OBJECTIVES: To prospectively evaluate the long-term societal economic and humanistic benefits of acute treatment of AECB with gemifloxacin compared with clarithromycin. **METHODS:** Patients with AECB were randomized to receive acute, double-blind, double-dummy treatment with either gemifloxacin 320 mg o.d. for 5 days or clarithromycin 500 mg b.d. for 7 days. Patients in US (n = 386) and Canadian centers (n = 52) were followed for 26 weeks from treatment initiation and the following assessments were made: AECB recurrence requiring antibiotic treatment; respiratory tract infection-related: health care resource utilization, time off and performance at work and usual activities; and health-related quality of life using the St George's Respiratory Questionnaire (SGRQ). **RESULTS:** In full sample analysis, significantly more patients who received gemifloxacin remained recurrence free after 26 weeks (73.8% [158/214] vs. 63.8% [143/224]; p = 0.024) and were hospitalized less (2.34% [5/214] vs. 6.25% [14/224]; p = 0.059). Cost-effectiveness analysis indicated average direct and indirect cost savings of $329 per patient for gemifloxacin vs. clarithromycin. Ninety-five percent confidence intervals for bootstrapped incremental cost-effectiveness ratios ranged from a cost saving of $14,175 to a cost of $8,888 per recurrence-free patient considering all costs. There was an 82.5% probability of gemifloxacin being both cost saving and more effective than clarithromycin from the societal perspective. A greater improvement in total weighted SGRQ score (lower scores being better), adjusted for baseline, was observed for gemifloxacin vs. clarithromycin at 4, 12 and 26 weeks after initiation of acute treatment (43.3 vs. 44.6 [p = 0.38], 39.4 vs. 41.8 [p = 0.20] and 37.7 vs. 41.0 [p = 0.09], respectively). There was significantly less impact on performance at work (p = 0.01) and usual activities (p = 0.03) at 26 weeks, due to bronchitis, among patients who received gemifloxacin. **CONCLUSIONS:** Gemifloxacin was very cost-effective from the societal perspective and improved long-term patient outcomes compared with clarithromycin for the treatment of AECB.

PAR12

PROSPECTIVE USE OF WEB BASED TECHNOLOGY TO EVALUATE HEALTH OUTCOMES IN A LARGE COHORT OF SEVERE OR DIFFICULT TO TREAT ASTHMATICS

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Severe and difficult to treat asthma patients represent a small percentage of all asthmatics, yet they account for much of the morbidity, mortality, and cost of the disease. The factors that make this group of asthmatics difficult to manage are poorly understood. **OBJECTIVE:** To establish a cohort of severe or difficult to treat asthmatics to examine the relationships between features of asthma, treatments and health outcomes using the Internet. **METHODS:** This study, "An Observational Study of The Epidemiology and Natural History of Asthma: Outcomes and Treatment Regiments (TENOR)," is designed to follow at least 5000 subjects for 3 years. Subjects 6 years or older with a diagnosis of asthma and considered by their physician to have severe or difficult to treat asthma are eligible for enrollment. Physicians and coordinators will conduct biannual visits to collect data including: health care utilization, days of work or school missed, the asthma therapy assessment questionnaire (ATAQ), asthma-related quality of life (AQLQ), medications, IgE level, and lung function. Data will be entered onto a secure website. **RESULTS:** Subjects are being enrolled into the cohort from over 300 US pulmonologists and allergists in managed care organizations, community practices, and academic centers. All study sites have Internet access. The TENOR website was built using WebCollectSM services and PhaseForward's InFormTM application. Built-in edit checks and an automatic electronic audit trail ensure data accuracy and completeness. This technology eliminates the need for paper case report forms and improves data cleaning efficiency. **CONCLUSIONS:** TENOR provides a unique opportunity to examine factors related to poor health outcomes in this understudied patient population. The Internet allows real time access to data and facilitates dissemination of data to investigators and the asthma community. TENOR may serve as a model for future large epidemiologic or clinical studies using web-based technology.

PAR13

HYPOTHETICAL VERSUS REAL WILLINGNESS TO PAY IN THE HEALTH CARE SECTOR: RESULTS FROM A FIELD EXPERIMENT

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OBJECTIVE: Despite increased use in the health care sector (HCS), the contingent valuation (CV) method remains controversial. The nucleus of the controversy is the extent to which hypothetical choices in the CV method mimic real economic choices. Correspondence between hypothetical and real willingness to pay (WTP) has been studied for private and environmental goods. These experiments demonstrate that dichotomous choice (DC) CV questions lead to hypothetical bias (overestimation of real WTP). Hypothetical bias has not been assessed in the HCS. We conducted an experiment directly comparing responses to a DC CV question with real purchase decisions using a pharmacist provided asthma management

