the induction period for each drug. Overall, 63% of patients experienced a dose escalation, of which 68% occurred within the first year, excluding induction. Peak frequency of dose escalation occurred between weeks 11-30. Calculated daily, escalated dose was greater than maintenance by 9% for adalimumab, 14% for etanercept, and 28% for ustekinumab. **CONCLUSIONS:** Across all treatments, dose escalation was recorded in over 60% of patients, most often in the first year of treatment, indicating that patients may require additional doses to maintain response. These data highlight the need for new treatments which provide high sustained efficacy, with a rapid onset of action.

PSY69

EFFECT OF FLORIDA'S PRESCRIPTION MONITORING PROGRAM AND PILL-MILL LAWS ON OPIOID PRESCRIBING AND UTILIZATION

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OBJECTIVES: To quantify the effect of the implementation of Florida's PMP and pill mill laws on overall and high risk opioid prescribing, utilization, and dispensing. **METHODS:** We applied comparative interrupted time series analyses to IMS Health LRx LifeLink data to characterize the effect of PMP and pill mill law implementation on a closed cohort of patients, prescribers and retail pharmacies between July 2010 and Sept 2012 in Florida (intervention state) compared with Georgia (control state). We conducted numerous sensitivity analyses including varying the length of observation and modifying requirements for continuous observation of individuals throughout the study period. **RESULTS:** From July 2010 to September 2012, a cohort of 2.6 million patients, 431,890 prescribers and 2,829 pharmacies was associated with approximately 480 million prescriptions in Florida and Georgia, 8% of which were for opioids. Average total monthly opioid volume (355.1 vs. 124.2 kilograms [kg]), average dose per transaction (55.2 vs. 46.6 milligrams [mg] MEDD), and average number of days supply (18.4 vs. 16.0 days) were each higher in Florida than Georgia prior to implementation of Florida's PMP and pill mill laws. Overall, Florida's laws were associated with statistically significant declines in opioid volume (3.7 kilograms/month) and MEDD (0.46 mg/month), without any change in days supply. Reductions were limited to prescribers and patients with the highest baseline opioid prescribing and utilization, respectively. Sensitivity analyses varying the time windows and enrollment criteria supported the main results. **CONCLUSIONS:** Implementation of PMP and pill mill laws in Florida was associated with decreases in prescription opioid dispensing relative to Georgia among patients and providers with high levels of opioid utilization at baseline.

PSY70

THE CHANGING COSTS OF CARING FOR HEMOPHILIA PATIENTS IN THE U.S.: INSURERS' AND PATIENTS' PERSPECTIVES

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OBJECTIVES: Hemophilia is an inherited condition requiring lifelong, expensive treatment. Initiating prophylaxis treatment with factors VIII (hemophilia A) or IX (hemophilia B) at an early age has been shown to be effective in improving health outcomes. In 2007 the medical advisory council of the National Hemophilia Foundation (NHF's MASAC) recommended prophylaxis treatment as the optimal therapy for these patients. The study objectives were:(1) To explore the economic burden over the patient's lifespan; (2) To quantify changes in factor VIII/IX utilization and related costs over the past decade. **METHODS:** A retrospective, US health insurance claim database (2004-2012) analysis was conducted. Males with ≥2 pharmacy claims for a hemophilia drug within 3 months, and continuous enrollment for ≥180 days were included. Patients utilizing inhibitor treatments were excluded. Annual payer and patient out-of-pocket (OOP) expenses were calculated by service category (inpatient, outpatient, medications), and stratified by patient's age and calendar year. Costs were adjusted to 2013USD. Annual supply days (ASD) per patient were calculated; ASDs over time were compared using a t-test. **RESULTS:** For hemophilia A (N=727), increase in payers' costs was observed during the first 4 decades of life, peaking at age 34 ($273,669) decreasing thereafter, and annual OOP staying constant at $2,589/year. For hemophilia B (N=161), an increase in payers' costs was observed during the first 3 decades of life peaking at age 29 ($281,981) decreasing thereafter with annual OOP at $2,401/year. Between 2007 and 2012, ASD per patient increased significantly for both factor VIII (ADVATE®: 160.5 vs. 249.9 days, p=0.00029) and factor IX (BENEFIX®: 132.8 vs. 214.7 days, p=0.0255) coinciding with payers' drugs cost over the same time period. (Hemophilia A: $186,283 to $212,747respectively; hemophilia B: $147,778 to $186,851 respectively). **CONCLUSIONS:** Over the past decade, the mean per patient consumption of factor replacement therapy has increased substantially, in line with new treatment guidelines.

