C L C CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

GAO REPORT ON COVERAGE OF PATIENT CARE COSTS IN CLINICAL TRIALS

Senators Jeffords and Lieberman requested that the General Accounting Office (GAO) conduct a study of policies and practices of health insurers with respect to coverage of routine patient care costs for patients wishing to enroll in clinical trials, especially those sponsored by the National Institutes of Health (NIH) and its National Cancer Institute (NCI). GAO has now issued a report (B-281108, Sept. 30, 1999), which confirms some information already known about this issue, but also leaves important questions unanswered.

What the GAO Report Shows

- There is no consistent or predictable policy among third-party payers concerning coverage of patient care costs in a clinical trial. Although most payers assert a policy against such coverage, in fact payment of routine patient care costs is the rule rather than the exception.

- Payers insist that they consider a range of factors in making coverage decisions, but these factors are not disclosed to insured persons and appear to be applied in a relatively random and inconsistent fashion.

- Because of lack of clarity in coverage policies, it appears that a substantial portion of routine patient care costs are in fact paid by third-party payers. Physicians who believe they are offering patients appropriate patient care in the context of a clinical trial submit claims, and those claims are usually reimbursed. This fact is strongly confirmed by as-yet-unpublished data collected by the American Society of Clinical Oncology (ASCO), which reflected that claims for patient care costs in clinical trials are submitted 95% of the time and denied in fewer than 10% of cases where claims are submitted.

- If third-party payers usually pay the routine patient care costs of patients in clinical trials, there are important implications for scoring of proposals to mandate coverage of such costs. Thus, such mandates would add little, if any, cost to either private insurance plans or to federally funded programs such as Medicare because they are already included in the system.

- It is difficult to quantify any significant negative impact on accrual to NIH-sponsored trials as a result of coverage policies of third-party payers, although NIH officials are convinced that these policies inhibit the clinical trials enterprise.

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What the GAO Report Fails to Address

- The GAO report is limited in its ability to assess the impact of payer policies on clinical trial participation because the inquiry focused on a sample of opinion drawn from NCI-designated cancer centers and specifically the directors of these centers or their designees. Most cancer patients are treated in a setting that is not associated with an NCI-designated cancer center, and, even when patients are treated in these centers, it is their personal physicians and not center directors who are most likely to observe the effects of coverage policies on the decision whether or not to participate in a clinical trial.

- The ASCO survey, which may represent the most complete review to date of clinical trials practices, identified a number of factors limiting participation in clinical trials. Foremost among them were too-restrictive eligibility requirements, as the GAO report notes. The GAO report, however, fails to mention that a full 83% of respondents to the ASCO survey believed that "assured reimbursement of clinical costs" would help to enroll patients in trials.

- The GAO report thus fails to address the human factor — i.e., the fear of reimbursement denial to physicians who may be forced to absorb the unreimbursed cost of care or, more pointedly, the fear of cancer patients, already under assault by their disease, that they may be held accountable for thousands of dollars of unreimbursed cost simply because they choose to participate in a clinical trial.

- Moreover, the system itself is burdened by gross inconsistencies in payment policies. In 1993, the Medicare program faced the same problem with regard to coverage of so-called off-label uses of drugs — i.e., uses other than those for which the drugs were specifically approved by the Food and Drug Administration (FDA). Congress required Medicare to adopt a consistent policy based on private independent medical compendia. The Medicare program objected that costs would skyrocket, but in fact consistency in approach has proved a boon to patients, with no additional cost to the program. The Medicare approach has also been widely accepted in the private sector with nothing but positive results.

- The same outcome should apply here. A consistent, predictable approach to coverage will enable patients to make informed decisions about their health care and will ensure, when they are confronted with life-threatening diseases like cancer, that they have access to the best of medical care, which often includes treatment in the context of a clinical trial.