questionnaire \((N = 222)\). RESULTS: From the best imaginable state, each 20-point decrement in respondent’s self-rated health status yielded significantly greater inconsistency in their valuation of EQ-5D health states controlling for age and sex. Inclusion of education and income reduced this effect slightly, yet it remained statistically significant. CONCLUSIONS: Respondents in poor health demonstrate greater difficulty in valuing health states in a logically consistent manner. Censoring survey data to remove inconsistent respondents may violate the principle of using representative population values in evaluating cost-effectiveness of health care.

QUALITY OF LIFE IN PRODUCT LABELING: A REVIEW OF MARKETED DRUG PRODUCTS
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Increasingly over the past several years, quality of life and patient-reported outcomes data have been submitted as part of NDA and sNDA packages to US and International regulatory agencies. These data provide important information to prescribing clinicians and patients regarding therapeutic and humanistic benefits of drug therapy. OBJECTIVES: To evaluate the marketed drugs with the terminology ‘quality-of-life’ in the product labeling. METHODS: A search of the Physician Desk Reference database was conducted to identify those products that included the term “quality-of-life” (QoL) within the Physician Package Insert. The Summary Basis of Approval (SBA) of each product was reviewed to evaluate the research processes followed, use of psychometrically validated instruments, and the final resulting language attained within the labeling with respect to QoL. RESULTS: Twenty-two products referencing the term “quality-of-life” in the product labeling were identified. FDA approval of these products occurred mainly in the years from 1982 to 2000 with increasing frequency of QoL inclusion in recent years. Upon SBA review we found the majority of the products (13/22) utilized a validated instrument during clinical investigations. Only one of the 22 SBAs specifically described and discussed the issue of instrument validation. In the early years approved labeling claims included more broad, sweeping terminology when describing QoL results. In more recent, cases, approved QoL labeling claims were more narrowly defined and more rigorously worded with respect to trial results and specific patient-reported instruments. CONCLUSION: Over the course of the time, the approach has become more rigorous resulting in a more refined QoL research process. These findings have demonstrated that the use of QoL descriptive data has increased, particularly a greater degree of comprehensive information pertaining to QoL instruments, research, and data can be found in the SBAs. Hence, more relevant and specific QoL information is claimed in the Physician Package Insert.

QUALITY OF LIFE MESSAGES IN PRESCRIPTION DRUG ADVERTISEMENTS IN LEADING MEDICAL JOURNALS, 1990–99
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OBJECTIVES: The use of health-related quality of life (HRQL) claims in drug promotions is under active discussion by the pharmaceutical industry, the FDA, and other stakeholders. However, the extent to which pharmaceutical companies have previously promoted HRQL messages in advertisements in medical journals, and the nature of those messages, has not been quantified. METHODS: We performed a content analysis of all pharmaceutical advertisements appearing in three general medical journals (AIM, JAMA, and NEJM), and three specialty journals (Circulation, Gastroenterology, and Neurology) in January, July, and October annually from 1990–1999. Two reviewers analyzed each advertisement for the presence and type of HRQL content, and for supporting evidence. We distinguished explicit HRQL claims, which used words, such as “quality of life or “patient satisfaction,” from implicit claims, which we defined broadly as pictures implying improved physical, emotional/mental, or social functioning. RESULTS: We judged that HRQL messages appeared in 520 (24.3%) of 2142 advertisements examined. Advertisements with HRQL content increased from 1990–94 to 1995–99 (19.9% vs. 29.6%, \(p < 0.0001\)). 56% of HRQL contained implicit messages only, followed by ads that used both implicit and explicit messages (35%), and ads containing explicit messages alone (9%). Overall, few ads (12%) contained any clear supporting evidence. Messages that implied or stated improved overall well-being or mental health were most common (78% of all HRQL ads), followed by enhanced physical or social functioning (63% and 25%, respectively) (numbers add to 100%, because a single ad could contain multiple messages). CONCLUSIONS: Advertisements conveying HRQL messages are used frequently by drug manufacturers in medical journals, and are increasing over time. In the future, researchers should better define HRQL, and probe more deeply into what comprises substantiating evidence, perhaps by incorporating the concept of “patient-reported outcomes.”

HEALTH POLICY

ETHNIC DISPARITY OF COMBINATION RIBAVIRIN/INTERFERON ALFA-2B PRESCRIBING AMONG HEPATITIS C-INFECTED MEMBERS IN A MANAGED CARE ORGANIZATION (MCO)
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