negative binomial regression model, controlling for age, gender, race/ethnicity, income education, general physical and mental health and co-morbidity burden. In 2014 depending on family income and employment status, the uninsured will either obtain private or Medicaid insurance coverage, thus the analysis was restricted to individuals less than 65 years with 12 months of continuous private or Medicaid coverage or uninsured for the whole year. Our study sample was nationally representative on behalf of 71.3% of US population. RESULTS: Five measures of health care utilization were used (emergency room (ER) visits, outpatient visits, office visit, inpatient visits, prescription use). Uninsured individuals had lower utilization for all health care services except ER visits. Holding everything else constant, the uninsured will have 1.98 (1.75-2.25) and 1.61 (1.24-2.1) times higher expected rate of office based visits, 2.39 (1.81-3.15) and 2.62 (1.41-4.86) times higher expected rate of outpatient visits, 2.17 (1.58-2.97) and 1.70 (1.11-2.62) times higher expected rate of inpatient visits, 1.70 (1.53-1.89) and 1.92 (1.57-2.34) times. The proportion of prescriptions filled for prescribed private or Medicaid coverage, respectively. CONCLUSIONS: Health care reform will increase the demand for health services and prescribed medications, except ER use for the uninsured. These results may be used by various stakeholders to estimate expected changes in health care expenditures.

PHP96 REASONS FOR REJECTION OF PRO LABEL CLAIMS: AN ANALYSIS BASED ON A REVIEW OF EMERGING NEW MOLECULAR ENTITIES AND BIOLOGIC LICENSE APPLICATIONS 2006-2010
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OBJECTIVES: Previous analyses of PRO label claims concentrated only on successful label claims. The goal of this research was to explore why reasons for PRO label claims were either denied or not sought. METHODS: Using the FDA Drug Approval Report Webpage, all approved new molecular entities (NMEs) and biologic license applications (BLAs) between February 2006 and December 2010 were identified. For identified drug products, medical review sections from publicly available summary basis of approvals (SBAs) were reviewed to identify PRO endpoint status and any PRO label claims. The goal of this research was to explore why reasons for PRO label claims were either denied or not sought. METHODS: Using the FDA Drug Approval Report Webpage, all approved new molecular entities (NMEs) and biologic license applications (BLAs) were reviewed to identify PRO endpoint status and any PRO label claims. The goal of this research was to explore why reasons for PRO label claims were either denied or not sought. RESULTS: Out of the 116 NMEs/BLAs identified and accompanying SBAs reviewed, 44.8% of products included PROs as part of the pivotal studies; however, only 24.1% received PRO claims. Primary reasons for denial (where data available) included a lack of demonstration of content validity (inclusive of general measures such as the EQ-5D and SF-36). The ability to assess symptoms in an open-label setting, lack of consensus on clinically meaningful change, interpretation of or missing PRO data, lack of measurement of full constellation of symptoms, issues of multiplicity and concerns of "bias" in certain PRO measures. CONCLUSIONS: Nearly half (45%) of submissions included PROs yet this rate is not reflected by claims granted. Underlying the nature of PRO claims granted under the current regulatory guidance is the influence of economic factors, prescribing patterns, and market dynamics, decisions to withdraw products from the market are driven by concerns over safety. This study evaluated new molecular entities (NMEs) approved by the FDA in the period 1980-2009 that were withdrawn from the market for safety reasons. METHODS: Data were obtained from the FDA and the US Federal Register. Descriptive analyses were used to classify product discontinuations by therapeutic category, year, and reason for discontinuation. RESULTS: There were 740 NMEs approved by the FDA during the study period. As of December 1, 2010, the European Medicines Agency (EMEA) had approved the use of drugs discontinued was 118 (15.5%). Safety was the reason for withdrawing 27 (3.6%) drugs from the market. Therapeutic categories with the most safety withdrawals as a percentage of approvals in the 1980s were respiratory (28.6%), musculo-skeletal (23.1%), and nervous system (7.4%). During the 1990s, classes with the most safety withdrawals as a percentage of approvals were musculo-skeletal (18.8%), alimentary tract and metabolism (12.0%), and blood and blood forming organs (7.7%). Therapeutic categories affected by safety withdrawals as a percentage of approvals in the 2000s were musculo-skeletal (20.0%), alimentary tract and metabolism (4.2%), and antineoplastic and immunomodulating agents (0.3%). Major problems that spurred safety withdrawal were hepatic toxicity, severe cardiovascular effects, and gastrointestinal issues. Average time from approval to safety withdrawal was 5.9 (SD = 5.0) years, with a range of 0.3-18.2 years, and a 95% CI of 4.0-7.8 years. CONCLUSIONS: Approximately one in seven NMEs approved in the period 1980-2009 discontinued from the market. More than one-quarter of the discontinuations were attributed to safety reasons. Products remained in the market for an average of six years before safety withdrawal. An ongoing evaluation of new drugs through their product life cycle is important to determine their long-term safety and value to society.