The Ohio Society of Health-System Pharmacists
Position Statement on Narrow Therapeutic Index (NTI) Drugs

DEFINITIONS:

Narrow Therapeutic Index (NTI) is a term used to describe drug products that have a narrow range of acceptable blood concentration between risk and benefit. Products that yield blood levels above that range can be toxic, while levels below the range can be ineffective or less than optimal for the patient. Small changes in the dose and/or blood concentration of these drugs could potentially result in clinically important changes in drug efficacy or safety.

Generic Substitution is the substitution of drug products that contain the same active ingredients and are chemically identical. When the Food and Drug Administration (FDA) approves products as generically equivalent they can be expected to have equivalent therapeutic and clinical effects.

POSITION:

OSHP opposes legislation restricting the generic substitution of drugs with a narrow therapeutic index.

OSHP supports the existing generic substitution laws that already serve as an adequate safequard in protecting the patient. The Food and Drug Administration (FDA) is the appropriate body to determine the generic equivalence of all drug products, including those termed NTI. Additional restrictions are an unnecessary burden on the healthcare professionals prescribing/dispensing these products.

The goal of healthcare professionals is to provide the patient with safe and effective care at a reasonable cost. We believe that the pharmacist, in collaboration with other healthcare providers, is in the best position to do this.

The prescriber and the pharmacist must exercise professional judgment to determine what is best for the patient. The key concept is not the brand of product which is initially selected for the patient. Rather, switching a patient between specific brands of a multi-source product should be carefully considered by the prescriber/pharmacist after initial therapy has been started and the patient is clinically controlled.

OSHP acknowledges that the prescriber has the option at the time of dispensing to stipulate the specific drug entity as well as the brand or supplier of a drug to be dispensed for a particular patient. The prescriber's decisioin should be based on therapeutic considerations relative to the specific patient.

Approved by the OSHP Board of Directors
June 19, 1999, pursuant to a motion
adopted by the OSHP House of Delegates
May 7, 1999