The calculation of utilization increases reflects the change in the aggregate number of prescriptions filled. The calculation of annual increase in expenditures reflects the change in expenditure from an old set of drugs to a new set. To estimate the impact of pipeline drugs, case scenarios were performed around HCFA's baseline projections for future drug trends. The compounded, annual, growth-rate decrease of new drug approvals was used as a lower bound, while a constant increase in the pipeline projection provided the upper bound.
RESULTS: Historically, slightly less than one-third of the increase in drug expenditure was due to price increases on existing drugs, approximately one-third was due to increases in the utilization of existing drugs, and slightly more than one-third was due to product shift. Based on our data, the historical increase in expenditures was 15% for all drugs, 25% for newer drugs and 7% for older drugs. Our lower and upper bound scenarios projected national drug expenditures of $191.56 billion and $215.62 billion, respectively, for 2004.
CONCLUSION: The impact of pipeline drugs on future drug trends is significant. There is considerable variation surrounding the impact of pipeline drugs on future drug expenditures based on several plausible scenarios.

CANCER II

CN4

THE IMPACT OF THE DIAGNOSIS OF CANCER ON OUT-OF-POCKET HEALTH-CARE EXPENDITURES MADE BY THE US ELDERLY

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If the "total" costs of a disease, such as cancer, are to be accurately quantified, out-of-pocket expenditures (OOPE) made by patients and caregivers must be added to costs incurred by third party payers (direct medical) and employers (lost productivity). Prior studies of OOPE by the elderly used small geographically restricted samples and narrow patient subgroups.
OBJECTIVES: To rigorously quantify OOPE for individuals older than 70 years in the United States. To emphasize cancer-related OOPE, three patient cohorts were examined: 1) no cancer (No CA); 2) history of cancer but not undergoing treatment (CA/No Tx), and 3) undergoing active cancer treatment (CA/Tx).
METHODS: Data from the Asset and Health Dynamics Study, a nationally representative, longitudinal survey of community-dwelling elderly were used. Respondents denoted cancer status and reported OOPE over two years for: 1) nursing home/hospitals; 2) doctor visits; 3) prescription drugs, and 4) "special" services. Using a multivariable two-part regression model to control for differences in co-morbidity, health status, living situation, and sociodemographics, the additional cancer-related OOPE was estimated.
RESULTS: Of the 6576 respondents, 5553 (84%) reported No CA, 843 (13%) reported CA/No Tx, and 180 (3%) reported CA/Tx. Cancer diagnosis and current cancer treatment were significant predictors of increased OOPE compared to no cancer. The mean annual OOPE for No CA, CA/No Tx, and CA/Tx groups was US$1900, US$2400, and US$3300, respectively ($p < .001$). Hospitals (US$1400/yr) and prescription drugs (US$1100/yr) were the largest OOPE components for the CA/Tx group. The incremental OOPE for CA/No Tx and CA/Tx patients approximates US$1.5 billion annually.
CONCLUSIONS: OOPE for elderly individuals with a history of cancer or ongoing therapy are substantial and significantly greater than for those without cancer. If OOPE remain unaccounted for, total costs of cancer will be consistently underestimated. Economic evaluations of interventions aimed at cancer prevention and treatment must account for OOPE.

CN5

A SPECIFIC QUALITY OF LIFE SCALE IN UPPER LIMB LYMPHOEDEMA: THE ULL-27 QUESTIONNAIRE

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OBJECTIVE: The aim of this study was to validate a self-completed questionnaire in Upper Limb Lymphoedema.
METHODS: A qualitative survey was conducted to identify patients' complaints. This questionnaire was administered to 154 patients. Principal component analysis was used to identify dimensions. A validation study was conducted in 304 patients. Six instruments have been used in the case report form: volume differences between the healthy and the affected arms; composite symptom scales completed by clinicians from patient interviews; ULL-27 and SF-36 scales completed by patients; overall opinion of doctors and patients. Internal validity was checked through factorial analysis. Trait validity was investigated by correlating the domains rated with ULL-27 with the SF-36 scale. Nomologic validity was tested by comparing the means of the ULL-27 subscales across severity stages. Sensitivity was tested only in patients with progressive disease between D0 and D28 by comparing mean sub-scores for the ULL-27 scale and by calculating the effect size.
RESULTS: Three hundred four patients were included in the study. Factorial analysis isolated three dimensions: physical (15 items), psychological (7 items), and social withdrawal (5 items). The Cronbach coefficients are greater than 0.80 for all dimensions. The Spearman correlations clearly distinguish the different life domains from each other. At D0 the physical and social dimensions of ULL-27 scale were significantly correlated with severity of illness but it was not the case for the psycho-

logical dimension. Correlation coefficients in patients clinically stable between D0 and D28; were all greater than 0.84 for all dimensions of ULL-27. The sensitivity analysis between D0 and D28 in patients with active disease demonstrated significant differences between mean scores for all ULL-27 dimensions.
CONCLUSION: Volume of oedema poorly reflects the impact of the illness upon the patient. The ULL- 27 scale seems to be a consistent instrument.

