medication ($p = 0.017$); more likely to become frustrated ($p = 0.003$) and annoyed ($p < 0.001$) with the patient for asking to try a medication; and less likely to provide samples ($p = 0.001$) or a prescription ($p < 0.001$) for a medication.
CONCLUSION: Clinicians are amenable to patients asking for drug information and medications, but their level of receptiveness is associated with the source from which the patient's questions originate.

HP6

RELATIONSHIP OF DIRECT-TO-CONSUMER ADVERTISING SPENDING AND DRUG PRICING FOR THE TOP TWENTY DRUGS FROM 1997 TO 2000: AN EXPLORATORY STUDY

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There exists an ongoing debate regarding the effect of direct-to-consumer (DTC) advertising spending on drug prices. The two opposite views are: (a) increase in DTC advertising spending would be added to drug prices (b) DTC advertising would increase competition and thus reduce drug prices.
OBJECTIVE: Explore the relationship of DTC advertising spending and drug pricing for the top twenty drugs from 1997 to 2000.
METHODS: Top twenty drugs were selected on the basis of their DTC advertising spending (source: Competitive Media Reporting, NY) for 1997. For analysis, average wholesale price (AWP) per unit was used from the Blue Book AWP Unit pricing. For each of the top twenty drugs, the following trend graphs were plotted for 1997 to 2000: (a) the total DTC advertising spending and per unit price of the drug; (b) the percent changes in the DTC advertising spending and drug price. The percent change in DTC advertising spending and drug price for a year was calculated as percent change from the previous year.
RESULTS: Only sildenafil (Viagra) and sibutramine (Meridia) showed an increase in the actual drug price with an increase in the DTC advertising spending. However, for these two drugs in year 2000, the percent change in DTC advertising spending decreased and the percent change in drug price increased. No trend was evident from the graphs of the other eighteen drugs. On an average DTC advertising spending for most of the drugs decreased with time while drug prices continued to increase.
CONCLUSION: Results indicate a very weak relationship between DTC advertising spending and drug prices. The increase in drug price in spite of the decrease in the DTC advertising spending contradicts both rationale i.e. DTC advertising spending reduces drug price through competition or increase in drug price is due to increase in DTC advertising spending.

HP7

IMPACT OF DIRECT TO CONSUMER ADVERTISING—THE CONSUMER SEARCH FOR INFORMATION

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OBJECTIVE: The purpose of this study is to identify factors associated with consumers' seeking various information sources about medications sought in response to direct to consumer advertising.
METHODS: In the spring and summer of 1999, the FDA, Division of Drug Marketing, Advertising, and Communication conducted a national telephone survey of adults regarding Direct-to-Consumer (DTC) promotion of prescription drugs and its effects on visits to the doctor. In addition to consumer attitudes, opinions and responses to direct to consumer advertising, the survey also elicited responses regarding consumer utilization of information sources such as reference books, 800-telelphone number, and health care providers. There were 1081 total respondents, of whom 769 completed the required questions regarding information sources. Chi Square analysis was used to assess associations between consumer demographic information and the different types of informational resources that consumers used after exposure of direct to consumer advertising.
RESULTS: The analysis showed significant associations ($p \leq 0.05$) between gender, race, education, health status, self-perceived knowledge of health, prescription medication use, and internet use and many of the following information resources: reference books, asking friends/neighbors, 800-telephone number, primary doctor, pharmacist, specialist, and nurse. Across all information sources, female gender, decreased health status, low education, and higher than average medication use were the variables that had the strongest associations. A model was developed depicting the associations between these findings. Results pertaining to specific sources will be presented.
CONCLUSIONS: This study evaluated how different consumers seek information from different sources as a result of direct to consumer advertising. This study will assist those interested in identifying and further educating consumers about their health and novel treatments or therapies.

