approved **Doxil (doxorubicin liposomal)** for multiple myeloma, in combination with vincristine and dexamethasone.

■New drug applications (NDAs) for Novartis's (East Hanover, N.J.) **Exjade® (deferasirox),** a once-daily oral iron chelator for the treatment of chronic iron overload due to blood transfusions, have been filed in the United States and the European Union. In the U.S., Exjade has been granted fast track status and priority review has been requested. Exjade has been granted orphan drug status in the U.S.

■Lorus Therapeutics, Inc., (Toronto, Canada), announced that the FDA has granted orphan drug status to **GTI-2040,** for the treatment of acute myeloid leukemia (AML). The drug was also granted orphan drug status for renal cell carcinoma in 2004. GTI-2040 is an antisense drug that specifically targets the R2 component of ribonucleotide reductase, which is required for DNA synthesis and cell proliferation. GTI-2020 is being investigated in a Phase II clinical trials program for AML, breast cancer, lung cancer, prostate cancer, color cancer, and a variety of solid tumors.

■BioVex Ltd. (Oxford, England) has submitted an investigational new drug application (IND) to the FDA to initiate a clinical trial in malignant melanoma of **OncoVEX (GM-CSF),** for the treatment of solid tumors. OncoVEX (GM-CSF) is an oncolytic virus that selectively kills tumor cells. It also induces tumor cells to secrete GM-CSF, a powerful immune stimulator, potentially enhancing the destruction of both injected and metastatic tumor deposits.

■Celgene Corp. (Summit, N.J.) has completed rolling submission of an NDA to the FDA for **Revlimid® (lenalidomide).** The company's NDA seeks approval to market Revlimid as a treatment for transfusion-dependent patients with myelodysplastic syndromes with a 5q deletion chromosomal abnormality.

■Spectrum Pharmaceuticals, Inc. (Irvine, Calif.) announced that its recently submitted IND for **SPI-153** received concurrence from the FDA to conduct a phase I/II clinical trial in patients with hormone-dependent prostate cancer in the United States. SPI-153 is a fourth generation LHRH (luteinizing hormone releasing hormone), also known as GnRH (gonadotropin releasing hormone) antagonist.

■Structural GenomiX, Inc. (San Diego, Calif.), has also received orphan drug designation from the FDA for **Troxatyl™** (troxacitabine) for the treatment of AML. Troxatyl is a novel nucleoside analog that is currently being evaluated in a Phase 1/2 trail for the treatment of relapsed AML and in a phase 1/2 trial for the treatment of various solid tumors.

■**Velcade® (bortezomib) for Injection** (Millennium Pharmaceutical, Cambridge, Mass) has received a new indication from the United States Pharmacopeia (USP) compendium for second-line treatment of mantle cell lymphoma. Velcade is indicated for the treatment of multiple myeloma patients who have received at least 1 prior therapy. Velcade is contraindicated in patients with hypersensitivity to bortezomib, boron, or mannitol.

■American Pharmaceutical Partners, Inc. (Schaumburg, Ill.) announced FDA approval for the abbreviated NDA (ANDA) of **Vinorelbine Tartrate Injection, 10 mg (base)/mL,** the generic equivalent of GlaxoSmithKline's Navelbine®. Vinorelbine Tartrate is indicated as a single agent or in combination with cisplatin for the first-line treatment of ambulatory patients with unresectable, advanced non small cell lung cancer (NSCLC). In patients with Stage IV NSCLC, vinorelbine tartrate is indicated as a single agent or in combination with cisplatin. In Stage III NSCLC, vinorelbine tartrate is indicated in combination with cisplatin.

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