THE ISSUES

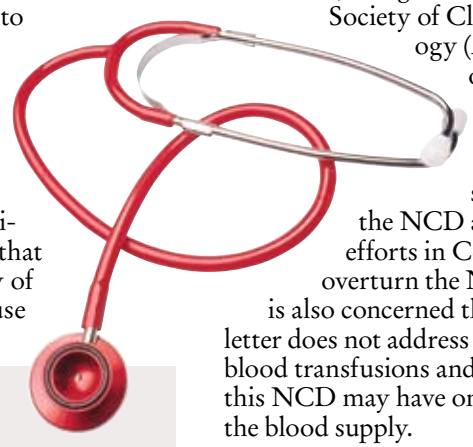
ACCC Supports Legislation to Overturn ESA National Coverage Determination

Representatives Anna Eshoo (D-CA) and Mike Rogers (R-MI), co-chairs of the House Cancer Care Working Group, introduced House Joint Resolution 54, a resolution to overturn the July 30 National Coverage Determination (NCD) issued by the Centers for Medicare & Medicaid Services (CMS) relating to the use of erythropoiesis stimulating agents (ESAs) in cancer and related neoplastic diseases. The Association of Community Cancer Centers (ACCC) supports this legislation and urges our members to voice their support.

The NCD from CMS may severely limit the access to ESA treatments, which can have an impact both on patients and physicians. ACCC also reiterated its findings that the NCD will have a major impact on hospitals, since they will have to perform a greater number of blood transfusions.

House Joint Resolution 54 follows a bipartisan majority of the House of Representatives joining Representatives Eshoo and Rogers in a July letter to CMS expressing concern about the proposed NCD. While CMS did not respond to the Congress, in the Final NCD on ESAs, CMS indicated that it believed the concerns of the Congress about the potential for increased transfusions for Medicare cancer patients to be incorrect. The Senate has also passed a similar resolution regarding ESAs.

On Oct. 16 Congressman Pete Stark (D-CA) released a letter from the Food and Drug Administration (FDA) in regard to the CMS NCD on ESAs. The letter supported CMS' decision and noted that it was not at odds with current FDA labeling. In addition, the FDA stated that "FDA sees no quality of life benefit from the use of ESAs: There is no evidence that ESAs result in improved survival, tumor control, health-related quality of life at any hemoglobin level in cancer patients undergoing chemotherapy." ACCC does not agree with this assessment, because there are differences between the NCD and the FDA label.



PHOTOGRAPH/BIG STOCK

ACCC, along with the American Society of Clinical Oncology (ASCO) and other groups, continues to call for the reconsideration of the NCD and to support efforts in Congress to overturn the NCD. ACCC is also concerned that the FDA letter does not address the issue of blood transfusions and the impact this NCD may have on patients and the blood supply.

PHOTOGRAPH/COMSTOCK

Most Hospitals to Receive Full Pay Increase for Reporting Quality Data

A "vast majority" of hospitals will receive a full payment rate increase of 3.3 percent in fiscal year 2008 because they have reported data on certain quality measures and have met requirements associated with reporting these quality measures. "Medicare payment must encourage reliable, efficient care, rather than reimbursement based on the quantity of services provided and resources consumed," Centers for Medicare & Medicaid Services acting Administrator Kerry N. Weems said in a statement. Under the Reporting Hospital Quality Data for Annual Payment Update program, hospitals reporting on quality measures, including quality of care provided to patients with heart failure, heart disease, and pneumonia, are eligible for a full marketbasket (price inflation index) update for FY 2008. However, those hospitals not participating in the voluntary program or that do not meet certain requirements associated with reporting these measures will experience a reduction of 2 percentage points to their marketbasket update. For FY 2008, this provision reduced the update to 1.3 percent, CMS said.

CMS Decides "No Change" to Clinical Trial Policy

CMS issued its final *Clinical Trial Policy* on Oct. 17. CMS has decided that "no change to the July 9, 2007, policy is appropriate at this time," and it will not impose any additional conditions of coverage. CMS received numerous comments, including those from ACCC, which questioned the authority of CMS to establish standards and provide limitations to coverage within research studies. ACCC had asked CMS to withdraw the proposed clinical research policy and issue a notice of proposed rulemaking, or NPRM. ACCC was concerned that the pro-

posed clinical research policy would undermine CMS' goal of increasing Medicare beneficiary access to clinical research studies by withdrawing coverage for reasonable and necessary items and services unless provided in the context of a qualifying clinical research study.

