PCN172
A CALL TO MONITOR DRUG SHORTAGES AND THE ROLE OF MARKET ATTRACTIONNESS IN EUROPEAN COUNTRIES
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OBJECTIVES: Drug shortages are a global problem. While extensively studied in the United States, numbers about drug shortages in European countries are scarce. This study aims to investigate publically available data about drug shortages in European countries in order to reveal a typology of drug shortages. METHODS: A standardised reporting template was designed based on a literature search to collect and structure information. Countries offering an online reporting system for drug shortages such as Belgium, The Netherlands, England, Italy, France, Germany and Spain were included in this study. The online reporting systems were consulted in May 2013. Typology and causes of drug shortages are mapped and a sub-analysis is performed for essential medicines and oncology drugs. RESULTS: Majority of drugs reported were oncology drugs (n=671), generics (55% for essential drugs, 64% for oncology drugs) and injectables (52% for essential drugs, 79% for oncology drugs) are more involved in drug shortages. Foods for drug shortages are underreported, as the cause is not known in 66% of the cases (n=671). Production problems are reported in 27% of the cases (n=671). Results are subject to the different scopes of the considered reporting systems. CONCLUSIONS: Reporting of drug shortages in Europe needs to be standardised and more transparency about the reasons for drug shortages is required to understand the problem. A link between production problems and market attractiveness and market capacity is recognized to be at the root of drug shortages in Spain and Italy. In case of lack of EMA approval, the EMA could ensure the sustainability of the drug market is required to present fundamental solutions for the problems of drug shortages in Europe.

PCN173
DOWNTOWNS OF THE FDA ACCELERATED APPROVAL PATHWAY – STRINGENT CONTROLS MUST BE IN PLACE TO ENSURE PROMPT SUBMISSION OF FOLLOW-UP CONFIRMATORY TRIAL DATA
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OBJECTIVE: Ponatinib was temporarily withdrawn by the FDA in October 2013 following safety concerns arising from its Phase III trial. This drug had previously been approved under the accelerated approval pathway. Three other oncologics have been withdrawn under similar conditions, further adding to concerns with this pathway. This research aims to provide an up-to-date systematic analysis of all oncologics approved under this pathway and analyse the time delay in obtaining regular approval. METHODS: Publically available assessments of any oncology approved under the FDA accelerated approval pathway were evaluated and the dates of accelerated approval and conversion to regular approval were extracted. RESULTS: 41 oncologics across 50 indications have been assessed under the FDA accelerated approval pathway, all but two of which have been approved. Of the approved indications, 50% (24/48) have been converted to regular approval with an average delay of 53 months (range 13-151 months). 6% (3/48) have been withdrawn from the market due to lack of efficacy and/or safety concerns arising from Phase III data. 44% (21/48) have not been converted to regular approval despite being on the market for an average of 53 months (range 4-109 months). In these cases the mandatory confirmatory trials have not been completed and to date the FDA has not withdrawn a single oncology drug following a failure of the confirmatory trials required. All 41 oncologics approved under the accelerated approval process have not been converted to regular approval despite some being on the market for up to 9 years. Given that 11% (5/47) of the drug approvals required confirmatory trials have been withdrawn without completion of confirmatory data should be handled with an appropriate requirement with a defined time limit by which the data must be submitted. A failure to do so should be seen as drug shortages for severe diseases to become available earlier in their development cycle but risks approving ineffective and/or unsafe drugs.

PCN175
A RETROSPECTIVE STUDY OF PATIENTS OUT-OF-POCKET EXPENSES FOR ORAL ONCOLOGY MEDICATIONS FOR MULTIPLE MYELOMA
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OBJECTIVES: To study patient’s out-of-pocket expenditures in patients taking oral oncology medication for the treatment of Multiple Myeloma who are enrolled in a specialty pharmacy program. METHODS: A retrospective analysis of pharmacy claims and reimbursement data for oncology patients enrolled in a specialty pharmacy program from January 1, 2013 through October 31, 2013 was conducted. Patients with a primary diagnosis of Multiple Myeloma (ICD-9 CM: 203.xx) prescription data were included. There were no exclusion criteria. The study evaluated patients’ costs per prescription, or cost per patient, and compared average co-pay responsibility per prescription after insurance to average patient co-pay per prescription after funding assistance. RESULTS: A total of 22,566 prescriptions were included. The average patient co-pay responsibility after insurance was $435.00 per prescription and the average patient co-pay after funding assistance was $81.00 per prescription. This resulted in 12,822 (91.17%) of the prescriptions had a patient co-pay of under $10.00 after funding assistance. The patient’s insurance type was as follows: private insurance was 59%, Medicare was 25%, Pharmacy Benefit Manager was 10%, Tricare was 1%, and Medicaid was 5%. CONCLUSIONS: In this retrospective analysis of pharmacy and financial claims data, Multiple Myeloma patients significantly reduced their out-of-pocket expenditures, from an average of $435.00 to $81.00 by the specialty pharmacy gaining funding assistance for the patient.

