FDA safety communications related to highly prescribed products including the thiazolidinediones and bisphosphonates in 2007, information on drug safety was present weekly, if not daily, in the newspaper and on television. To assist consumers in understanding their risk of developing serious side effects and put into context the relative risk of their various medications, we have developed a 5-color drug risk rating system. METHODS: The iGuard Risk Rating system is a patented process for summarizing serious adverse events contained in each medication’s Prescribing Information. Specifically, we focus on: 1) the severity of the reaction (serious disability or death); 2) the likelihood of the reaction (e.g., >1 in 10,000); and 3) proportion of the population affected (e.g., 0–15%). We also adjust for lack of experience with a product on the market: <1,000,000 prescriptions or <2 years post-launch. Our iGuard Risk Ratings, from lowest to highest, are as follows: 1) Green: Low Risk—Suitable for widespread use; 2) Blue: General Risk—Use under normal care of a doctor; 3) Yellow: Guarded—Be on the lookout for safety events; 4) Orange: Elevated Risk—Create a personal risk reduction plan with your doctor; and 5) Red: High Risk— Requires careful consideration of risk versus benefit. RESULTS: To date, we have rated 106 medications. Risk Ratings associated with individual medications are available on the project website at www.i-guard.org. A total of 80 of 106 medications (75%) were rated Level 2/Blue: General Risk. An additional 20% were rated Level 4/Orange: Elevated Risk. Ratings across molecules within a therapeutic class are very similar. CONCLUSION: Consumer feedback on the iGuard Risk Ratings has been very positive, especially in understanding which of their medications they need to be most diligent in monitoring.

**PHP1**

**ETHNIC DISPARITIES IN HOSPITAL DISCHARGES AGAINST MEDICAL ADVICE AMONG CARDIOVASCULAR DISEASE PATIENTS: THE ROLE OF HOSPITAL QUALITY**

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OBJECTIVE: Ethnic disparities in hospital discharges against medical advice (AMA) have been examined in previous studies. However, the institutional factors affecting health decision making have received much less attention. This study examines the evidence for a joint impact of ethnicity and hospital quality on the likelihood of a discharge AMA in patients with cardiovascular disease (CVD). METHODS: Adult patients hospitalized with a primary admissions diagnosis of CVD from 2000 to 2005 were identified in a state-wide confidential inpatient hospital discharge dataset. The dataset was augmented with information from several sources, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). A high quality hospital was defined as a hospital whose performance exceeded the state average on each JCAHO hospital performance measure. A hierarchical generalized linear logistic model of a discharge against medical advice controlling for various individual and contextual factors was estimated using cross-sectional data. RESULTS: A total of 2593 of the 328,342 hospitalizations for CVD (0.8%) resulted in a discharge AMA. The patients self-identified as non-Caucasian in thirty percent (N = 100,074) of the hospitalizations. Fifteen percent (N = 48,177) of the hospitalizations occurred in high quality hospitals. The adjusted odds of a discharge AMA in a low quality hospital were lower for non-Caucasians (OR = 0.74; p = 0.005) compared to Caucasians while the adjusted odds of a discharge AMA in a high quality hospital were unchanged between Caucasians and non-Caucasians (OR = 0.95; p = 0.6). Among Caucasians, a discharge AMA was less likely (OR = 0.75; p = 0.01) at a high quality hospital compared to a low quality hospital while, among non-Caucasians, the odds of a discharge AMA were unchanged (OR = 0.96; p = 0.74) across hospital quality groups. CONCLUSION: The two unique and complementary findings here are that: 1) institutional quality mediates the relationship between ethnicity and hospital discharges AMA; and 2) the relationship between hospital quality and discharges AMA varies with ethnicity.

