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.

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

Parthian AG, Anantharaman RT, Shepherd MD
The University of Texas at Austin, Austin, TX, USA

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.

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

Belazi DT, Crawford A, Pizzi L
1Thomas Jefferson University & Abbott Laboratories, Philadelphia, PA, USA; 2Thomas Jefferson University, Philadelphia, PA, USA

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-telephone 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, 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.

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.

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

Stewart KA, Neumann P
Harvard School of Public Health, Boston, MA, USA
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

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”.

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

Lee TA, Hollingworth W, Sullivan SD

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.