Public statement from Robert L. Comis, MD, and Mitchell D. Schnall, MD, PhD, Group Co-Chairs, May 16, 2014:

We are concerned over recent changes to the federally funded clinical research program sponsored by the National Cancer Institute (NCI). Our major concern is that adequate resources may not be available to continue providing the best science-based clinical trial opportunities for the many patients we serve. The current ECOG-ACRIN portfolio of trials includes investigations of targeted agents and new approaches to imaging technologies and statistical designs. We must maintain a strong infrastructure (scientific programs, operations, biostatistics, data management, auditing, etc.) to support such opportunities, which continually flow into the public system from our scientific committees, whose members are expert clinical and laboratory researchers. These capabilities are essential to ensure the integrity of our trials and patient safety. Discussions are ongoing with the NCI, and we are working on solutions; however, it is unclear as to how we can preserve these critical capabilities within the current funding structure.

With the launch of the National Clinical Trials Network (NCTN) on March 1, 2014, an entirely new algorithm was introduced for funding publicly sponsored clinical trials. Funding for core capabilities is now determined by the number of patients the NCI projects that we will accrue each year. Rather than having a fixed annual amount for core support over the 5-year grant period (which also began on March 1), core support will now ebb and flow each year as trials open and close and accrual fluctuates accordingly. Although some efforts are clearly linked to accrual and some fluctuation in funding may be in order, the current process does not account for the significant costs to maintain our scientific community and to design, develop, execute, and monitor new trials. What is not covered is the cost of ongoing treatment and follow-up of patients after accrual. The process does not provide a mechanism to proactively adjust support based on trial activity.

A quota system for patient accrual went into effect March 1—quite literally, overnight—with a proposed ceiling of 17,000 accruals per annum overall. About 12,000-13,000 of the slots are available for adult cancer patients, and the remainder are available for children with cancer. For the past 2 years, patient accrual was more than 21,000 patients (averaging 23,674 patients over the past 7 years).

The accrual target of 17,000 patients has imposed an unplanned reduction of about 4000 adult patient accrual opportunities. This decrease is inconsistent with our existing accrual rates in NCI-approved studies. For instance, the accrual target for ECOG-ACRIN was set at 2772 for both therapeutic and advanced imaging studies during the first year of the NCTN, whereas we estimate that accrual to our current studies will reach about 3150. Not only will we consume all of the allocated slots for the existing studies and those approved to open this year, we will also require additional funding. We cannot ethically, morally, or with any scientific responsibility, close current studies, to which patients have consented and institutional review boards have approved.

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So, what is at stake? New scientific initiatives. There are a number of new efforts in progress that are not included in the accrual calculation noted above. Among these are 30 studies developed by ECOG-ACRIN scientific committees that are currently in, or being prepared for, NCI review. We have been commissioned to coordinate international trials to evaluate new approaches for rare tumors, such as anal, penile, and thymoma. Some studies employ immune checkpoint inhibitors and various tyrosine kinase inhibitors, and some are aimed at common cancers, such as lung, breast, prostate, and colon, and their molecular subtypes. Our investigators, staff, and patient advocates have worked diligently to move these studies forward. Will they see the light of day? The ECOG-ACRIN infrastructure is supporting a major new NCTN initiative based on molecular characterization of patients’ tumors, accrual to which is scheduled to begin this year. ECOG-ACRIN has been designated by the NCI to provide the various components of the NCTN with highly technical scientific, operational, informatics, and biostatistical expertise to evaluate new imaging agents in advanced imaging trials. The results of these trials will enhance the NCTN’s ability to conduct more efficient studies.

Although the grant year began without a Notice of Grant Award, we were provided with preliminary funding estimates on March 1. The estimates indicated cuts totaling over $4 million and were confirmed when we received our Notice of Grant Award on April 29. The cuts have led to the loss of several million dollars in support of our laboratory programs, researchers, and institutions. More than 20 FTEs were released from our operations and biostatistical centers. Lost were experienced research personnel across therapeutic and diagnostic imaging disciplines that had already been deemed essential following our merger in 2012. We are not alone. Other groups and our member institutions, which we value greatly, are facing similar situations. The financial and programmatic elements of the accrual-based funding algorithm of the new NCTN were poorly planned and abruptly implemented without adequate transition planning. Although the new NCTN announcements come with promises of a vastly improved system, these actions have far-reaching implications that threaten the continued viability of a publically funded clinical trials program.

About the ECOG-ACRIN Cancer Research Group

The ECOG-ACRIN Cancer Research Group is a multidisciplinary, membership-based scientific organization that designs and conducts biomarker-driven cancer research involving adults who have or are at risk of developing cancer. The Group was formed in May 2012 by a merger that combined the complementary strengths of the Eastern Cooperative Oncology Group (ECOG) in cancer therapy and the American College of Radiology Imaging Network (ACRIN) in cancer imaging. ECOG and ACRIN were two highly respected National Cancer Institute (NCI)-sponsored cancer cooperative groups. ECOG-ACRIN comprises nearly 650 member institutions in the United States and around the world. Approximately 6000 physicians, translational scientists, and associated research professionals from the member institutions are involved in Group research, which is organized into three scientific programs: Cancer Control and Outcomes, Therapeutic Studies, and Biomarker Sciences. ECOG-ACRIN is supported primarily through NCI research grant funding, but also receives funding from private sector organizations through philanthropy and collaborations. It is headquartered in Philadelphia, PA, as is PrECOG, LLC, a not-for-profit company that partners with ECOG-ACRIN and industry to develop and conduct clinical trials in all areas of oncology. For more information, visit www.ecog-acrin.org or call 215.789.3631.

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