PSY71

INCREASED LENGTH OF STAY FOR OBESE PATIENTS BY CHRONIC DISEASE

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OBJECTIVES: An obese body mass index (BMI) increases morbidities, however there are few chronic disease registries that can quantify the cost of obesity. Clalit Health Services (CHS), with complete longitudinal data of over 4 million members, provides an ideal format for comparing health care utilization between obese and non-obese patients to inform the need for improved health care policy. **METHODS:** For the years 2011-2013 inclusive, we took two random samples of 10,000 obese (BMI>30) patients and 10,000 normal and underweight (BMI<=25) from the CHS database both according to Clalit population age standard. We then extracted their additional chronic diseases from the CHS registry. Finally, we compared the average length of stay (LOS) for inpatient admissions between the groups, by disease. **RESULTS:** Obese patients with underlying chronic disease had, on average, a 27% increased LOS compared to non-obese patients with chronic disease. The greatest effect was seen among obese patients with chronic renal failure, whose LOS was 2.7 times or nearly 20 days longer. By disease: ischemic heart disease, 1.9 times or 10 days longer; hypertension 1.3 times or 4 days longer; congestive heart failure, 1.2 times or 3 days longer; and rheumatoid arthritis, 1.4 times or 2 days longer. Obese patients with diabetes and s/p cerebral vascular accident had a shorter LOS (0.8 times or 3 days, and 0.8 times or 4 days respectively). **CONCLUSIONS:** Obesity increases the LOS for all-cause hospital admissions among patients with various underlying chronic diseases. This may be due to insufficient diagnosis by the primary provider or specialist, inadequate medication dosing (eg, pain management), or inadequate support during an inpatient stay. A proactive health care policy is needed to guide the management of patients with chronic disease who are also obese, with the potential for cost-savings of interventional, pharmaceutical, or surgical treatment of obesity at baseline.

PSY72

THE AVAILABILITY AND EXPENDITURE OF ORPHAN MEDICINES IN POLAND

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OBJECTIVES: The aim of the present analysis was to identify the level of the availability and total expenditure of medicines for rare diseases with European authorization and orphan designation. In Poland all innovative medical technologies and services claiming public money founding have to be assessed by Agency for Health Technology Assessment (AOTM). Pharmacoeconomic evaluations of new therapies are required for all reimbursement decisions and orphan drug manufacturers cannot be exempted from providing a full pharmacoeconomic or HTA reports. The criteria of assessment connected with clinical and cost effectiveness (threshold is 3xGDP for ICUR/QALY) are the same for all kind of drugs. **METHODS:** All orphan designation admitted by European Medicines Agency (EMA) until the end of 2014 were reviewed and analyzed from the official website of EMA. Among 792 EMA's orphan registrations studied 78 (9,8%) applied to orphan drugs. We compared the outcomes with reimbursement list officially published by Ministry of Health. Then it was checked what was the share of orphan drugs in overall reimbursement spending. **RESULTS:** At the end of 2014 there were 28 orphan drugs available on the reimbursement list (36% of designed by EMA). The total public payer reimbursement spending was €2.41bn in 2012 and €2.26bn in 2013. Orphan drugs have only accounted for a small percentage of the overall drug budget in polish health care system (1,5% in 2012 and 3,2% in 2013). **CONCLUSIONS:** In the literature we can find opinions that the relatively low budget impact of orphan drugs is often used as an argument in reimbursement decisions. In Poland reimbursement was awarded to the minority of orphan drugs designed by EMA. Very strict requirements in order to ensure compatibility with law directives could potentially influence negative reimbursement decisions for orphan drugs.

