Chapter: **New York City Society of Health-system Pharmacists**

Topic: Incidence and Prevalence Informed Clinical Trial Design to Support Generalizable and Equitable Medication Evidence

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Whereas,

Whereas, pharmacists are responsible for optimizing medication-related outcomes by applying evidence that is scientifically valid, clinically relevant, and generalizable to the populations expected to use the medication;

Whereas, gaps in clinical trial representation across populations defined by race, ethnicity, sex and gender, age, disability status, geography, socioeconomic access barriers, and other protected or suspect classes can limit external validity, undermine the reliability of benefit–risk assessments, and contribute to evidence gaps that can perpetuate inequities in medication outcomes;

Whereas, federal standards and scientific principles support equitable representation, including the NIH Revitalization Act and NIH inclusion policy for women and racial and ethnic minority groups, ICH E8(R1) emphasizing representative participant populations, and FDA efforts to improve demographic subgroup evidence through FDASIA Section 907 and transparent reporting mechanisms such as Drug Trials Snapshots;

Whereas, FDA guidance related to Diversity Action Plans supports using estimated U.S. incidence and prevalence of the disease or condition to inform enrollment goals when such epidemiologic data are available, and FDA guidance on enhancing participation encourages trial design, eligibility criteria, and recruitment practices that increase applicability of evidence to populations likely to use the therapy; therefore, be it

Resolved That: The New York State Council of Health-system Pharmacists supports clinical trial designs that establish enrollment goals aligned with the estimated incidence and prevalence of the disease in intended-use populations, including populations characterized by suspect class.

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