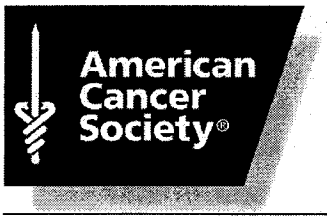
EXHIBIT 2
DATE 3/22/11
HB ~~620~~ 615



The Costs of Routine Care Provided in a Clinical Trial are comparable to the Costs of Standard Therapy

The evidence from numerous studies has overwhelmingly shown that patient care in clinical trials costs approximately the same as care delivered in standard therapy. In some cases, because the third-party payer is not billed for the drug or treatment under investigation, the costs associated with care in a clinical trial can actually be less than the care delivered in standard therapy.

Several studies specifically focused on the costs of cancer clinical trials have recently been published in highly respected peer-reviewed publications.

- A pilot study conducted by the American Association of Cancer Institutes (AACI) showed that the total mean direct medical charges for patients enrolled in a clinical trial *were less than the charges for patients receiving standard therapy.*[1]
- A December, 2001 article similarly found that some clinical trials may actually result in *lower* patient care costs. In addition, in cases where trials resulted in modest increases in patient care costs, the authors concluded that these costs were justified by the benefits that clinical trials bring to all patients.[2]
- The Mayo Clinic has found that the cost of care for patients enrolled in clinical trials is often little more than for patients who received standard therapy.[3]
- Authors of a study conducted at Kaiser Permanente found that the cost of medical care for enrollees in clinical trials without bone marrow transplant were no higher than for patients who were not enrolled in a trial. Kaiser further states, "Kaiser has been participating in cancer clinical trials without substantial increases in the direct costs of medical care."[4]
- The most comprehensive study yet confirms that there are only slightly higher patient-care costs associated with treating patients in cancer clinical trials compared to treating similar patients outside of trials.[5]

Some esteemed hospitals and universities have also conducted cost analysis studies.

- A study at Memorial Sloan-Kettering Cancer Center in New York City showed that the overall average cost of treating clinical trial patients was 17% *less* than treating patients receiving standard care.[6]
- A study conducted at the Karmanos Cancer Center in Detroit showed that the 6-month costs for treating advanced lung cancer were an average $1400 less for patients enrolled in a clinical trial.[7]

The Institute of Medicine has also concluded that the cost impact of providing coverage for routine patient care costs is likely to be "quite small."[8] The IOM's reasoning included the following:

- The reimbursement costs are limited to the cost of "standard care" which would be covered if the patient were not enrolled in the trial;[8]
- Only a small percentage (approximately 20%) of cancer patients are eligible to participate in a clinical trial and very few (approximately 3% of cancer patients and less than 0.5% of Medicare patients) currently enroll. Even if enrollment was increased to the full 20 percent, it is unlikely that these numbers will significantly impact overall costs to health plans;[8]
- Through clinical trials, we will be able to identify ineffective treatments, which could save health plans money and will benefit the nation as a whole.[8]

1. Bennett CL, Stinson TJ, Vogel V, *et al.* Evaluating the financial impact of clinical trials in oncology: Results from a pilot study from the Association of American Cancer Institutes/Northwestern University Clinical Trials Costs and Charges Project. *J Clin Oncol* 2000;18:2805-10.
2. Bennett CL, Adams JR, Knox KS, Kelehan AM, Silver SM, Bailes JS. Clinical trials: Are they a good buy? *J Clin Oncol* 2001;19:4330-9.
3. Wagner JL, Alberts SR, Sloan JA, *et al.* Incremental costs of enrolling cancer patients in clinical trials: a population-based study. *J Natl Cancer Inst* 1999;91:847-53.
4. Fireman BH, Fehrenbacher L, Gruskin EP, Ray GT. Cost of care for patients in cancer clinical trials. *J Natl Cancer Inst* 2000;92:136-42.
5. Goldman DP, Berry SH, McCabe MS, Kilgore ML, Potosky AL, Schoenbaum ML, Schonlau M, Weeks JC, Kaplan R, Escarce JJ. Incremental treatment costs in National Cancer Institute-sponsored clinical trials. *JAMA* 2003; 289: 2970-76.
6. Quirk J, Schrag D, Radzyner M, *et al.* Clinical trial costs are similar to and may be less than standard care and inpatient (InPT) charges at an academic medical center (AMC) are similar to major, minor, and non-teaching hospitals. *Proc Am Soc Clin Oncol* 2000;19:433a. (abstr 1696).
7. Bennett CL, Stinson TJ, Vogel V, *et al.* Evaluating the financial impact of clinical trials in oncology: Results from a pilot study from the Association of American Cancer Institutes/Northwestern University Clinical Trials Costs and Charges Project. *J Clin Oncol* 2000;18:2805-10.
8. Aaron HJ, Gelband H, editors. Extending Medicare reimbursement in clinical trials. Washington, DC: National Academy Press; 2000. p 13.