CMS Releases Final Rule Barring Physician Self-Referrals

CMS published the final Phase III of the physician self-referral rule in the Sept. 5 *Federal Register*, and it will become effective 90 days later. The agency said that it added no new exceptions to the prohibition on self referrals, but rather refined certain areas of the regulation.

The rule finalizes the Phase II interim final rule that was published March 26, 2004, (69 Fed. Reg. 16054) and responds to public comments on Phase II (No. 58 HCDR 3/26/04). CMS also advised that, although it had republished the rule in its entirety, providers should consult all three phases to get a full understanding of the physician self-referral prohibition and the exceptions to the prohibition.

Compendium Update: Changes to USP DI Drug Information

As of October 12, 2007, ACCC is including information from Thomson Healthcare's *DrugPoints*® on its Oncology Drug Search Engine *(www.accc-cancer.org/pubs/pubs_drugpoints.asp)*.

This online drug database is made available through an agreement with ACCC and Thomson Healthcare to provide the oncology professional community with *DrugPoints*®, the successor publication to the *USP DI. DrugPoints* uses a new rating system for indications. The three-tier rating system will include three evidence-based rating categories for FDA-labeled and off-label indications.

New Lung Cancer Guidelines Oppose General CT Screening

New evidenced-based guidelines from the American College of Chest Physicians (ACCP) recommend against the use of low-dose computed tomography (LDCT) for the general screening of lung cancer. Published as a supplement to the September issue of *CHEST*, the peer-reviewed journal of the ACCP, the guidelines cite there is little evidence to show lung cancer screening impacts mortality in patients, including those who are considered at high risk for the disease. The guidelines also recommend against the use of vitamin or mineral supplements for the prevention of lung cancer. Due to the lack of supporting evidence, the guidelines recommend against the use of LDCT, chest radiographs, or single or serial sputum cytologic evaluation for lung cancer screening in the general population, including smokers or others at high risk, except in the context of a well-designed clinical trial. For the first time, the ACCP lung cancer guidelines have included recommendations on mind-body modalities as part of a multimodality approach to reduce the anxiety, mood disturbances, and chronic pain associated with lung cancer.

McKesson to Purchase OTN

McKesson Corporation announced Oct. 4 that it has signed a definitive agreement to purchase Oncology Therapeutics Network (OTN), one of the nation's largest distributors of specialty drug products. Its annualized revenues are approximately $3 billion. McKesson plans to combine the operations of OTN with the operations of McKesson Specialty, which is reported in the McKesson Distributions Solutions segment. Between 2006 and 2010, sales of oncology drugs are forecast by IMS Health to increase from $30 billion to $60 billion. The acquisition is subject to customary closing conditions, including any necessary regulatory review.

Updated Recommendations for Breast Cancer Tumor Marker Testing

The American Society of Clinical Oncology (ASCO) has updated its clinical practice guideline on the use of tumor markers in breast cancer. To update its clinical practice guideline, first published in 1996 and subsequently updated in 2001, the ASCO expert committee reviewed the use of tumor markers in breast cancer and made recommendations based on their effectiveness for early detection of the disease, as well as their benefit in helping to plan treatment, monitoring response to treatment, and determining a patient's prognosis.

Since the 2001 guideline, researchers have identified six new categories of tumor markers. Although currently there are insufficient data to recommend the use of any of these new tumor markers in diagnosing breast cancer, both ER/PR and HER-2 testing are still recommended for diagnosis, as noted in previous versions of this guideline. However, two new tumor marker tests were recommended for their use in determining a breast cancer patient's treatment or whether or not breast cancer is likely to return after initial treatment. The Onco*type* DX™ tumor marker test is recommended for patients with node-negative breast cancer that is ER-positive and/or PR-positive, which is the case for 20 percent of breast cancer patients.

Other tumor markers that doctors can test are urokinase plasminogen activator (uPA) and plasminogen activator inhibitor (PAI-1) markers. Testing these tumor markers can help estimate a patient's prognosis. Patients with tumors that do not have uPA and PAI-1 have a good prognosis and may not need chemotherapy. No test for these tumor markers is currently commercially available in the U.S. A test is, however, available in Europe. More studies of these tumor markers are currently under way.

The guideline also encourages patients to enroll in clinical trials that focus on the use of additional tumor markers as a surveillance tool for breast cancer. These guidelines are available online at *www.asco.org/guidelines*.