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

(<1/100,000) were given no points; conditions with incidence >1/5000 were given 100 points. Intermediate incidence data received intermediate points (25/50/75). Alongside these scores was an assessment by ACMG of the incidence. We rescored the question using the ACMG's facts on incidence for each condition to see how this would affect total scores and recommendations. **RESULTS:** After eliminating conditions with missing data, 78 remained. All had score changes. We (arbitrarily) defined a positive score change as one where the fact-based score was less than the opinion-based score (OBS – FBS > 0). Most of the changes were positive (74%). The range was from -37 to +68. The overall mean change was +4 (for positive and negative changes, +12.7 and –20.4). There were two EPA changes, but only one had potential to lead to a change in final recommendation. Thirteen (17%) of the others moved to within 50 points of an EPA change. **CONCLUSIONS:** Rescoring this one question had minimal effect on the EPA and therefore on the final ACMG recommendations, however, we only explored one question of the 19. Similar adjustments to other survey responses could reinforce trends seen here and result in more reclassifications.

PSY81

HOW MUCH IS NICE REALLY PREPARED TO PAY FOR ORPHAN AND END-OF-LIFE DRUGS?

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OBJECTIVES: New health technologies are required to demonstrate clinical and cost-effectiveness before recommendation by the National Institute for Health and Care Excellence (NICE) for reimbursement in England; however, higher cost-effectiveness thresholds may be considered for orphan and end-of-life (EOL) therapies. To help inform future submissions, the incremental cost-effectiveness ratios (ICERs) of – and rationale behind – accepted NICE submissions for orphan and EOL therapies were assessed. **METHODS:** All NICE single technology appraisals from January 2009 to December 2014 were included in the analysis. The decision, rationale, and manufacturer's ICER (including patient access scheme where applicable) for each submission were extracted. Appraisals were then assessed for meeting NICE EOL or European orphan drug criteria. Multiple technology appraisals, resubmissions, vaccination programmes, requests for advice, and submissions where an ICER could not be determined were excluded. **RESULTS:** Of 111 relevant NICE submissions, 12 met orphan drug criteria, 16 met EOL criteria and 4 met both. For orphan drugs, 8/12 (67%) were accepted, with a mean ICER of £33,725 for accepted submissions (range: £24,544 - 56,693). For EOL drugs, 12/16 (75%) were accepted, with a mean ICER of £40,906 for accepted submissions (range: £14,795-£62,829). This compared with an overall acceptance rate for non-orphan/EOL NICE submissions of 71/87 (82%), with a mean ICER of £15,303 for accepted submissions (range: £1,537-£35,208). Rationale for acceptance of orphan and EOL drug submissions included unmet therapeutic need, lack of alternative treatment options, and innovation. **CONCLUSIONS:** Based on the evidence, NICE's decision threshold was significantly higher for orphan/EOL drugs than for others (p<0.001). However, the overall acceptance rate was lower, and restrictions to patient sub-populations as well as patient access schemes were often applied. Nevertheless, the incorporation of elements such as unmet need into the decision-making process makes high ICERs appropriate where there is strong evidence of demonstrable clinical benefit.

PSY82

HOW INFLUENTIAL ARE PATIENT AND PROFESSIONAL GROUP SUBMISSIONS ON REIMBURSEMENT DECISIONS FOR EUROPEAN MEDICINES AGENCY ORPHAN DRUGS?

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OBJECTIVES: Uncertainty often surrounds orphan-drug reimbursement, given the small sample sizes and limited availability of clinical trials. Consequently, manufacturers and Health Technology Assessment (HTA) agencies are turning to real-world evidence to understand the patient experience. Both SMC and NICE encourage patient/professional group involvement in the HTA reimbursement process, but do these submissions influence reimbursement decisions? **METHODS:** Using the Context Matters' proprietary database, the analysis was restricted to full HTA submissions from NICE and SMC for European Medicines Agency (EMA) orphan drugs. The reimbursement decision, the presence of a patient/professional group submission, and any agency comments on the submissions were extracted from each assessment. Reimbursement decisions were categorized as either positive or negative. **RESULTS:** Fifty assessments across 13 disease conditions were analyzed. There was no association between patient/professional group submissions and positive reimbursement decisions (p=0.70); 48% (20) of assessments with a patient/professional group submission resulted in a positive decision while 52% (22) of assessments with a patient/professional group submission resulted in a negative decision. When stratified by agency or disease condition, there was still no relationship between decision and patient/professional group submission. Individual assessments were examined to determine how SMC and NICE use patient/professional group submissions. **CONCLUSIONS:** Results indicate that patient/professional group submissions are not directly associated with positive reimbursement decisions; this presentation will detail how SMC and NICE use these submissions in their decision-making. Due to the increasing rate of development in the orphan-drug space and the importance of incorporating the patient voice, manufacturers need to understand how these submissions influence HTA agencies.

