

**STATEMENT OF ELLEN L. STOVALL
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**ON CANCER CLINICAL TRIALS
BEFORE THE
HOUSE COMMITTEE ON GOVERNMENT REFORM
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I am Ellen Stovall, President and CEO of the National Coalition for Cancer Survivorship, or NCCS, and a 32-year two-time survivor of cancer. NCCS is a survivor-led advocacy organization for people with all kinds of cancer; our mission is to achieve quality cancer care for all Americans. Since its founding in 1986, NCCS has recognized that access to clinical trials is a major component of quality cancer care. We are extremely pleased that the Committee on Government Review would focus its attention on the achievements and shortfalls of the federal government's support for clinical cancer research, and we hope our perspective will aid the Committee in recommendations for change.

A quick review of the NCCS web site at www.CancerAdvocacy.org reveals the importance of clinical trials to cancer survivors as well as the central role of various government agencies and government-funded academic entities in organizing and conducting these trials. What is less obvious is the growing—and indeed now preeminent—position of private industry in planning, funding and carrying out cancer clinical trials. This development is not necessarily unwelcome, but it does raise questions about the appropriate balance between public and private investment in research. If we believe as a society that there is a role for the federal government in the clinical research enterprise, then we should pay special attention to challenges confronting that involvement, and this Committee is well placed to conduct that inquiry.

There are no doubt many reasons why the rate of participation in cancer clinical trials is much lower than we would wish. For a long time, those of us involved in cancer patient advocacy felt that the problem was one of education—that is, people were not adequately informed of the benefits, both to the individual patient and to society, and were excessively focused on the risks of research participation. It is still true that some may be discouraged from enrolling in clinical trials because of rare but nevertheless troubling media reports of unethical conduct by researchers, but for the most part we believe that organizations like ours and many others referenced in our web site have gotten the word out that clinical trials are a positive, both for the patient and for the sake of medical progress. With widespread internet access and many educational outlets on the web and otherwise, cancer patients and their families should now be much better informed about clinical trials.

Another issue of concern for many years was the tendency of third-party payers, including most prominently the Medicare program, to disallow coverage of routine patient care costs for patients participating in clinical trials. The rationale for this unenlightened policy was that clinical trials were by definition “experimental” and thus excluded from most insurance coverage. Various legislative proposals during the 1990’s sought to change the policy, particularly for Medicare, but these did not prevail, mostly for reasons of perceived cost. Fortunately, we were able to persuade the Clinton Administration to issue an executive memorandum instructing the Medicare program to allow all beneficiaries, those with cancer and also with other diseases, to participate in high quality clinical trials, such as those sponsored by federal programs or those under the oversight of the Food & Drug Administration. With this change, and the leadership role of Medicare in health policy, reimbursement has seemingly become less of an obstacle than before.

Cost remains a primary concern, however. Clinical research is expensive, requiring an extensive infrastructure, both at the central points of control—that is, the research centers providing overall management of the trial—and at the level of the individual provider. Research requires sophisticated dedicated personnel, such as research nurses, as well as the means for data collection and management, not to mention additional time commitment from physicians involved in the research. One of the reasons why privately-sponsored research has overtaken that sponsored by the National Institutes of Health and other federal sources is that industry is willing and able to pay the full cost of research, whereas the government’s funding seems to lag behind. Despite some increases in per-patient payment by the National Cancer Institute, the NCI payment falls far short of covering the actual per-patient cost.

At the same time, trials sponsored by NCI seem to be burdened by unnecessary duplicative review and bureaucratic control by the Cancer Therapy Evaluation Program, or CTEP. I understand that the cooperative research groups are developing recommendations to streamline the review process at NCI and to facilitate collaboration with industry funders. Another source of unnecessary duplication and cost is the numerous reviews conducted by the Institutional Review Boards, or IRBs, at local institutions participating in multi-site trials. The duplication of review clearly adds to the overall costs of the research enterprise, but it also contributes to delay—delay in commencing trials, delay in getting results and delay in medical progress. The American Society of Clinical Oncology, or ASCO, will be convening a large meeting of federal officials, academic and industry scientists, and patient advocates later this month to attempt to address this problem in a constructive manner.

