



American Society of Clinical Oncology

PRESIDENT

Douglas W. Blayney, MD

IMMEDIATE PAST PRESIDENT

Richard L. Schilsky, MD

PRESIDENT-ELECT

George W. Sledge, Jr., MD

TREASURER

Clifford Hudis, MD

CHIEF EXECUTIVE OFFICER

Allen S. Lichter, MD

DIRECTORS

Dean F. Bajorin, MD

Monica M. Bertagnolli, MD

Eduardo L. Cazap, MD

Susan L. Cohn, MD

Bruce E. Johnson, MD

Robert M. Langdon, Jr., MD

Robert S. Miller, MD

Kathleen I. Pritchard, MD

Deborah Schrag, MD, MPH

Lynn M. Schuchter, MD

Sandra M. Swain, MD

Joel Tepper, MD

Everett E. Vokes, MD

Peter P. Yu, MD

July 2, 2009

Submitted Electronically Via www.regulations.gov

Jerry Moore, NIH Regulations Officer
National Institutes of Health
Office of Management Assessment
6011 Executive Boulevard, Suite 601
MSC 7699
Rockville, MD 20852-7669

RE: [Docket No. RIN 0925-AA53 and NIH-2008-0002] Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors

Dear Mr. Moore:

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the Advanced Notice of Proposed Rulemaking (ANPRM) published on May 8, 2009, regarding whether the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) should amend the regulations that address the responsibility of applicants for promoting objectivity in research for which Public Health Service (PHS) funding is sought (74 Fed. Reg. 21610).

With more than 27,000 members, ASCO is the leading professional organization representing physicians who are involved in cancer treatment and research. ASCO is committed to advancing the education of oncologists and other oncology professionals, to advocating for policies that provide high-quality cancer care, and to supporting rigorous clinical and translational research. ASCO's scientific and educational programs, which present cutting-edge developments in cancer research, are accessed and valued by cancer specialists worldwide.

ASCO adopted its Conflict of Interest Policy ("Policy") in 1994, and was one of the first professional medical associations to formally address this issue. The Policy initially relied on disclosure to manage potential conflicts of interest. As the role of industry in clinical trials and the importance of clinical trials in cancer care became more apparent, ASCO revised the Policy to include restrictions on financial relationships of principal investigators (PIs). The restrictions were intended to promote integrity in the conduct of research, and to preserve public trust in the clinical trials system, cancer research, and resulting treatments. To ensure that the restrictions would not prevent the presentation or publication of important research results, ASCO created an exemption for studies funded by NIH. This



PRESIDENT

Douglas W. Blayney, MD

IMMEDIATE PAST PRESIDENT

Richard L. Schilsky, MD

PRESIDENT-ELECT

George W. Sledge, Jr., MD

TREASURER

Clifford Hudis, MD

CHIEF EXECUTIVE OFFICER

Allen S. Lichter, MD

DIRECTORS

Dean F. Bajorin, MD

Monica M. Bertagnoli, MD

Eduardo L. Cazap, MD

Susan L. Cohn, MD

Bruce E. Johnson, MD

Robert M. Langdon, Jr., MD

Robert S. Miller, MD

Kathleen I. Pritchard, MD

Deborah Schrag, MD, MPH

Lynn M. Schuchter, MD

Sandra M. Swain, MD

Joel Tepper, MD

Everett E. Vokes, MD

Peter P. Yu, MD

exemption is based on ASCO’s assessment that “NIH-sponsored trials feature sufficient safeguards to ensure objectivity and independent review of safety and other data developed in the trials.”¹ As a result, the implementation of ASCO’s Policy depends in part on the rigorous enforcement of NIH rules. ASCO supports NIH’s continued commitment to ensuring that its regulations and enforcement levels are commensurate with the rapidly evolving research and policy environment.

ASCO’s comments on the ANPRM are as follows:

- 1. ASCO supports the principles for ensuring the objectivity of research results set out by NIH, including that interactions between government, academia, and industry have beneficial outcomes and should continue subject to appropriate management.**

ASCO supports the principles set out by NIH, which reaffirm the importance of conducting research with high standards of integrity and objectivity. These principles, which are reflected in ASCO’s Conflict of Interest Policy, promote transparency by calling for disclosure and appropriately rigorous management of conflicts of interest. In addition, these principles are consistent with ASCO’s position that the combined efforts of academic researchers and industry are beneficial in facilitating the delivery of new drugs, devices, and therapies from laboratories to patients’ bedsides. Though certain relationships are not appropriate and should be prohibited, many can be disclosed and managed in a manner that is designed to minimize actual and perceived conflicts of interest, and ensure objectivity of research results.

