HOUSE RESOLUTION

WHEREAS, The Nu Paradigm Foundation has proposed legislation to be presented before the U.S. Congress that would ensure that the demographic profile in clinical drug trials is representative of the population that will use the drug upon approval by the U.S. Food and Drug Administration (FDA), thereby promoting equitable access to safe and effective medication for all communities; and

WHEREAS, For the purpose of this proposed legislation, "demographic representation" means the inclusion of diverse participants in clinical trials, taking into account factors such as age, gender, race, ethnicity, socioeconomic status, and health conditions, and "clinical trial" refers to any research study that involves human participants and is designed to evaluate the effects and efficacy of a drug; and

WHEREAS, Under this proposed legislation, all sponsors of clinical trials for drug approval shall submit a diversity plan as part of their Investigational New Drug (IND) application; this plan shall outline strategies to ensure that trial participants reflect the demographics of the intended patient population; this plan must establish specific recruiting goals for demographic groups that are underrepresented in trial, including, but not limited to,

racial and ethnic minorities, women, and individuals with disabilities; sponsors shall also be required to report the demographic composition of the trial participants at the end of the trial and provide an explanation in the event the trial did not meet the established recruitment goals; and

WHEREAS, Under this proposed legislation, the FDA shall review the diversity plan as part of the IND application process and may require modifications to ensure sufficient representation; the FDA may also withhold approval of a new drug application if the sponsor fails to demonstrate adequate efforts to achieve demographic representation; the FDA shall publish aggregate data on the demographic composition of its participants in approved clinical trials, including an analysis of trends over time; and

WHEREAS, Under this proposed legislation, the U.S. Department of Health and Human Services shall establish a diverse task force to oversee the implementation of this legislation, provide guidance to sponsors, and evaluate the effectiveness of strategies aimed at enhancing demographic representation in clinical trials; and

WHEREAS, The suggested effective date of this proposed legislation would be 180 days following its enactment; therefore, be it

RESOLVED, BY THE HOUSE OF REPRESENTATIVES OF THE ONE HUNDRED FOURTH GENERAL ASSEMBLY OF THE STATE OF ILLINOIS, that we urge the U.S. Congress to consider passing legislation proposed by the Nu Paradigm Foundation that promotes equity regarding safe and effective medication for all communities.