

Research

Research on Drug Use in Obese Patients (1013)

Source: Council on Therapeutics

To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in obese patients to facilitate safe and effective dosing of medications in this patient population, especially for medications most likely to be affected by obesity; further,

To encourage manufacturers to include in the Food and Drug Administration (FDA)-approved labeling detailed information on characteristics of individuals enrolled in drug dosing studies; further,

To advocate that the FDA develop guidance for the design and reporting of studies that support dosing recommendations in obese patients; further,

To advocate for increased enrollment of obese patients in preapproval clinical trials of new medications; further,

To encourage independent research on the clinical significance of obesity on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms.

Institutional Review Boards and Investigational Use of Drugs (0711)

Source: Council on Pharmacy Practice

To support mandatory education and training on human subject protections and research bioethics for members of institutional review boards (IRBs), principal investigators, and all others involved in clinical research; further,

To advocate that principal investigators discuss their proposed clinical drug research with representatives of the

pharmacy department before submitting a proposal to the IRB; further,

To advocate that IRBs include pharmacists as voting members; further,

To advocate that IRBs inform pharmacy of all approved clinical research involving drugs within the hospital or health system; further,

To advocate that pharmacists act as liaisons between IRBs and pharmacy and therapeutics committees in the management and conduct of clinical drug research studies; further,

To strongly support pharmacists' management of the control and distribution of drug products used in clinical research.

This policy supersedes ASHP policy 0230.

Clinical Investigations of Drugs Used in Elderly and Pediatric Patients (0229)

Source: Council on Professional Affairs

To advocate increased enrollment of pediatric and geriatric patients in clinical trials of new medications; further,

To encourage pharmacodynamic and pharmacokinetic research in geriatric and pediatric patients to facilitate the safe and effective use of medications in these patient populations.

This policy was reviewed in 2006 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.