Research

Research on Drug Use in Obese Patients (1515)
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 and outcomes reporting of obese patients in clinical trials of 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.

This policy supersedes ASHP policy 1013.

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 was reviewed in 2011 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

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 2011 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

ASHP Policy Positions 2009–2016 (with Rationales): Research

1515
RESEARCH ON DRUG USE IN OBESE PATIENTS
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 and outcomes reporting of obese patients in clinical trials of 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.

This policy supersedes ASHP policy 1013.

Rationale
Given the growing rate of obesity in the United States, ASHP is concerned about the uncertainty surrounding how obesity affects drug dosing, effectiveness, and safety. The FDA does not require that studies of obese patient populations be performed, despite the growing proportion of obese patients in America. Obese patients are subject to variable pharmacokinetic effects of oral and injectable therapeutic agents. Drug product manufacturers should be encouraged to complete pharmacokinetic and pharmacodynamic dosing studies of obese patients, especially for drugs for which obesity is expected to have significant clinical impact (e.g., antimicrobials, highly lipophilic drugs, etc.). If these voluntary studies are not completed, then manufacturers should include in the FDA-approved labeling complete information on the population enrolled in dosing studies and the methods used to determine dosing so that clinicians can assess the extent to which that population reflects patients being treated.

ASHP advocates that the FDA develop guidance for voluntary drug dosing studies of obese patients that would define study design and reporting with the intent of standardizing this research to the extent possible. The need for this guidance is supported by the complexity of drug dosing for obese patients, which varies based on drug and patient characteristics. A

paucity of research in this population is noted, similar to the lack of preapproval studies in geriatric and pediatric patients. Such studies could help standardize research methods and promote comparative effectiveness research. ASHP also encourages independent clinical and practice-based research to further define clinical use of drugs in the treatment of obese patients, as well as clinician reporting of patient experience in articles and clinical registries.