

***“Harnessing Science: Advancing Care by Accelerating the Rate of
Cancer Clinical Trials Participation”***

House of Representatives Committee on Government Reform

Thursday, May 13, 2004

Rayburn House Office Building, Room 2154

Testimony of Dr. Robert L. Comis, M.D.

Professor of Medicine, Drexel University College of Medicine

Group Chair, Eastern Cooperative Oncology Group (ECOG)

President and Chairman, Coalition of National Cancer Cooperative Groups

Congressmen Davis, Waxman and members of the committee, I want to thank you for this opportunity to testify on behalf of the 8000 cooperative group members from cancer centers, community practices and patient advocacy groups across the country. Most importantly, we should all thank the courageous patients who enter our clinical trials; they are the real pioneers who move the frontiers of cancer treatment forward.

There are two distinct forces in cancer clinical trials: those studies directly supported by industry, and overseen by the FDA, and those studies supported by the NCI which are conceived, designed and executed in academic and community practices throughout the nation. Pivotal industry supported trials are directed towards drug approval. Cooperative group trials are designed to evaluate new approaches and establish new, evidence-based standards of care.

We estimate that approximately 50,000 patients participate in clinical trials yearly. The NCI funded cooperative groups account for about half, or 25,000 patients/year.

The cooperative groups have always played a key role in the nation's clinical research system. We developed curative therapies for childhood cancers; improved the post-surgical survival for patients with breast and colorectal cancer by 25-30%; and showed that cancer can indeed be prevented in high-risk patients.

As importantly, though, the publicly funded system allows us to ask and answer questions that challenge the mainstream. Our studies evaluating high dose chemotherapy for breast cancer showed that this extraordinarily expensive and toxic treatment was of no clear benefit—saving the country hundreds of millions of dollars and patients unquestionable toxicity.

Much has changed since President Nixon declared the War on Cancer. The understanding of the biology of cancer has increased tremendously; the public and private sector has invested huge resources into the development of biologically directed therapies, and new, targeted agents are entering the oncology practice, and our Phase II and III trials.

The cooperative groups have adjusted to the opportunities and challenges created by these changes. We are investigating the newest molecules and approaches. Virtually all of our studies now include laboratory correlative studies, which attempt to define why something does or does not work. In order to do this, we have established excellent tissue banks and laboratory programs in cancer centers throughout the country, which collect, store and analyze tissue specimens and correlate biology with clinical events occurring in our controlled clinical trials.

But we must do more to ensure that patients have the opportunity to benefit from our work.

First, let me address the issue of accrual of adults onto cancer clinical trials. We estimate that only about 3-5% of adult cancer patients participate in clinical trials. This number was confirmed prospectively in our Harris Survey, which also revealed that only 15% of patients were aware that participation was an option. That survey also reinforced the critical role of the oncologist in informing and educating patients about this option. Increasing awareness, dispelling misconceptions and engaging physicians are key elements of the solution to the accrual problem. These considerations led the Coalition of National Cancer Cooperative Groups to launch a National Awareness Campaign along with Newsweek which is in its fourth year, develop web based tools to facilitate trial searches, and work with the American Society of Clinical Oncology in

developing both recognition and educational programs for physicians. . Indeed the efforts of the Coalition have borne some fruit. There has been a 30% increase in overall accrual onto cooperative group studies from 1997 to 2002- from about 20,000 patients/year to about 26,000. But more work needs to be done.

However, the system is stressed even at this level of accrual. The cooperative groups have been and remain chronically under funded. Two extensive reviews of the system in the mid 1990s recommended that the cooperative groups be funded at the full peer review recommended level. We continue to be funded at approximately 60% of that level, and funding has been flat for the last three years. This stifles innovation, destabilizes key functions such as our tissue banks, data management and informatics platforms, and acts as a disincentive to both academic and community physician participation.

Keep in mind that about 60% of accrual comes from community based physician practices. The NCI reimburses \$2000/case to perform the research at the site. It is estimated in the ASCO survey that the actual cost is more like 4000-6000 dollars/ case. The ability for both academic and community sites to continue to do government sponsored work will be increasingly challenged, particularly when the full effect of the Medicare Modernization Act of 2003 takes place in 2005.

The entire system is being buried under a regulatory mountain. It is estimated that about 30% of the clinical trials research dollar now goes towards ensuring regulatory compliance. Our studies are overseen by about 1600 separate IRBs; HIPAA compliance complicates our scientific work. The current discussions about off label drug use in oncology could have a huge impact on our studies, which try to explore new indications, and uses for targeted agents as they become available. We all believe that there is an important balance

between the need for innovation and critical societal concerns—but the balance must ultimately be struck for the advantage of all who suffer from cancer.

The cooperative groups remain totally committed to providing high quality care and new opportunities for cancer patients. But rest assured, the development of the newer cancer treatments will make clinical trials more complicated and more costly. Accrual will remain a major issue as we enroll patients based more on their biologic characteristics than clinical ones.

The cooperative groups chairs have developed a White Paper entitled “Harnessing the Science: A proposal to improve the publicly-funded cancer clinical research system” which I have submitted for the record which outlines our thoughts on what can be done to ensure the continued vitality and importance of the cooperative groups in the publicly funded system which is so critical to cancer patients in our country.

Thank you,

Robert L. Comis, MD