PSY73

BARIATRIC SURGERY IN THE BRAZILIAN HEALTH CARE SYSTEM: RESOURCES UTILIZATION

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BACKGROUND: Obesity is a pathology that leads to several co-morbidities such as diabetes and hypertension. In Brazil obesity rates (BMI >30kg/m2) raised from 11.8% in 2006 to 17.5% in 2013. Bariatric Surgery is the most effective treatment to achieve excess weight lost for morbid patients. It is estimated that Brazil has around 1.8 million people with BMI >40kg/m2, considering that Brazil has an universal health care system and 25% of the population relies in the private health care sector, several people are eligible to get bariatric surgery **OBJECTIVES:** Evaluate the use of the resources dedicated to treat morbid obese patients in the Brazilian public health care system (SUS) from 2008 to 2013 **METHODS:** Revised data of expenditures, number of surgeries and length of stay related to bariatric surgery in the database of the IT Department of SUS (DATASUS) **RESULTS:** The number of certified hospitals that perform bariatric surgery increased by 35% and the percentage of states covered by certified hospitals rose from 60% to 74%. During the same period the number of procedures increased by 113%. Despite the increase in the number of procedures by 113%, the days of hospitalization required for surgeries increased only 52%; this is due the average length of stay reduction from 5.7 days to 4.1 days, showing a better efficiency among hospitals. The total expenditure in bariatric surgeries rose by 161%. **CONCLUSIONS:** Analysis demonstrated that the access to the bariatric procedure in Brazil has increased in the past five years. The hospitals' efficiency improved during the same period, decreasing the average length of stay. Today the Brazilian public health care system provides surgery to less than 0.75% of the eligible population and despite the access increase; more resources (physicals and infrastructure) are needed in order to treat the morbid obese population

PSY74

CANADIAN RETROSPECTIVE CLAIMS DATA ANALYSIS OF BIOLOGICS SWITCHING AND RETENTION PATTERNS IN PSORIASIS PATIENTS

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OBJECTIVES: To describe treatment patterns and cost in patients with PSO (psoriasis) receiving biologic therapies (BT). **METHODS:** A retrospective cohort of medication claims data from IMS Brogan Private (Canadian national) and Public (Ontario and Quebec) Drug Plan databases was analysed. Biologic-naïve PSO patients >18 years of age were selected between 01/01/2007 and 03/30/2011 and followed for 24 months to understand lines of therapy, retention on BT, and annual therapy costs. Target biologics included adalimumab, etanercept, infliximab and ustekinumab. **RESULTS:** 3,546 patients were identified. Of those, 44% initiated etanercept, 26% adalimumab, 19% ustekinumab, and 10% infliximab. 32% of patients remained on 1st line therapy, 16% switched, and 52% stopped therapy over the 24 month period. Median days on 1st line therapy was longer in public than private plans (502 vs. 357). Of those who switched, 556 received 2 lines, and 105 received 3 or more lines of BT. In a retention model of private plan patients, those who supplemented with non-biologic PSO therapies were 16% - 42% more likely to stay on BT than those tak-

ing BT alone (P<0.001); patients receiving non-PSO concomitant medications were 19% - 32% more likely to stay on their BT (p<0.001) than those not receiving; and patients who switched BT were 2.35x more likely to stop BT within 24 months versus non-switchers (p<0.001). Using a cost model, patients who switched BT had higher average annual costs of $4,355 and $3,679 in private and public plans respectively compared to those who didn't switch (P<0.001). **CONCLUSIONS:** 68% of PSO patients on BT either switch or stop therapy, indicating there remains an unmet need for new treatment options. In addition, switching is associated with significantly higher therapy costs. With better understanding of predictors for retention, patient support programs can be designed to address the specific needs of at-risk groups.

PSY75

COMPARISON OF ULTRA ORPHAN AND CANCER DRUG PRICING IN THE US AND THE UK

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OBJECTIVES: Both ultra orphan and cancer drugs are premium priced therapies with high annual per patient costs. The local legislation and reimbursement mechanisms have had significant impact on pricing trends for these therapies. The objectives of this analysis were to compare the price differential for ultra orphan and cancer drugs in the US and the UK, and understand the impact of local reimbursement mechanisms. **METHODS:** A set of 22 drugs (10 ultra orphan and 12 cancer drugs) was selected based on their availability in the US and the UK. The 2014 AWP, WAC and net prices were obtained for all 22 drugs. All UK prices were converted to USD. Primary discussions with ex-payer and policy experts were conducted to understand the basis and implication of the price differentials. **RESULTS:** For ten selected ultra orphan drugs, the median WAC price premium for the US compared to the UK net price was 10%. For 12 selected cancer drugs the median WAC price premium for the US compared to the UK net price was 106% (based on AWP the premiums were 29% and 149%, respectively). Eight out of 10 ultra orphan and 12 out of 12 cancer drugs were higher priced in the US compared to the UK. Primary discussions with experts suggest the role of legislation for coverage of cancer drugs in the US and special coverage of rare disease products in the UK and reimbursement mechanisms (use of cost effectiveness driven HTAs in the UK and the use of co-pay in the US) as primary drivers of high price differential for cancer drugs versus ultra orphan therapies. **CONCLUSIONS:** The local reimbursement mechanisms are major drivers of price differential for ultra orphan and cancer drugs in the US and the UK.

