OBJECTIVES: From 2006 – 2013 the FDA approved 207 new molecular entities with PRO statements in NME labels. In addition to NMEs, many previously-approved product labels were updated with PRO statements during this period. The purpose of this research was to review the efficacy claims supported by PROs to identify trends amongst the approved indications. PRO statements were categorized into three levels of evidence; level 3 was considered to be PRO-based if it assessed symptoms, side effects, or impacts on functioning and daily activities, entirely from the patient perspective.

RESULTS: From 2006 – 2013, the FDA approved an average of 25.9 NMEs per year. The average number of PROs included in NME labels from 2006 – 2010 was 14.2 (n = 71). From 2011 – 2013, the average was 4.3 PROs approved per year (n = 13). The difference between these two periods is statistically significant (t = 4.85, p = 0.001). This study found that PRO statements were more likely to be approved during this period, with no notable per-year trends.

CONCLUSIONS: The FDA’s PRO Guidance may not be the lone cause for the reduction of approved PROs in NME labels, but there was a significant drop in the number of approvals following its release. While the number of PROs approved in 2010 was similar to the numbers approved 2006 – 2009, submissions reviewed in 2010 may not have been asked to meet the standards of the PRO Guidance, thus impacting our analysis. Inclusion of non-NME labels approved from 2006 – 2013 does not increase the percentage of PROs approved.

PIH65
RISK PERCEPTION OF MEDICATION SIDE EFFECTS: A PRODUCT OF SIDE EFFECT severity and stylistic factors of the COMMUNICATION MESSAGE OR BOTH?
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OBJECTIVES: To determine the frequency and severity of side effects in the communication of adverse drug products (ADPs).

METHODS: A secondary, cross-sectional analysis of PROs was conducted. The study reviewed the FDA’s Guidance for Industry on PROs during the finalization. While the number of PROs approved in 2010 was similar to the numbers approved 2006 – 2009, submissions reviewed in 2010 may not have been asked to meet the standards of the PRO Guidance, thus impacting our analysis. Inclusion of non-NME labels approved from 2006 – 2013 does not increase the percentage of PROs approved.

PIH66
DEVELOPMENT OF A MEDICATION-PROBLEM COPING SCALE (MPCS) AND ITEMS CALIBRATION USING ONE-PARAMETER LOGISTIC (1PL) AND TWO-PARAMETER LOGISTIC (2PL) MODELS
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OBJECTIVES: Adverse drug problems (ADPs) have caused significant morbidity and mortality to patients. The objective of this study was to develop a medication-problem coping scale (MPCS) to measure patients’ coping responses to ADP; and calibrate the developed items using one-parameter logistic (1PL) and two-parameter logistic (2PL) models.

METHODS: A comprehensive literature review was conducted to identify candidate items to measure patients’ coping strategies when dealing with perceived ADPs. Supplementary items were then added to fill in the content gaps. The items were administered to patients in the community pharmacies which are incorporated into the Minnesota practice-based research network (PBNN). After collecting data from 140 patients, eleven items which met the assumptions of item response theory were calibrated using the 1PL and 2PL models respectively to determine which model is favored. RESULTS: The 1PL and 2PL models were compared by taking goodness-of-fit statistics, reliability of the fit index (AIC) and the RMSEA value, all of which favored the 2PL model. First, the chi-squared difference test was highly significant (X²(14, 61, 10), P<0.001) indicating that the 2PL model performs better than the 1PL model compared to the 1PL model. This result was supported by the information-theoretic fit index (AIC) and the RMSEA value, all of which favored the 2PL model. In addition, the 2PL model was preferred with a score of value of redundancy estimated (ADPs) compared to the 1PL model (0.78). Finally, the 2PL model had much more information and much lower SEM over most of the coping behavior range.

CONCLUSIONS: Our findings indicated that the 2PL model was preferred than the 1PL model. It suggests that the 2PL model be used to obtain item parameters and to assess information function.