All of these factors tend to make the cancer clinical trial process much less efficient and user-friendly than should be the case. I fear, however, that the situation is about to become much worse by virtue of changes in Medicare reimbursement mandated for next year by the Medicare Modernization Act, or MMA, enacted by Congress last year. Congress had been concerned for many years about the “profit” that physicians made through the spread between the Medicare payment rate, based on an inflated “average wholesale price,” or AWP, and the actual cost of the drugs used to treat cancer and other diseases. My organization and most others interested in cancer sought to reform this system, but the fear is that the MMA solution adopted by Congress will reduce total payments for cancer care to such an extent that services will have to be reduced, and clinical trial participation may be among the first to go.

During 2004, total payments for cancer chemotherapy are maintained at roughly the same level as in the past by simultaneously reducing payments for drugs and increasing payment for services by an additional 32%. In 2005, however, drug payments will be reduced even further—perhaps to the point where individual physicians may not be able to purchase drugs for the amount Medicare will pay—and the “add-on” will be reduced from 32% to 3%. Then, in 2006 and thereafter, the additional payment for services disappears entirely. The Congressional Budget Office has estimated that drug payments will fall by \$300 million in 2005, and payment for services will decline more than 20%. Some speculate that the total reduction could amount to 40% of current levels. As another measure, the CBO has scored savings in excess of \$1 billion per year over the next 10 years resulting from these provisions.

For most oncologists, clinical research is a cost, not a profit, center. It seems inevitable that payment reductions of this magnitude will make it extremely difficult for oncologists in private office-based practice (which is where most of the nation’s cancer care and most of the cancer clinical trials occur) to continue the investment necessary to enable them to offer clinical trials as an option for their cancer patients. In fact, this fear is confirmed by surveys conducted by ASCO, the leading oncology medical society.

A survey of domestic ASCO members prior to enactment of the MMA legislation reflected that reimbursement changes like those that were eventually adopted would lead to the following results:

- 73% of practicing oncologists would send cancer patients to a hospital for cancer chemotherapy rather than treating them in an office setting;
- 53% would limit the number of Medicare patients they treat;
- 42% would stop conducting clinical trials in their offices; and
- 44% (55% of those over age 55) would plan to retire from practicing medicine earlier than anticipated.

A second ASCO survey is of even more interest because it was directed not to office-based practitioners but to cancer centers that would not be directly affected by the reimbursement declines. Surveying 20 national cancer centers, ASCO found a degree of concern commensurate with that of physicians in private practice. Among the responding centers, 70% concluded that such legislation would affect their operation “a great deal.” With respect to clinical trials, three-fourths of the centers felt their program would be scaled back, with a third of all responders saying that clinical trials would be scaled back to a large degree.

Thus, from two very different cohorts of cancer providers, the view seems entirely consistent: reimbursement changes of the sort that were enacted by Congress in the MMA legislation would likely cripple clinical research, with most believing there would be an adverse impact on clinical trial enrollment at both the individual physician office and the cancer center. Across the spectrum of cancer clinical trials, the pullback will be substantial and potentially irreparable.

Today, we can be proud to have the very best cancer care in the world, and our cancer clinical research is second to none. But a great threat is looming in the form of unreasonable cuts in payments for total cancer care, which surveys show will inevitably affect not just individual patient care but also longer-term progress against the disease. If something is not done, and done soon before these reimbursement cuts take effect in January 2005, I fear that the damage will be irreparable and that we as a society will be paying for many years to come.

The charge to the Committee on Government Reform could obviously be far-ranging with so many problems confronting the cancer clinical research effort, but none is more immediate or fundamental than the threatening Medicare reimbursement cuts, which will take effect next January if legislative or administrative relief is not forthcoming. I hope that you will consider analysis of this issue and recommendations for prompt action to be priorities of the Committee.