

SUBJECT: Restricting use of articles detained or embargoed by the Health Department

COMMITTEE: Public Health — favorable, without amendments

VOTE: 5 ayes — Berlanga, Hirschi, Davila, Glaze, Maxey

0 nays

4 absent — Coleman, Delisi, Janek, Rodriguez

WITNESSES: None

BACKGROUND : The Texas Food, Drug and Cosmetic Act authorizes the commissioner of health to affix a tag or other appropriate marking on a food, drug, device, cosmetic or consumer commodity that gives notice that the article is suspected of being adulterated, misbranded, contaminated or not a federally approved drug and that such article has been detained or embargoed. Articles so tagged may not be removed or disposed of without permission by the commissioner or a court.

DIGEST: HB 358 would amend the act to prohibit also the *use* of a detained or embargoed article without permission from the commissioner or a court.

HB 358 would take immediate effect if finally approved by a two-third record vote of the membership of each house.

SUPPORTERS SAY: HB 358 would help protect the public from unsafe devices and practices by those who rank making profits over public safety. Fraudulent health care is a \$40 billion nationwide industry, and part of that industry involves selling or misusing drugs or devices for purposes other than those for which they were specifically designed and for which they have received federal approval.

HB 358 would close a loophole in the law that allows unsafe articles to be used even though they have been identified and detained by the health department. The loophole rarely posed a problem in the past because embargoed food, drugs and cosmetics usually cannot be used without first being removed or disposed of. Now, however, as technology has advanced,

new devices increasingly are being used for unapproved purposes that may actually be quite hazardous.

For example, one company has used sonogram devices to make videos of in-utero babies, despite a health department embargo on the equipment because of the safety threat posed by the heat generated when the sonogram is used in a way that is not federally approved. Other examples of devices that have been or could be used despite health department embargoes include tanning beds, tattoo needles, electronic muscle stimulators and laser acupuncture devices.

The health department has an excellent history of using its detention and embargo authority judiciously and appropriately and has never had an embargo overturned. Entities that wish to challenge a health department embargo may appeal directly to the commissioner and also have recourse in administrative and civil courts. Both the state and federal food and drug acts place the burden of proof for demonstrating the safety of a device used for an *unapproved* purpose on the seller or on the user of the device. HB 358 would not impose any additional constraints on legitimate commerce.

OPPONENTS  
SAY:

Just because a device is federally approved for one specific purpose does not mean it is dangerous when used for another purpose. The federal government is well known for dragging its heels on approving new medicines and medical devices, even when these articles have been used without problem for years in other countries. Some individuals have been forced to travel abroad in order to receive alternative medical treatment not yet available in this country.