PSY83

TREATMENT OF OBESITY: PHARMACOTHERAPY TRENDS IN THE UNITED STATES FROM 1999 TO 2010

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OBJECTIVES: To determine the antiobesity-drug prescribing patterns of U.S. physicians over the last decade (1999-2010) by quantifying trends in antiobesity medication prescriptions; reliance on pharmacotherapy in obesity treatment; the odds of a specific patient's being prescribed antiobesity medication; and consistency of prescribing with the 1998 obesity guidelines. **METHODS:** Data for adult patients were obtained from the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey, and were appropriately weighted to produce national estimates of prescribing patterns. Obesity was identified using ICD-9 codes, BMI values, and a chronic-obesity-condition variable. For obese patients, a logistic regression model was estimated to determine the odds of receiving pharmacotherapy. **RESULTS:** The number of outpatient visits with any mention of an antiobesity medication increased from 6.5 million from 1999-2001 to 13.0 million from 2008-2010. Only 2.0% of the 987 million obese-patient visits from 2005-2010 mentioned an antiobesity drug. Additionally, there were 6.5 million visits by nonobese patients with an antiobesity drug mention. Visits made by females (OR = 2.89; 95% CI: 2.08–4.03), by white patients (OR = 1.55; 95% CI: 1.08–2.24), by younger adults (OR = 1.71; 95% CI: 1.34–2.20), and in the South (OR = 3.39; 95% CI: 1.49–7.72) were more likely to involve an antiobesity drug prescription. **CONCLUSIONS:** Pharmacotherapy has been underutilized as a treatment option for obese patients. Only 1 in 50 patients is receiving a prescription for an antiobesity medication. Prescribing regulations and drug safety concerns have clearly discouraged the use of pharmacotherapy. Moreover, in contrast to what the 1998 guidelines suggested, physicians have tended to prescribe antiobesity medications to self-paying young, white, females, many of whom lived in the South, and not all of whom were obese; they have tended not to prescribe them to patients with comorbidities like hypertension.

PSY84

IMPLEMENTATION OF A STATEWIDE OPIATE PRESCRIBING POLICY IS NOT ASSOCIATED WITH A SIGNIFICANT DECREASE IN OPIATE PRESCRIPTIONS FROM THE EMERGENCY DEPARTMENT

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OBJECTIVES: Determine whether the implementation of a statewide opiate prescribing policy is associated with a decrease in the number of prescriptions for opiates for discharged emergency department patients. **METHODS:** Retrospective review of opiate prescriptions written by medical professionals comparing a 4 month period before and after the implementation of an opiate prescribing policy. **RESULTS:** An independent samples t-test was conducted to examine the differences in the mean number of total prescriptions per patient per day, opiate prescriptions per patient per day, total number of visits per day, and total number of opiate prescriptions per day. In the four-month period prior to implementation of the policy, there was an average of 0.196 (SD=0.005) opiate prescriptions per patient per day. This decreased to 0.188 (SD=0.015) opiate prescriptions per patient per day in the four-month period after the policy. The difference was not statistically significant (mean difference = 0.009; 95% CI: -0.014, 0.03; p = 0.35). Before the policy, there was also an average of 0.84 (SD=0.015) prescriptions/day and, after the policy, this decreased to 0.79 (SD=0.04) prescriptions/day (mean difference = 0.046; 95% CI:-0.018, 0.11; p = 0.10). The average number of total visits per day decreased over this time period (483 (SD=4.1) vs, 463 (SD=11.2); mean difference=20.2; 95% CI: 3.2, 36.8; p =0.03) as did the total number of opiate prescriptions per day (405 (SD=4.5) vs 367 (SD=27.9); mean difference=37.7; 95%CI: -4.9, 82.7; p = 0.07). **CONCLUSIONS:** Controlling for daily emergency department volume and total prescriptions, the proportion of prescriptions written for opiates remained relatively unchanged with the implementation of a statewide opiate prescribing policy. This may indicate that the effect of prescribing policies cannot be accurately measured using number of prescriptions written. Alternatively, quantity of pills per prescription may be a more appropriate measure of such a policy's success.

PSY85

ASSESSING THE IMPACT OF VARYING THRESHOLD CRITERIA FOR OPIOID OVERUTILIZATION

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OBJECTIVES: The CMS Medicare Part D Overutilization Monitoring System and Pharmacy Quality Alliance (PQA) draft overutilization measures include members receiving opioid prescriptions from ≥4 prescribers and ≥4 pharmacies ("shoppers"). This study examines the impact of varying prescriber and pharmacy definitional thresholds on the prevalence of overutilization and the likelihood of drug abuse indicators in shoppers and non-shoppers. **METHODS:** Medical and pharmacy claims for 2013 from adult, non-cancer, commercial and Medicare members in the Humana Research Database (Humana, Louisville, KY) receiving ≥2 prescriptions for an opioid were analyzed. Overutilization prevalence was examined for thresholds of ≥3 to ≥6 prescribers and for ≥3 to ≥6 pharmacies. For each combination, the odds ratios of shoppers to non-shoppers for presence of an opioid abuse diagnosis, non-opioid drug abuse diagnosis, and prescription for other commonly abused medications (e.g., stimulants, benzodiazepines) were calculated. **RESULTS:** In the final study cohort (n=359,656), prevalence of overutilization ranged from 5.48% at the ≥3 prescriber and ≥3 pharmacy definition to 0.17% at ≥6 prescribers and ≥6 pharmacies. The percentage of shoppers with an opioid abuse diagnosis was 12.26% and 28.11%, respectively, for those two definitions. For the ≥4 prescriber and ≥4 pharmacy case, shoppers (1.48% prevalence) were 4.43 times more likely than non-shoppers to have a diagnosis of opioid abuse (95%CI 4.13-4.75; p<0.001), 2.52 times more likely to have a diagnosis for other drug abuse (95%CI 2.40-2.65; p<0.001), and 1.65 times more likely to have pharmacy claims for other commonly abused medications (95%CI 1.58-1.73; p<0.001). Poster will include results for shoppers and non-shoppers across all threshold combinations studied. **CONCLUSIONS:** These results can aid the development and interpretation of opioid overutilization quality measures and support better informed intervention strategies to address the public health crisis of prescription drug abuse.