the level of supportive clinical data (Phase 1: a mean of 158 days, Phase 2: 170 days, Phase 3: 192 days), whether the drug was a first approval, line extension (175 vs. 192 days), or whether it was approved under an accelerated FDA pathway or not (172 vs. 184 days). **CONCLUSIONS:** The FDA breakthrough therapy designation is proving a popular means by which promising drugs can gain patient access on preliminary data and could be de-broadening regulatory and judicial intervention and the use of prescription drugs cited as evidence, without medical expertise. Ensuring the constitutional right to health was the speech used in more shares. It was observed that the focus of judicial claims and the rational use of medicines recommended by the World Health Organization (WHO). **CONCLUSIONS:** The annual expense to ensure access to medicines for litigation is growing and represents a major challenge for the public manager. The high prevalence of new medicines prescribed by trademark and growth of biological drug prescriptions show the need to review and strengthen the policy of generic drugs in Brazil.

**PHP33**

**COMPETITION AND STRATEGIC REGULATION IN THE ARGENTINE PHARMACEUTICAL MARKET: A COMPARATIVE STUDY OF SIX THERAPEUTIC CLASSES**

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**OBJECTIVES:** To analyze how main determinants of competition in six therapeutic target groups - analesgesics, tranquilizers, peptic ulcer treatment, cholesterol treatment, benign prostatic hypertrophy and ACE inhibitors - were affected by regulations and drug policies implemented at national level during the last decade in the pharmaceutical market in Argentina. **METHODS:** The database corresponds to the evolution on retail sales in the Argentine domestic market generated by IMS for the period 2005-2012. The estimation strategy takes the form of econometric models of ordinary least squares with year fixed effects and robust standard errors. The dependent variables explain the market shares of each product, brand per therapeutic class, explained by prices, participant active principles, and a set of variables capturing product differentiation mechanisms implemented by pharmaceutical firms. Each therapeutic class’ regression was exposed to a single vector of variable. The framework for strengthening pharmaceutical manufacturing in sub-Saharan Africa.

**CONCLUSIONS:** The main health policy recommendations suggest the need to develop new areas of collaboration with the pharmaceutical sector, enhancing competition in markets with high levels of concentration, facilitating the evaluation of policies on generic medicines, and successfully regularizing the structure of drugs and products available through the CHP.

**PHP34**

**AN ANALYSIS OF WARNING LETTERS ISSUED TO PHARMACEUTICAL COMPANIES REGARDING MISLEADING HEALTH OUTCOMES CLAIMS 2009-2013**

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**OBJECTIVES:** While analyses of FDA warning letters issues to pharmaceutical companies for promotional materials issued by the FDA to pharmaceutical manufacturers focus on the growth of biological drug prescriptions show the need to review and strengthen the policy of generic drugs in Brazil.

**PHP35**

**CHARACTERISTICS OF PRODUCTS WITH PRICE CHANGES AFTER A POLICY CHANGE IN EGYPT**

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**OBJECTIVES:** In Egypt, the Ministry of Health and Population (MOHP) sets pharmaceutical prices from ex-factory to retail. In July 2012, the pricing policy changed from a cost plus to an external reference pricing method which was effective in October 2012. Our goal was to identify the characteristics of products with price changes after the policy implementation. Methods: We used MOHP lists and IMS data to identify products priced products with price changes. In addition, purchase and sales data were obtained from a chain pharmacy in Alexandria for all transactions (Apr 2012 – Jun 2013) to validate price changes, assess sales activity, and identify any additional products with price changes. Bivariate analysis and a logistic regression model were done to identify factors that determine or describe the initial Dose (DDD). **RESULTS:** A total of 206 products were subject to price changes; 66% of the products had price increase, 70% were generics, 36% were essential drugs, 40% of the products had less than 1EGP/DDD, 30% were between 1 and 5EGP/DDD, and 24% were higher than 5EGP/DDD. Half of the products were produced by domestic private companies, 27% by multinational firms, 21% by state-owned companies, and 23% were imported. The products of state-owned firms had 23 times the odds of products of multinational firms to have a price increase. Similarly, the cheapest products had 9 times the odds of a price increase compared to high priced products. Compared to brand name drugs, generics had 6.8 times the likelihood of a price increase. **CONCLUSIONS:** Being the product of State-owned, and a product whose price was <1EGP/DDD or a generic were the main determinants of price increase. [1] EGP-$0.14 USD

**PHP37**

**A FRAMEWORK FOR STRENGTHENING PHARMACEUTICAL MANUFACTURING IN SUB-SAHARAN AFRICA**

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**OBJECTIVES:** The healthcare infrastructure in sub-Saharan Africa is changing due to economic growth, an increasing middle class, urbanization, and rising incidence of non communicable diseases. Pharmaceutical spending in the region is projected to reach $45 billion by 2016. Despite this rapid growth and gap between availability and demand, companies have yet to initiate local pharmaceutical manufacturing due to the challenges of doing business in a framework to assess these challenges and feasibility of overcoming them. **METHODS:** We undertook a series of key stakeholder interviews in Namibia, including distribution, private sector, regulatory, and governmental representatives. Namibia had virtually no drug manufacturing at time of assessment despite political will to undertake manufacturing. **RESULTS:** In-country pharmaceutical manufacturing is viewed as important for health and economic development and stability. Key areas identified for concern included product selection, education, training, quality control, perceptions of quality, supply chain, role of public and private sectors, and market demand. Creation of a facility at the local university was recommended to build public trust, enhance training, and facilitate distribution. Product areas for initial consideration may include sterile water/saline, alcohol hand rub, oral preparations, topical preparations, total parenteral nutrition, or cancer chemotherapy. **CONCLUSIONS:** In order to create a sustainable health venture, sub-Saharan African pharmaceutical manufacturing will be necessary to provide a consistent supply of medicine. Product selection is of key importance to market local demand and be reasonably competitive economically. Viable choices could be niche products or large volumes generics. Regulatory and quality concerns will have to be thoroughly addressed to establish a successful system. Technical expertise will have to be increased and maintained. Overall, if concerns are addressed early and thoroughly, local manufacturing could provide important political and economic stability in sub-Saharan Africa while improving health.

**PHP38**

**DEVELOPING ALGORITHMS FOR IDENTIFYING BENEFICIARIES WITH HIGHER THAN EXPECTED UTILIZATION OF OPIOIDS ANALGESICS**

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**OBJECTIVES:** Considerable attention is given to managing opioid use in order to avoid addiction and possible diversion problems. A Pharmacy Quality Alliance workgroup has been working on a pharmacy quality measure where morphine equivalent letters containing 655 violations for 204 drugs across multiple therapeutic areas were issued by the FDA of all which were clinical. Most often multiple violations for a +1 drug were contained in a single letter. On average, ~36 warning letters were issued per year. Omission of risk information was the most frequently viola- tion claim (29.0%) followed by unsubstantiated/overstatement of efficacy claims (24.3%), (31.1%). There were also economic claims issued. Warning letters were primarily directed to manufactur- ers of oncology (17.5%), psychiatry (9.6%), cardiovascular (9.6%), and pain (8.5%) products. Approximately half (49.5%) of claims contained promotional materials directed to physicians. **CONCLUSIONS:** We found that misleading clinical outcome claims, specifically omissions of risk information and inaccurate efficacy, formed the majority of the promotional violations. Compared to the preceding 6 years (2005-2009), the annual mean number of warning letters have pos- sibly indicating greater surveillance by the FDA of pharmaceutical promotional materials 2009-2013.