PCN176
ASSESSMENT OF IMAGING UTILIZATION AND TREATMENT PATTERNS FOR HEAD AND NECK CANCER PATIENTS IN THE UNITED STATES
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OBJECTIVES: To assess imaging and treatment patterns in head and neck cancer (HNC) patients using a large commercial-insurance database from the United States (U.S.). METHODS: We used the Marketscan® Research Databases (2007-2011) to identify adult (age ≥18), parotid (oral, pharynx, paranasal sinus, larynx) using ICD-9 codes. We evaluated three periods of imaging and treatment patterns: 1) three months pre-diagnosis, 2) diagnosis-to-treatment initiation, and 3) post-treatment initiation. Patients receiving single-imaging modalities and multiple-imaging modalities were identified, as were patients treated using surgical, chemotherapy, radiation therapy, and combinations. Imaging and treatment intensity and variability by cancer types and geographic regions (Northeast, North Central, South, and West) were assessed using univariate and multivariate logistic regression. RESULTS: 80,987 patients were analyzed (39% female, mean age: 60 years). During pre-treatment, comparing all cancer types to oral cancer, pharynx cancer patients had the greatest likelihood of single-modality imaging and multi-modality imaging. Patients with higher comorbidity index scores were more likely to receive more imaging prior to treatment. Pre-treatment imaging was more likely to occur in other regions compared to West (OR range: 1.07-1.29), with consistent imaging patterns versus the West. CONCLUSION: Imaging and treatment patterns were very different in enjoy and post-treatment intervention patterns. In the post-treatment period, patients receiving multiple treatment interventions, a proxy for advanced cancer, were more likely to undergo PET/CT. A high portion of cases can change treatment response (37%). Pharynx cancer patients were more likely to require radiation therapy (24%) or chemotherapy (30%). During all phases combined, females were less likely to get imaging of any type (a-CT, CT, or PET/CT) (OR range: 0.71-0.91). CONCLUSIONS: Commercially insured HNC patients in the U.S. vary in imaging usage and in the types of imaging modalities used, prior to and following initial diagnoses. Receiving multiple treatment interventions was associated with undergoing multiple imaging tests and more specifically, PET/CT.

PCN177
DESCRIPTIVE ANALYSIS OF PATIENTS INITIATING REGORAFENIB THERAPY
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OBJECTIVE: To describe treatment patterns among patients initiating regorafenib, an oral kinase inhibitor indicated for the treatment of metastatic colorectal cancer in patients who have tried other first-line therapies. METHODS: Pharmacy and medical claims data from Humana, a large national U.S. payer, were used. The study sample included patients aged 19 to 89 years with at least one claim for regorafenib from 9-27-2012 and 6-1-2013. A subset of patients with pharmacy and medical claims and reimbursement data for oncology patients enrolled in a specialty pharmacy program. To study patient’s out-of-pocket expenditures in patients taking oral oncology medication for the treatment of Multiple Myeloma who are enrolled in a specialty pharmacy program. RESULTS: A total of 407 patients with claims for regorafenib were identified. The median age of the male was 64, years, whereas the median age of the female was 64 (range of 0-140 days) (range of 0-357 days). Median length of pre-index continuous enrollment was 779 days. The majority resided in the southern (51.6%) and midwestern (26.0%) U.S. and most patients had Medicare Advantage (26.0%) or Medicare Part D (69.3%) coverage. 87% of patients met at least one inclusion criterion. Metastatic cancer diagnosis was observed in 93.4% of patients; the majority had liver metastases. Common pre-index comorbidities included hypertension (72.5%), hyperlipidemia (41.8%), chronic pulmonary disease (52.3%), diabetes (34.1%), and depression (15.4%). Evidence of chemotherapy, biologic therapy, and