PSY76

ORPHAN DRUG DESIGNATION: A COMPARISON OF POLICIES, PROCESSES AND RESULTS FROM THE US AND THE EU

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OBJECTIVES: Pharmaceutical manufacturers can apply to the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for orphan drug status for pharmaceuticals that treat rare medical conditions. This study compares the policies and processes that influence orphan drug designation in the US and the EU and examines the approval data to explain any differences and/or trends in decision making. **METHODS:** We conducted a quantitative analysis on the publicly available data on orphan drug approvals released by the FDA and EMA. By looking at the numbers of drugs approved each year, the drugs submitted and approved for orphan indications, and their relevant disease areas we were able to identify any trends and dissimilarities in the organizations final approval decisions. Following this, we performed qualitative research with a focused literature search of the Medline database and relevant websites, to explore the differences in policies and processes between the organizations that may have led to conflicting decisions. **RESULTS:** There were significant differences in the processes, policies and requirements for orphan drugs. The FDA consistently approved more orphan drugs each year during 2002-2014 (when comparison data were available). However, the numbers of products accepted are converging (e.g. in 2005, the EMA approved approximately 81% fewer orphan drugs; by 2013, this gap was 36%). Some differences in decisions were identified, largely due to different evidence requirements. **CONCLUSIONS:** The likelihood of a drug gaining orphan drug status in either the US or the EU is dependent on a number of different factors. If the trends persist, it is likely that the organizations will designate a similar number of products as orphan drugs each year, although the approved products may differ. These may affect which organization manufacturers choose to submit applications to first.

PSY77

TIMING OF EU5 & US ORPHAN DRUG APPROVALS AND PRMA BETWEEN 2009 AND 2013

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OBJECTIVES: To examine pricing, reimbursement and market access of orphan drugs approved by EMA and FDA between January 2009 and December 2013. **METHODS:** Analyzed the orphan drugs approved by both EMA and FDA between Jan 2009 and Dec 2013, by country (US & EU5) regarding; time to market, benefit evaluations, pricing and reimbursement differences, as well as any similarities or differences by size of population. **RESULTS:** In the time frame, 102 orphan drugs were approved in the US vs. just 31 by the EMA. Of those, only 13 orphan drugs were approved by both agencies. For these 13 drugs, approval took an average of 66 weeks from filing with the EMA and 45 weeks with the FDA. Average US time to launch from approval was 9 weeks (only 2 weeks if one outlier is removed). In the EU, all 13 drugs were available and reimbursed on the German market in an average of 16 weeks while only 5 had completed P&R in Spain in an average of 97 weeks. Early access to reimbursement via the ATU program in France and L648 program in Italy was sometimes pursued. In the UK, SMC recommendations for orphan drugs were often negative, and NICE only reviewed oncology orphans thereby resulting in inconsistent access. Alternative funding mechanisms sometimes provide a temporary reimbursement fix in the UK. Ex- factory pricing varied by country both at launch and over time. **CONCLUSIONS:** Significant differences exist between the number of orphan drug approvals and time to access in the US vs. EU. The US is notably faster than the EU5 and Germany is notably faster than other EU5 countries. For pricing, the US is not always the high price country. Furthermore, there appears to be an inverse relationship between size of the indicated patient population and reimbursed price.

PSY78

DRIVERS OF HEALTHCARE RESOURCE UTILIZATION AND FACTORS ASSOCIATED WITH INCREASED RESOURCE USE IN PATIENTS WITH FIBROMYALGIA: AN EVALUATION USING ELECTRONIC MEDICAL RECORDS