CN6

MEN'S PREFERENCES FOR THE CONSERVATIVE MANAGEMENT OF NON-METASTATIC PROSTATE CANCER: THE USE OF CONJOINT ANALYSIS

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OBJECTIVES: Selecting conservative therapies for men with non-metastatic prostate cancer involves trade-offs between treatment attributes. An interview-based survey using conjoint analysis was undertaken to establish which treatment attributes are important to men in selecting treatments, and how attributes are traded off.
METHODS: On the basis a pilot study, eight treatment-related attributes were selected for the survey: diarrhea; hot flushes; ability to maintain an erection; breast swelling/tenderness; physical energy; sex drive; life expectancy, and out-of-pocket personal costs. A discrete choice preference elicitation mechanism was used. One hundred eighty men with non-metastatic prostate cancer from two London hospitals were invited to participate. Of these, 129 men, mean age of 70 years, 58% T-stage 1 or 2 at diagnosis, were interviewed. Data were analyzed using random effects probit models.
RESULTS: On average, men's responses to the conjoint questions were sensitive to variation in the levels of all attributes ($p < .01$) and coefficient signs on all attributes were as expected. A statistically significant interaction was shown which indicated that the attribute ability 'to maintain an erection' was less important to older men ($p = .001$). Most men were willing to make trade-offs between avoiding side effects and both losses in life expectancy and out-of-pocket costs. In terms of the former, they were, on average, most willing to forgo life expectancy to avoid limitations in physical energy (mean of 3.01 months), and least willing to trade life expectancy to avoid hot flushes (mean of 0.58 months to move from 'moderate' to 'mild' or 'mild' to 'none').
CONCLUSIONS: Men with prostate cancer are willing and able to participate in a relatively complex exercise that weighs-up the benefits and harms of various conservative treatments for their condition, and to make trade-offs between attributes. The results provide an indication of the relative importance of different aspects of treatment to patients with prostate cancer.

CARDIOVASCULAR DISEASE II

CV4

COMPARISON BETWEEN INVESTIGATOR AND PATIENT'S GLOBAL HEALTH ASSESSMENTS USING CALCULATED HUI-III AND SF-36 UTILITY VALUES

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OBJECTIVE: To compare patients' own global health assessment item of the SF-36 (SF-1) and investigators' global health assessment (GLBHLT) with values calculated for Health Utilities Index (HUI-III) and SF-36 preference-based (SF-6D), in patients with coronary artery disease (CAD). SF-1 is considered a coarse measure for patients' own health assessment while GLBHLT is a widely used clinical-trials endpoint.
METHODS: Baseline data of the SF-36, HUI-III and GLBHLT were collected for 331 patients enrolled in a double-blind, multinational, phase III clinical trial. Both the SF-1 and GLBHLT rate patients' health on a scale of one to five, where one is excellent and five is poor.
RESULTS: Correlation coefficients (r) between the SF-1 and HUI-III, and the SF-1 and SF-6D were 0.501, 0.508, respectively ($p = .001$). An $r = 0.27$ between the SF-1 and GLBHLT was found significant, albeit the magnitude was almost half of those calculated for the SF-1 and SF-6D or the SF-1 and HUI-III. Calculated SF-6D and HUI-III values for GLBHLT = 1 (excellent) were 0.74 and 0.74 compared with the corresponding SF-1 values of 0.81 and 0.83, respectively. Also the SF-6D and HUI-III values for GLBHLT = 5 (poor) were 0.59 and 0.43 compared with the corresponding SF-1 values of 0.54 and 0.21, respectively.
CONCLUSION: The SF-1 as a rough estimate of the patient's own health, yielded a stronger correlation with utilities calculated for HUI-III and SF-6D while GLBHLT, considered a routine measure in clinical trials, yielded much weaker correlation. Confirmation of these findings is needed to assess if GLBHLT is a fair representation of the health of patients with CAD.

CV5

ORLISTAT IN OBESE TYPE 2 DIABETIC PATIENTS: ASSESSMENT OF LONG TERM OUTCOMES AND COST-EFFECTIVENESS

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OBJECTIVES: Obesity is a very common condition in type 2 diabetic patients. Treating obesity may enhance hypoglycemic treatment and, thus, may contribute to a reduction in long-term microvascular and macrovascular