HP8

FDA REGULATORY ACTIONS AGAINST MISLEADING OR UNSUBSTANTIATED ECONOMIC AND QUALITY-OF-LIFE CLAIMS: AN ANALYSIS OF WARNING LETTERS AND NOTICES OF VIOLATION

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OBJECTIVES: To examine the frequency and nature of FDA regulatory actions against pharmaceutical companies for unsubstantiated or misleading economic and quality-of-life (QOL) claims.
METHODS: Review of publicly-available FDA warning letters and notices of violation (n = 566) sent to pharmaceutical companies between January 1997 and November 2001 for inappropriate promotional claims. A standard data collection form was developed to capture the frequency and type of violation and the medium in which violations were found. We classified economic violations into several categories (e.g., "unsupported comparative claim of effectiveness, safety or interchangeability," "claims of cost-savings when there are obvious additional costs that may affect cost savings," "implied claims of cost-savings to a broader audience than applicable"). QOL violations for false or misleading claims using the words improved 'quality of life' or 'patient well-being' were classified into the following categories: "lack of substantial evidence for QOL claims," "promoting QOL claims in investigational or unapproved drug," and "selective presentation of QOL information".
RESULTS: 28 (4.9%) letters cited false and/or misleading economic claims. The most common economic violation was an economic claim containing an "unsupported comparative claim of effectiveness, safety or interchangeability" (n = 14). 28 (4.9%) letters cited QOL violations (4 letters contained both economic and QOL violations). The most common QOL violation was "lack of substantial evidence for QOL claims" (n = 15). Violations were found most frequently in brochures and on websites.
CONCLUSIONS: A body of evidence is emerging that illustrates how the FDA is regulating promotional material containing misleading or unsubstantiated economic and QOL claims. Knowing what constitutes an economic or QOL violation remains unclear, because there are no formal guidelines about what constitutes a violation, nor what level of substantiating evidence is required. More guidance may be needed to ensure appropriate use in drug promotions.

ASTHMA & RESPIRATORY DISORDERS/INFECTIONS

AR1

RELATIONSHIP BETWEEN DIFFERENT MEASURES OF ASTHMA SEVERITY: PATIENT-PERCEIVED, SYMPTOM DERIVED, AND FEV1 DETERMINED SEVERITY MEASURES

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OBJECTIVE: In health services research, obtaining objective measures of pulmonary function to classify asthma severity is often not possible. Researchers must rely on methods such as frequency of self-reported symptoms and patient perceived severity. This study examined the relationship between FEV1 determined severity and severity determined by patient-reported information.
METHODS: Data from adult patients with asthma were obtained from a pulmonary clinic via chart review and patient self-report during a scheduled physician visit. Patients in acute exacerbation were excluded. Patient-Perceived Severity (PPS) was determined by asking "How severe do you think your asthma is?" with a five-point Likert scale from Very Mild to Very Severe. Overall Symptom-derived Severity (OSS) and Nocturnal Symptom-derived Severity (NSS) were determined from two separate questions regarding symptom frequency during the preceding four weeks. Responses were based on the NHLBI 1997 Asthma Guidelines. Pulmonary function tests were obtained the same day as part of standard care. FEV1-Determined Severity (FEV1-DS) was derived by comparing the FEV1 with the Guideline classification of severity based on spirometry. Three severity categories were derived for each severity method. Percent agreement between FEV1-DS and each patient-reported severity was determined by constructing 3×3 tables. Correlations (Spearman's rho) were conducted between FEV1-DS and the patient-reported severity measures.
RESULTS: 57 patients with a mean FEV1 percent predicted of 80.2% (27.5) were studied. The percent agreement between FEV1-DS and PPS was 59.7% (33.3% over-estimate, 7.0% under-estimate); 56.4% between FEV1-DS and OSS (14.5% over-estimate, 29.1% under-estimate); and 40.7% between FEV1-DS and NSS (25.9% over-estimate, 33.3% under-estimate). The correlations between FEV1-DS and PPS were 0.58 ($p < 0.01$); 0.53 with OSS ($p < 0.01$); and 0.13 with NSS ($p = 0.13$).
CONCLUSIONS: PPS and OSS demonstrated reasonable agreement and correlation to FEV1-DS, albeit opposite trends in over- and under-estimates. These two measures of asthma severity appear useful for population based studies when FEV1 is unavailable.

AR2

DIRECTLY ELICITED PREFERENCES COMPARED TO PREFERENCES DERIVED FROM THE SF-36 IN ADULT ASTHMATICS

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OBJECTIVES: Several empiric algorithms have been developed to derive preference estimates from the SF-36. The objective of this study was to compare the validity and responsiveness of SF-36 derived preference estimates to directly elicited preferences in persons with persistent asthma.
METHODS: We used data from a one-year clinical trial of adult asthmatics to derive preferences from the SF-36. Preferences were estimated using five published algorithms for converting SF-36 scores to non-choice based preference estimates. Derived preferences were compared to directly elicited visual analog scale (VAS) values.