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OBJECTIVES: To explore use of electronic medical records (EMR) for identifying drivers of all-cause healthcare resource utilization and factors associated with increased resource use in patients with fibromyalgia (FM). **METHODS:** This retrospective analysis used structured de-identified EMR data from the Humedica database including demographics, clinical characteristics, healthcare resource utilization, and prescriptions. Adults (≥18 years) with FM were identified based on ≥2 ICD-9 codes for FM (729.1) ≥30 days apart between January 1, 2008 and December 31, 2012, and were required to have ≥12 months continuous enrollment pre- and post-index; the first FM diagnosis was the index event. Multivariate analysis using generalized linear models evaluated how demographic and clinical characteristics relate to 12-month post-index resource utilization. **RESULTS:** Patients were predominantly female (81.4%), Caucasian (87.7%), with a mean±SD age of 54.4±14.8 years. Primary drivers of resource utilization were "medication orders" and "physician office visits," used by 91.6% and 87.5% of patients, respectively, with 12-month post-index means of 21±21.5 drug orders/patient and 15.1±18.1 office visits/patient, the latter accounting for 73.3% of all healthcare visits. Opioids were the most common prescription medication, 44.3% of patients. The chance of being a high healthcare resource utilizer was significantly increased (p<0.001) 1.26-fold among African-Americans relative to Caucasians and for patients with specific comorbid conditions ranging from 1.06-fold (musculoskeletal pain and depression/bipolar disorder) to 1.21-fold (congestive heart failure). Similarly, factors significantly (p<0.001) associated with increased number of medications ordered included being female (1.23-fold) and the presence of conditions such as sleep disorders (1.08-fold), depression/bipolar disorder (1.07-fold), and anxiety (1.06-fold). **CONCLUSIONS:** Physician office visits and pharmacotherapy were drivers of all-cause healthcare utilization; opioids were the most commonly prescribed medication class. Comorbid conditions were key factors associated with high resource use. EMR can be a useful tool for identifying and potentially managing FM patients with high healthcare resource utilization.

PSY79

SUGAR-SWEETENED BEVERAGES CONSUMPTION AND PRICE SENSITIVITY AMONG BRAZILIAN ADULTS: IMPLICATIONS FOR OBESITY POLICIES

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OBJECTIVES: In this context, the challenge of this essay is to estimate the price elasticity for soda and fruit drink in Brazil and the price effects on weight outcomes and obesity prevalence. **METHODS:** The elasticity was measured through a two-part model (TPM) estimated for all sample and different subgroups. The empirical model explains the quantities of SSB demanded as function of its prices and other variables. Considering the estimated elasticity, we converted the reduction on consumption into weight transforming the consumption elasticity from grams to kilocalories and then we applied a frequently used rule, which considers that a reduction of 3,500 calories induces a 0,450 kg loss in body weight, everything else remaining equal. **RESULTS:** Overall, the results display a smaller prevalence and lower consumption with higher prices. The TPM model predicts a reduction of 348.3g in weekly soda consumption and 4.5g of fruit drink to each one Real increased price. For all sample estimates, price elasticity is -0.61 for soda and -1.32 for fruit drinks, suggesting that a 20% increase in price was associated with a decline of soda and fruit drink in weekly consumption by 12.2% and 26.4%, respectively. This evidence shows a higher sensitivity to price changes for juice drinks than for soda, in spite of the higher consumption of soda. TConsidering that weight reductions, the prevalence of overweight among adults could decline from 48.13 to 47.75 percent and obesity prevalence could be reduced from 18.77 to 18.5 percent in one year. **CONCLUSIONS:** Our main findings suggest that tax policy might be an effective tool to reduce the soda and juice drink consumption and body weight. We also identified that subgroups who consume higher amounts of SSB are relatively more price sensitive and in these cases pricing policies have an expressive potential in reducing SSB consumption and body weight.

PSY80

WHY ASK IF YOU KNOW? ACMG'S POTENTIAL ERRORS IN MAKING NEWBORN SCREENING (NBS) RECOMMENDATIONS FROM USING SURVEYED OPINIONS FOR INCIDENCE SCORING WHEN ACTUAL DATA ARE AVAILABLE

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OBJECTIVES: In 2006, the American College of Medical Genetics (ACMG) recommended expanding NBS, relying largely on scoring from a stakeholder survey on 19 attributes of 84 rare conditions. Points were scored according to mean answers from the responders. Sums of scores resulted in 3 different entry points into an algorithm (EPA) that determined ACMG final screening recommendations. This research examines one of the survey questions about condition incidence and compares the ACMG use of surveyed opinions versus the actual facts that they also report. **METHODS:** The report indicated each condition's mean scores for survey questions. The incidence question scored 0-100 points. Very rare conditions