

SENATE BILL REPORT

EHB 1415

AS REPORTED BY COMMITTEE ON HEALTH & HUMAN SERVICES,
APRIL 2, 1993

Brief Description: Modifying the imprinting law for over-the-counter medications in solid dosage form.

SPONSORS: Representative G. Cole

HOUSE COMMITTEE ON HEALTH CARE

SENATE COMMITTEE ON HEALTH & HUMAN SERVICES

Majority Report: Do pass.

Signed by Senators Talmadge, Chairman; Wojahn, Vice Chairman; Deccio, Erwin, Franklin, Fraser, McDonald, Moyer, Niemi, Prentice, Sheldon, L. Smith, and Winsley.

Staff: Martin Lovinger (786-7443)

Hearing Dates: April 2, 1992

BACKGROUND:

For poison control purposes, the Legislature enacted a requirement that prohibits the manufacture or distribution of solid dosage over-the-counter (nonprescription) medications without clearly identifying the medication and the manufacturer or distributor by name or symbols. All containers or packages of over-the-counter medication must identify the manufacturer of the medication. No such drugs may be manufactured in or shipped into this state after January 1, 1993, without being identified. No such drugs may be sold in this state after January 1, 1994, unless there is compliance with the identification requirements.

There is no requirement that the distributor or packer be identified on these drugs. There is a question whether those requirements cover liquid as well as solid dosage over-the-counter medications.

The Board of Pharmacy was required before January 1, 1993, to determine if the federal government has established a substantively equivalent system for imprinting and identifying drugs. State requirements would cease to exist upon the implementation of the federal requirements.

To date, no federal system for imprinting and identifying over-the-counter drugs has been implemented, and the requirements of state law are now technically in effect.

SUMMARY:

The implementation date for identifying over-the-counter medications manufactured and distributed in this state is deferred until January 1, 1994, and these medications may not be sold in this state after January 1, 1995.

The law is clarified to cover only over-the-counter medications in solid dosage forms.

The packer and distributor as well as the manufacturer are required to be identified on packages and containers of over-the-counter medications sold in this state after January 1, 1995.

Appropriation: none

Revenue: none

Fiscal Note: none requested

Effective Date: The bill contains an emergency clause and takes effect immediately.

TESTIMONY FOR:

This bill is necessary because the federal government has not yet issued national regulations. Federal regulations were anticipated by the beginning of this year, but have been delayed. Manufacturers are working hard to push for federal regulations to avoid the burden of meeting different requirements in each state. The intent of the original bill was to avoid poison risks, not to place an onerous burden on small manufacturers of over-the-counter drugs. Many manufacturers have complied with current law requirements, so it is reasonable to delay the implementation date to avoid placing an expensive burden on the small manufacturers which have not yet complied.

TESTIMONY AGAINST:

There is no specific date for issuance of federal regulations. There is a great deal of compliance with the requirements of the current state law. Ninety percent of the industry already imprints over-the-counter medicine in solid dosage form. It is unfair to those manufacturers who have complied for the implementation date to be delayed on behalf of those who have not complied. The original time delay was designed to give manufacturers time to comply and to pressure the federal government to issue federal regulations. It is not fair for those who have not complied to ask for more time to do what they were already given time to accomplish.

TESTIFIED: Kevin Krausehaar, Nonprescription Drug Manufacturers Association (pro); Tim Fuller, Board of Pharmacy (con); Susie Tracy, Washington State Medical Association, Poison Control Network (pro); Lars Hennem, Pharmacists of Washington (con)