- 2. ASCO supports the standardization of disclosure requirements.**

Investigators are subject to a variety of conflict of interest disclosure and reporting requirements from their academic institutions and, in some cases, the federal government. In addition, the federal government,² and some states,³ pharmaceutical companies,⁴ and academic institutions^{5,6} have recently proposed or enacted applicable public reporting requirements. So far, the framework for reporting financial relationships adopted or suggested by each group is unique. Differences in the scope of disclosure (including *de minimis* disclosure thresholds

¹ American Society of Clinical Oncology: Revised conflict of interest policy. J Clin Oncol 24:10.1200/JCO.2005.04.8926

² Physician Payments Sunshine Act of 2009, S. 301, 111th Cong. (2009).

³ Ross JS, Lackner JE, Lurie P, et al: Pharmaceutical company payments to physicians: early experiences with disclosure laws in Vermont and Minnesota. JAMA 297:1216-1223, 2007.

⁴ Carey B: Drug maker to report fees to doctors. New York Times. <http://www.nytimes.com/2008/09/25/health/policy/25drug.html>.

⁵ Johns Hopkins Medicine. Johns Hopkins Medicine Policy on Interactions with Industry. http://www.hopkinsmedicine.org/Research/OPC/Policy_Industry_Interaction/policy_interaction_industry.html. Accessed July 1, 2009; Partners HealthCare. Partners Commission on Interactions with Industry Report. http://www.partners.org/documents/CommissionReport_PartnersHealthCare2009.pdf. Accessed July 1, 2009

⁶ Steinbrook R: Online disclosure of physician-industry relationships. NEJM 360:325-327, 2009.



PRESIDENT

Douglas W. Blayney, MD

IMMEDIATE PAST PRESIDENT

Richard L. Schilsky, MD

PRESIDENT-ELECT

George W. Sledge, Jr., MD

TREASURER

Clifford Hudis, MD

CHIEF EXECUTIVE OFFICER

Allen S. Lichter, MD

DIRECTORS

Dean F. Bajorin, MD

Monica M. Bertagnolli, MD

Eduardo L. Cazap, MD

Susan L. Cohn, MD

Bruce E. Johnson, MD

Robert M. Langdon, Jr., MD

Robert S. Miller, MD

Kathleen I. Pritchard, MD

Deborah Schrag, MD, MPH

Lynn M. Schuchter, MD

Sandra M. Swain, MD

Joel Tepper, MD

Everett E. Vokes, MD

Peter P. Yu, MD

and other exemptions) and in the definitions of key terms result in the provision of publicly available information that— even when technically correct – appears to be inconsistent or inaccurate.

As NIH considers expanding the scope of the regulations and re-evaluates the definition of “significant financial interest,” ASCO hopes NIH will consider that its framework for disclosure and reporting could serve as a model for other entities with disclosure and reporting requirements. As part of this effort, NIH may choose to develop a standard, electronic disclosure form that can be used by all investigators and institutions. Where possible, standardizing mechanisms for disclosure and reporting of conflicts of interest eases the administrative burden of compliance on individual researchers and academic institutions. For this reason, among others, ASCO supports expanding the scope of the regulation to apply to extramural research funded through SBIR and STTR.

3. ASCO supports the development of conflict of interest management mechanisms that are timely and efficient, and that permit the participation of experts where appropriate.

ASCO supports the development of conflict of interest management plans that manage, reduce, or eliminate conflicts of interest as appropriate. Under the guidance of NIH, conflict of interest management plans developed by institutions should promote timely and efficient management resolutions that do not slow the pace of vital research. Any restrictions on the relationships of grant recipients should be reasonably targeted to protect against research bias, but should not be so sweeping as to deter top scientists from applying for PHS funding. If NIH opts to restrict certain investigator relationships, the regulations should allow for limited waivers that ensure the participation of experts, subject to disclosure and rigorous conflict of interest management. In addition, NIH should issue guidance explaining any waiver criteria.

ASCO appreciates the opportunity to comment on this ANPRM. Any questions should be directed to Suanna Bruinooge (Director, Cancer Research Division, Cancer Policy and Clinical Affairs), suanna.bruinooge@asco.org, and Courtney Storm (Associate Counsel, Ethics and Compliance), courtney.storm@asco.org.

Sincerely,

Douglas W. Blayney, MD
ASCO President