**PHP12**

**ASSOCIATION BETWEEN DIRECT-TO-CONSUMER ADVERTISING (DTCA) AND DRUG UTILIZATION IN THE U.S. MEDICAID MARKET FOR SELECTED DRUG CLASSES**

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OBJECTIVE: Spending on direct-to-consumer advertising (DTCA) has seen exponential growth since the late 1990s. The purpose of this research was to assess the association between DTCA spending and drug utilization and reimbursement in the U.S. Medicaid market. METHODS: National direct-to-consumer advertising expenditures were obtained from Advertising Age for selected brands in three drug classes: HMG Co-A reductase inhibiting agents (statins), anti-ulcer/GERD medications, and antidepressants. The drug utilization and reimbursement (sales) data were extracted from the national Medicaid pharmacy files provided by the Centers for Medicare & Medicaid Services. The annual advertising expenditures, drug utilization, and reimbursement were charted from 2000 to 2005. Correlation analysis was used to assess the association between both contemporaneous and lagged DTCA spending by pharmaceutical companies and drug utilization and reimbursement for each of the three therapeutic classes. RESULTS: A wide range of estimated Pearson correlation coefficients were derived, including some negative coefficients. The strongest positive correlations were found for the statins and antidepressants for the year 2003. Only antidepressants had a statistically significant correlation (r = 0.58, p < 0.05) between DTCA and reimbursement/utilization based on a pooled correlation analysis from 2000 to 2005. CONCLUSION: Utilization rates and reimbursement in the Medicaid market for the investigated medications were not consistently statistically impacted by DTCA. While there is evidence of a strong correlation for antidepressants, there is less compelling evidence for statins, and none for the anti-ulcer drugs. Although both utilization and expenditures in Medicaid were growing for all three classes, their growth was due to factors beyond DTCA.

**PHP13**

**CONTROLLED SUBSTANCE WASTE IN HOME HOSPICE SETTINGS**

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OBJECTIVE: To describe the amount and types of unused controlled substances (CS) at the time of death in home hospice and to describe methods used by hospice nurses to destroy CS after
patients expire. METHODS: Retrospective chart review of 105 home hospice patients with a narcotic waste destruction record who expired during a 3-month period in 2007 while receiving care from 4 small hospices (average daily census [ADC] <60) and 1 large (ADC = 160) hospice in the Southeastern Pennsylvania region. Data were collected through review of narcotic waste destruction records as recorded by nurses at the time of patient death. Strength of formulation was recorded sporadically. Hospice nurses were surveyed about CS disposal methods. RESULTS: Mean age of the patients was 78, (range 44–103); majority (57%) was diagnosed with cancer, followed by heart failure (24%). Average length of stay in hospice was 42 days (median 21). Almost all patients had unused CS; morphine concentration (20 mg/ml) was the most common medication (average 31.8 mL/patient). Collectively, over 3 liters (64,680 mg) of morphine were destroyed. Lorazepam was the next most common drug with 990 tablets and 397 ml liquid wasted. Other CS remaining at the time of death included varying strengths of long-acting morphine (251 tablets); OxyContin (90 tablets); and unused transdermal fentanyl (57 patches). Hospice nurses disposed of all unused CS by flushing them down the toilet. CONCLUSION: Although not excessive on an individual level, the amount of CS waste in hospice is significant when viewed in the aggregate. When flushed, these medications reach waterways, potentially posing environmental or health hazards. Regulatory changes are required to address disposal of unused CS. Future analyses should examine the cost of CS medication waste in hospice.

