RESOLUTION 45 – 06A

Title: **Pharmaceutical Litigation**

Introduced by: **Robert S. Levine, MD, for the Oakland County Delegation**

Original Author: **Robert S. Levine, MD**

Referred to: **Reference Committee B**

House Action:

Whereas, the cost and potential cost of pharmaceutical litigation may be a significant factor in the cost of medications, and

Whereas, the threat of potential litigation may adversely affect the availability of medications, and

Whereas, no medication is without some risk of having an adverse event, and medication prescribing is a matter of balancing risks and benefits, and

Whereas, the long, complicated, and expensive Food and Drug Administration (FDA) approval should prevent medications that have a poor risk-benefit ratio from reaching the market; therefore be it

RESOLVED: That the Michigan Delegation to the AMA ask the AMA to seek federal legislation that would prohibit pharmaceutical manufactures from being sued for adverse events allegedly caused by Food and Drug Administration (FDA) approved medications unless it can be shown that the pharmaceutical company withheld or provided misleading information to the FDA while seeking approval for the medication or that the alleged adverse event was caused by a manufacturing error, such as improperly sterilizing an injectable agent or contaminating a product by not properly cleaning a production line when changing to the manufacturing of another medication or when changing to the packaging of different medication.

WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE