their uninsured status. The current study aimed to evaluate the effect of a new health system from the perspective of the insured students one year after program implementation. METHODS: Based on the Chinese Customer Satisfaction Index and review of the literatures, we built a satisfaction evaluation system for URMS of university students, with one first-level, 7 second-level (latent variable, x) and 24 third-level indicators (Explicit variable, y) to be scored on a five-point Likert-type scale. Theoretical measurement model and construct validity were tested with the help of AMOS. 400 questionnaire surveys were submitted to students in 4 universities in NE China. After obtaining the affecting order of third indexes to their corresponding secondary index through the correlation test, a Structural Equation Model (SEM) for the satisfaction assessment of URMS was built basing on the calculated Path coefficient between the x and y after multiple variable regressions. Goodness of fit statistics of SEM were used to assess the match between this model and satisfaction assessment. RESULTS: A total of 393 questionnaires were returned giving a recovery rate of 93.8%. The path coefficients between x and y were: customer trust 0.26, the perceived quality 0.88, customer complaint 0.22, and monitoring mechanism of its performance; as well as enhancing awareness of the government 0.29. The satisfaction score of UMRS (29.06 out of 69.75 points) consisted of 38 questions. RESULTS: A total of 51.6% of the patients were provided with drugs by the reduced price with the substitution coefficient of 0.5. Almost 47% of the patients were refused to be provided with medical assistance and drugs within the scope of the extent of the free guaranteed medical assistance; further more, 80.3% of the asked had to use additional amount of their own money during not only at the ambulatory but also at the hospital level. At the same time, it was unaffordable for 63.8% of the asked to buy drugs. A total of 57.9% of the patients defined the drug availability provided within the scope of the guaranteed free medical assistance as poor and unsatisfactory. Moreover, 76.8% of the patients suggested that educational brochures containing information regarding teething symptoms and severity. Regardless of the treatment prescribed or not, they followed the prescribed treatment, the overall teething management by the paediatricians satisfied them.

PIH48 DEVELOPING AN INSTRUMENT TO ASSESS PRODUCT PREFERENCE FOR TESTOSTERONE REPLACEMENT THERAPY
Steinbach SL1, Seoane-vazquez E2, Summers KH3
1Ohio State University, Columbus, OH, USA, 2Massachusetts College of Pharmacy and Health Sciences, Boston, MA, USA, 3Edna H. McConnell, Inc., Chicago, IL, USA
OBJECTIVES: Patients’ perceptions of products used for testosterone replacement therapy (TRT) may vary according to product attributes such as application site, duration of use and physical qualities. The objective of this study was to assess the dominance associated with the preference for TRT products, to identify items and themes and attributes, and to develop a patient-reported outcomes (PRO) instrument for use in clinical trials. METHODS: The study used a standard qualitative approach to develop a theoretical framework and to identify items and develop concepts of interest (PIH49) for the development of TRT items and themes gleaned from a literature review and expert opinion were used to develop a theoretical framework and a discussion guide. This guide was used by trained researchers to interview patients, who were experienced using TRT and voluntarily agreed and consented to participate in the research study using IRB-approved documents. Results from telephone interviews were transcribed using NVivo 9 qualitative analysis software (QSR International, Cambridge, MA) and classified according to TRT themes. Demographic and other data collected through the interview process were entered into a spreadsheet for descriptive analysis. RESULTS: The saturation of items and evaluation of themes was accomplished by 58 male patients with an average age of 55.0±1.3 years (22-69). Patients used TRT for an average of 183.40.5 days, with approximately 50% of patients having experience with more than a single form of TRT. Five patients participated in cognitive debrieﬁng: the study revealed that patients tend to search for relevant product attributes during purchase, the physiological impact, psychological impact, side effects, and treatment experience. CONCLUSIONS: Themes and items related to TRT use were in concordance with the theoretical framework developed in the study. The PRO instrument can be further developed for potential use in clinical trials.

PIH49 PATIENT REPORTED OUTCOMES AS PRIMARY ENDPOINTS IN CONFIRMATORY CLINICAL TRIALS
Gnanaskothy A1, Lewis S2, Clark M3, Evans P2, Mordin M1, Demuro C2
1Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, 2RTI Health Solutions, Research Triangle Park, NC, USA, 3RTI Health Solutions, Ann Arbor, MI, USA
OBJECTIVES: The purpose of this research was to determine the impact of patient-reported outcome (PRO) endpoint type (primary vs. nonprimary) on PRO-based labeling claims. This review examines PROs as both primary and nonprimary endpoints used to demonstrate treatment benefit of new molecular entities (NMEs) and biologic license application (BLAs) in the United States (US) in the years 2000-2010. METHODS: Food and Drug Administration (FDA) Drug Approval Reports were reviewed to identify all approved NMEs and BLAs between January 2000 and December 2010. Generic products with tentative approvals were excluded. For all identified products with publically available drug approval packages, the medical review sections were reviewed to identify PRO endpoint use. Product label indications and clinical trials sections were reviewed to determine the number and type of PRO claims. RESULTS: A total of 264 NMEs/BLAs were identified. Of these, 63 NMEs/BLAs (24%) were grant-funded-based claims. The majority of product claims were for disease- or condition-specific signs and symptoms. Of the 63 products with PRO-based claims, the PRO was the primary endpoint for 54 (86%). All 54 primary endpoints were signs and symptom evaluation; of these, 3 included a functioning measure as a coprimary endpoint. CONCLUSIONS: Successful PRO label claims are typically based on primary endpoints assessing signs and symptoms. Based on this research, studies with PROs dedicated as primary endpoints, compared with nonprimary, are more likely to facilitate positive regulatory review and acceptance of PROs in support of label claims.

PIH50 FACTOR STRUCTURE OF THE NHANES PHYSICAL FUNCTION LIMITATION QUESTIONNAIRE AND ITS RELATIONSHIP WITH MUSCLE MEASUREMENTS IN US ELDERLY AGED 60-80 YEARS
El Lilly and Company, Indianapolis, IN, USA
OBJECTIVES: Physical function limitation and muscle wasting are commonly associated with many chronic conditions and the aging process. The National Health and Nutrition Examination Survey 2001-2002 included a physical function limitation questionnaire, as well as examinations measuring muscle mass and muscle strength. The factor structure of the physical function limitation questionnaire, however, is unknown. The aim of this study was to evaluate the factor structure of the questionnaire and to examine the relationship between physical function and muscle measurements in the elderly in the United States. METHODS: Data from NHANES 2001-2002 participants aged 60-80 years (n=1394) was used for this study. First, a maximum likelihood based exploratory factor analysis (EFA) with oblique rotation (an assumption that the loadings for the set of attributes in high correlation between these attributes) was used to develop a theoretical framework and a discussion guide. The EFA produced a 3-factor solution consisting of 3 factors, with 3 factors accounting for 58.5% of the variance. The median age was 71.5% of the patients suggested that educational brochures containing information regarding teething symptoms and severity. Regardless of the treatment prescribed or not, they followed the prescribed treatment, the overall teething management by the paediatricians satisfied them.