service as the item being valued. We examined whether DC CV questions lead to hypothetical bias for this good, and we tested whether "definitely sure" hypothetical yes responses, as identified in a follow-up question, correspond to real yes responses. **METHODS:** 172 subjects with asthma were recruited from 10 Kentucky community pharmacies. Subjects received either a DC CV question or were given the opportunity to actually purchase the service. Three different prices were used: $15, $40, and $80. **RESULTS:** In the hypothetical group 38% of subjects stated they would purchase the good at the given price, but only 12% of subjects in the real group purchased the good ($p = 0.000$). We cannot, however, reject the null hypothesis that "definitely sure" hypothetical yes responses correspond to real yes responses. **CONCLUSIONS:** The DC CV method overestimates WTP in the HCS, but it may be possible to correct for this by sorting out "definitely sure" yes responses.

PAR14

ASSESSMENT OF THE RELATIONSHIP BETWEEN DISEASE SEVERITY, QUALITY OF LIFE AND WILLINGNESS TO PAY IN ASTHMA

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OBJECTIVE: The primary objective was to evaluate the relationship between willingness to pay (WTP), quality of life (QOL), and disease severity measures in asthma patients. The hypothesis studied was that asthma patients with more severe disease, as measured objectively via forced expiratory volume percent predicted (FEV1%), are willing to pay more for a hypothetical cure from asthma than those with less severe disease. **METHODS:** One-hundred asthmatic patients were recruited from community pharmacies in Kentucky for 30 minute face-to-face interviews. Spirometry was used to assess objective disease severity while a multiple choice question assessed subjective disease severity. The Short Form 36 (SF-36) and Asthma Technology of Patient Experience (Asthma TyPE) measured QOL. WTP was obtained via a dichotomous choice contingent valuation question. **RESULTS:** WTP was significantly related to both objective disease severity ($p = 0.02$) and subjectively assessed disease severity ($p = 0.01$). For objective disease severity the mean monthly WTP was $90 for mild asthma, $131 for moderate asthma and $331 for severe asthma; and for subjective disease severity the mean monthly WTP was $48 for mild asthma, $166 for moderate asthma and $241 for severe asthma. A majority of the QOL measures were correlated with WTP. **CONCLUSIONS:** The results suggest that the WTP for a cure from asthma is related to both objective and subjective disease severity.

PAR15

COMPARISON OF HEALTH CARE RESOURCE UTILIZATION OF COPD PATIENTS ON CILOMILAST, 15 MG BID VERSUS PLACEBO

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OBJECTIVES: Cilomilast is a potent and selective phosphodiesterase type 4 (PDE4) inhibitor currently under development for the treatment of chronic obstructive pulmonary disease (COPD) and asthma. **METHODS:** COPD-related health care resource utilization including physician visits, emergency room visits, hospitalizations and medication use were prospectively collected in a 6 month randomized, double-blind, placebo controlled, parallel group study of patients on cilomilast, 15 mg bid ($n = 431$) versus patients on placebo ($n = 216$). Methods of analysis included descriptive statistics, Kaplan-Meier estimates and Poisson regression. **RESULTS:** In the year prior to the study, COPD-related health care resource utilization was comparable between patients eventually randomized to cilomilast and those randomized to placebo; the majority of all patients had no or one emergency room visit or hospitalziation. During the entire 24-week study period, the cumulative incidence of health care utilization was significantly lower in the cilomilast group than the placebo group in terms of all utilization (11.0% vs. 21.1%, $p = 0.004$); including physician visits (11.9% vs. 23.1%, $p = 0.002$), emergency room visits (0.6% vs. 4.5%, $p = 0.004$) and hospitalization (0.5% vs. 3.4%, $p = 0.021$). The relative utilization rates per patient-month of follow-up for each of the utilization types were lower in the cilomilast group than in the placebo group. Treatment with cilomilast resulted in reduction of all utilization by 51% (C.I.: 31%, 65%), physician visits by 41% (C.I.: 15%, 59%). ER visits and hospitalizations were also significantly reduced. **CONCLUSIONS:** In this study, cilomilast was associated with significantly less COPD-related health care resource utilization, including hospitalizations, emergency room visits and physician visits than placebo.

PAR16

COST OF TREATING ASTHMA IN A MANAGED CARE POPULATION

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OBJECTIVES: Asthma is a common medical condition that is increasing in prevalence. The purpose of this study was to examine costs associated with treating asthma patients within a managed care organization (MCO). **METHODS:** Data for this study were obtained from a managed care organization located in the Western region of the US. Patients were eligible for inclusion if they met one of the following criteria: a diagnosis of asthma (ICD-9 code of 493.xx); two or more prescriptions used to control asthma (e.g., inhaled corticosteroid, leukotriene