



## INTERCHANGE OF NARROW THERAPEUTIC INDEX DRUGS<sup>1</sup>

A drug is commonly referred to as having a narrow therapeutic index (NTI) when small variances in blood levels of the medication cause changes in the effectiveness or toxicity of that drug. Safe and effective use of NTI drugs requires careful dosage adjustment and patient monitoring, regardless of generic or brand name product use. The U.S. Food and Drug Administration (FDA) has taken the position that when an FDA approved and therapeutically equivalent generic drug is selected, patients, physicians, and pharmacists can be assured that they will obtain the same clinical results and safety profile as would be expected from the equivalent brand name product.

### **AMCP Position:**

**The Academy of Managed Care Pharmacy (AMCP) opposes legislation that restricts the appropriate generic substitution of narrow therapeutic index (NTI) drugs.**

- **The FDA reviews drug applications to assure that all drugs approved as generic equivalents are pharmaceutically and therapeutically equivalent to the brand name product.**
  - Due to its strict generic approval process, the FDA does not consider NTI drugs as separate from any other generic drug substitution.
  - Generic drugs are held to the same strict quality manufacturing standards as innovator products.
- **Generic substitution frequently offers a substantial cost-savings for patients and payers, while retaining the clinical effectiveness of the brand-name equivalent.**
  - Patients receiving treatment via NTI drugs should not have barriers to generic drug access.
  - Establishing barriers to access to generic drugs can unnecessarily increase costs for patients and payers.

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*The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to assist patients in achieving positive therapeutic outcomes. The Academy's 6,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. More news and information about AMCP can be obtained on its website, at [www.amcp.org](http://www.amcp.org).*

<sup>1</sup> See AMCP's Where We Stand Position Statement on Narrow Therapeutic Index Drugs, Interchange of, Revised January 2004. <http://www.amcp.org/Tertiary.aspx?id=8742>