ESTIMATION OF USAGE OF NEW DRUG AFTER REIMBURSEMENT FOR BUDGET IMPACT ANALYSIS
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OBJECTIVE: The estimation of budget impact is important in listing a new drug, but there are a lot of uncertainties. We analyzed usage of new drug after reimbursement and investigated various factors influencing budget impacts of the new drug to get a guidance for public insurance BIA in Korea. METHODS: We used 3 year claims data of 23 new drugs listed in 2004 to analyze usage pattern and market share. We evaluated influencing factors that clinical improvements, treatment cost, disease burden, patient number, market competition, type of company, etc. and conducted multiple regression analysis using these factors. RESULTS: The indications of the 23 listing drugs were for cancer, hypercholesterolemia, diabetes, schizophrenia, pneumonia, peptic ulcer, rheumatoid arthritis, hepatitis B, HIV treatment, etc. At third year after new drug listing, average market share incrementally rose to 20% (0.06–78%, range) both in patient number and volume of use. In case of the new drug with clinical improve and higher cost, the average market share amounted to 33% (n = 4). The market share of drugs with no improve and lower costs amounted to 26% (n = 8). When total patient number of new and pre-listed drugs were under 50,000, market share of new drugs amounted to 25%, 35% of total volume and patient number, respectively. But in case of over 250,000 of patients, market share of new drugs were less than 10% in both. New drugs commanded 27%, 4%, 0.08% of market when number of pre-listed competing drugs were <25, 5–25, 25<, respectively. When the company is domestic, new drugs amounted to about 4% of market share and 25% when it is not. CONCLUSION: Clinical improvements, disease burden, number of patients, number of pre-listed drug, and company type may affect to market diffusion of new drugs. So we suggest these results be considered in forecasting future usage of new drug and conducting budget impact analysis.

EVALUATING THE USE OF PROVISIONAL PATENTS BY THE PHARMACEUTICAL INDUSTRY: THE EXPERIENCE OF THE UNITED STATES
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OBJECTIVE: The U.S. intellectual property regulations allow for claiming the right of priority by filing a patent in a foreign country or by filing a U.S. provisional patent. The study evaluated the provisional patent system introduced in 1994 by the Uruguay Round Agreement Act (URAA). METHODS: Data on patents listed in the FDA Orange Book (OB) for new chemical entities approved between 1980 and 2007 were derived from the USPTO. Descriptive statistics were calculated for the variables included in the study. Chi-square and t-tests were used to assess differences between groups. RESULTS: The OB listed 1452 patents, of which 9.6% claimed priority from a U.S. provisional patent and 39.5% claimed priority from a foreign priority filing. The mean time gained was 328.9 ± 75.2 days from provisional patents and 340.8 ± 60.3 days from foreign rights of priority. The proportion of U.S. companies that obtained a foreign or provisional right of priority increased from 27.4% prior to 1995 to 75.2% after 1995 (p < 0.001). This increase was due to the use of provisional patents. A significant increase in the use of provisional patents and a significant decrease in the use of foreign right of priority also occurred in non-US companies, nevertheless, no increase in the combined use of a foreign and provisional right of priority was found for non-US companies. CONCLUSION: The foreign companies significantly decreased the use of foreign priority patents while increasing the use of provisional patents. The introduction of provisional patents to the existing foreign priority system resulted in a three-fold increase in the use of these systems by U.S. companies. The 1995 URAA change in the USPTO priority system has significantly influenced the frequency by which U.S. companies seek a foreign or a provisional right of priority.

IMPROVING HEALTH TECHNOLOGY APPRAISAL AND DECISION-MAKING: WHAT HAS THE BRITISH PARLIAMENT’S INQUIRY OF NICE TAUGHT US?
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OBJECTIVE: The British Parliament recently held an inquiry into the National Institute for Health and Clinical Excellence (NICE) health technology appraisal (HTA) process. We summarized stakeholder concerns about health economic and decision methodology used for HTAs appraisals and funding decisions, particularly with regard to serious/life-threatening illnesses, and drew comparisons to standards among other nations that use HTA to understand why criticisms might have arisen. METHODS: A systematic review was conducted of written evidence submitted to Parliament about the appraisal process and corresponding health economic methods. Stakeholders were limited to manufacturers, professional and trade associations, and patient/disease advocacy organizations (limited to oncology). We excluded evidence from individuals. We extracted themes from this evidence and generated items for a comparison of methods of other countries that conduct appraisals. Only publicly available, English-language qualitative data were considered. RESULTS: We identified written evidence from 92

PHP15

PHP14

PHP16

Abstracts

A33