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2005 Annual Meeting
May 14–May 17, 2005
Orlando, Florida

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January 28, 2005

Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Room C5-25-25
Baltimore, MD 21244-1850

Dear Dr. McClellan:

On behalf of the more than 20,000 physicians involved in cancer treatment and research who are members of the American Society of Clinical Oncology (ASCO), I want to thank you for your recent initiatives on coverage of new technologies under Medicare. Today's announcement of a final National Coverage Determination on off-label uses of colorectal cancer drugs is the latest in a series of innovative coverage analyses that work to promote quality cancer care by giving greater access to life-extending anti-cancer therapies.

The decision by CMS today is important to patients because it will ensure that the drugs used in these trials will be available to Medicare patients if pharmaceutical companies do not provide them. In addition, we appreciate the clarifications in the final NCD in response to comments submitted by ASCO and others, including leading national patient advocacy organizations. The fact that patients may enroll in the specified clinical trials without fear of negative coverage decisions by Medicare contractors will encourage participation in these important clinical trials while enhancing patient care for the participating individuals. We look forward to discussions with CMS about other clinical trials that should be granted similar coverage. Other clinical trials would include:

- NCI trials in other diseases and involving other drugs;
- Trials sponsored by industry; and
- Trials involving rare or "orphan" cancers where there is less incentive to study new uses of marketed drugs.

As we understand the CMS decision, it will in no way preclude individual decisions by Medicare contractors to cover off-label uses that have been established through clinical trials. Nor does it alter in any way the existing rights to Medicare coverage under the statute for uses specified in the drug labeling or referenced in the medical compendia. Finally, it is reassuring to

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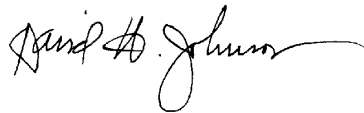
Richard L. Schilsky, MD

know that CMS remains committed to the coverage of routine patient care costs for beneficiaries enrolled in clinical trials pursuant to the 2000 NCD.

In addition to today's decision for the benefit of colorectal cancer patients, other coverage decisions promise access to new technologies that will help beneficiaries control nausea and vomiting while receiving chemotherapy, better diagnose cancers and treatment responses through improved imaging, and provide counseling support for beneficiaries seeking to cease tobacco use. These and other thoughtful coverage approaches are providing concrete advantages for people with cancer. We at ASCO look forward to ongoing dialogue and partnership with you, your able coverage staff, and the patient advocate community to make certain that cancer patients continue to benefit from our nation's investment in clinical cancer research.

Thanks to you for your enlightened leadership and to your coverage experts for their efforts in pursuit of quality cancer care.

Sincerely,



David H. Johnson, MD
President

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