orphan drugs (ODs). This study examined the characteristics of OD designations and approvals in the U.S. and in the EU centralized system between August 1, 2000 and December 31, 2007 and compared the characteristics of sponsors, products and indications. **METHODS:** Data derived from the US FDA and the European Medicines Agency (EMEA). Chi-Square and Fishers' exact tests, and group comparison t-tests were used in the analysis. **RESULTS:** In the study period, the FDA listed 773 orphan designations and 65 (8.4%) approvals, and the EMEA listed 492 designations and 37 (7.5%) approvals. Orphan designations were granted to 472 sponsors by the FDA and to 293 sponsors by the EMEA. The sponsors included 30 universities, public organizations and individual sponsors in the U.S. and 20 in the EU. The average OD designations per sponsor were 1.64 ± 1.63 in the U.S. and 1.68 ± 1.51 in the EU. 68.9% of sponsors in the U.S. and 65.9% of sponsors in the EU had only 1 OD designation. The time from OD designation to approval was 1.74 ± 1.45 years in the FDA and 2.73 ± 1.43 years in the EMEA ($p < 0.001$). 98 (14.7%) sponsors had OD designations in both agencies. There were 102 designations in both agencies that had the same sponsor, product and indication; and 76 designations that had the same product and indication and different sponsor. **CONCLUSIONS:** US had more designations and approvals, but the analysis excludes ODs approved by national European agencies. OD incentives encourage R&D by small sponsors that, otherwise, could not assume the risk and opportunity cost associated with developing such products. The implementation of the FDA/EMEA common OD application in November 26, 2007 aims to reduce the duplication in OD development found in this study.

HP2
NEONATAL INTENSIVE CARE UNITS (NICUS) IN GREECE: FACTORS AFFECTING THE LENGTH OF STAY (LOS) OF THE NEONATES AND THE DRIVERS OF COST

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OBJECTIVES: This study aimed to identify the most important factors affecting the total cost and the length of stay (LOS) of neonates who were hospitalized in six neonatal intensive care units (NICUs) in Greece. **METHODS:** The study sample consisted of 218 neonates who entered the NICUs of six maternity, pediatric and general hospitals, of Greece. Multivariate Regression analysis was performed in order to examine the factors affecting the LOS and the total cost of hospitalization. Data on mother and father educational and occupational status, type and number of delivery, place of residence (rural or urban), age of the mother, birth weight and the gestational age of the infants were available. The costs used for the analysis, emerged from a detailed cost analysis, bottom up approach, based on daily consumption of each neonate for the whole period of hospitalization, until discharge of the hospital. Bootstrap simulation was used with 1000 iterations in order to check for the stability of the cost analysis. **RESULTS:** Factors influencing the LOS (in days) and the total cost (in Euro) were identical in both regression models. Factors for LOS were the type of the hospital, since in the pediatrics hospitals neonates stayed longer than in the maternity hospitals (coefficient 17.44; 95%CI 4.61 to 30.28, $p = 0.004$) and the birth weight of the neonate (coefficient 25.03; 95%CI: 8.304 to 41.77, $p = 0.004$). Factors for the total cost were the length of stay (coefficient 228.11; 95%CI: 218.53 to 237.68, $p < 0.001$), the type of the hospital (coefficient 993.72; 95%CI 301.03 to 1686.42, $p = 0.005$) and birth weight of the infant (coefficient 1528.07; 95%CI 700.61 to 2355.54,

$p < 0.001$). **CONCLUSIONS:** The findings, as expected, proved that the lower the birth weight, the more prolonged and more costly the hospitalization. Differences in the type and organization between hospitals need further attention.

HP3
TREATMENTS PATTERNS, RESOURCE USE AND RELATED HEALTH CARE COSTS IN DEPRESSED PATIENTS WITH CO-MORBID ANXIETY IN A LARGE US CLAIMS DATABASE

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OBJECTIVES: Anxiety is frequently associated with major depressive disorder (MDD). Antidepressants are approved for MDD and some anxiety disorders. However, few data exist on real-life utilisation and outcomes of antidepressant treatments in patients with MDD and co-morbid anxiety. This study aims at describing and comparing treatment patterns, health care resource use and associated costs in these patients. **METHODS:** This cohort study using the US claims database PharMetrics included adults with a first prescription of an antidepressant (escitalopram, an SSRI or venlafaxine) associated with a diagnosis of MDD in 2003–2005, and with two diagnoses of anxiety in the year surrounding this first prescription. Treatment patterns, health care resource use and related costs were assessed during the 6-month before and after first prescription, and compared across treatment groups. **RESULTS:** Of 18,676 patients, 69% were women, and mean age was 40. 25% of patients were prescribed escitalopram, 64% SSRIs, and 11% venlafaxine. Treatment patterns showed a 15% switch rate, a 16% combination rate and 23% of stops with no subsequent relapse (successful treatment stop). Both switch and combination rates were lower with escitalopram vs. SSRIs and venlafaxine ($p < 0.001$ and $p = 0.002$ respectively). Successful treatment stops were more frequent with escitalopram vs. venlafaxine ($p < 0.001$). 6-month total health care costs after treatment initiation were not significantly different than before (US$ 4,656 vs. US$4,254), but the structure of costs differed, with more pharmacy costs (20% vs. 10%), and less inpatient care (36% vs. 51%) after treatment start. Compared with baseline costs, health care costs were decreased with escitalopram and increased with SSRIs and venlafaxine (−US$74 vs. + US$496 and + US$916 respectively). **CONCLUSIONS:** In patients with MDD and co-morbid anxiety, antidepressant treatment was generally associated with decreased inpatient care. Compared with SSRIs and venlafaxine, escitalopram was associated with less treatment changes and with decreased costs.

HP4
THE IMPACT OF A MEDICAID EXPANSION TO INCLUDE POPULATION WITH LOW INCOME ON THE PREVENTABLE HOSPITALIZATIONS

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OBJECTIVES: This study was designed to investigate the impact of medicaid expansion on preventable hospitalization(PH) trend. **METHODS:** Data from the Korea National Health Insurance(NHI) claims and medicaid claims database, covering 48 million Korean people, was used. The new medicaid people were selected who were enrolled first time during the medicaid expansion period, the year 1998–1999. The NHI enrollees were randomly selected for control group. All were continuously enrolled from 1996 to 2001 and aged more than 17 years. Multinomial logit regression models of comparing PH versus marker admission were