

SUBJECT: Authorizing pharmacies to promote specific compounded drug products

COMMITTEE: Public Health — favorable, without amendment

VOTE: 5 ayes — Laubenberg, Truitt, Dawson, Taylor, Zedler

0 nays

4 absent — Capelo, Coleman, McReynolds, Naishtat

SENATE VOTE: On final passage, March 27 — 31-0

WITNESSES: For — Steve Hotze

Against — None

BACKGROUND: Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. In 2002, the U.S. Supreme Court ruled in *Thompson v. Western States Medical Center*, 535 U.S. 357, that federal law against advertising or promoting the compounding of any particular drug, class of drug, or type of drug was an unconstitutional restriction on commercial speech in violation of the First Amendment to the U.S. Constitution.

Texas State Board of Pharmacy rules (T.A.C., Title 22, Part 15, sec. 291.33) state that compounding pharmacies or pharmacists may advertise and promote the fact that they provide nonsterile prescription compounding services but may not solicit business by promoting that they compound specific drug products.

DIGEST: SB 803 would authorize a compounding pharmacist or pharmacy to advertise or promote nonsterile prescription compounding services that the pharmacy or pharmacist provided and specific compounded drug products that the pharmacy or pharmacist dispensed or delivered.

The bill would take effect September 1, 2003.

**SUPPORTERS
SAY:**

SB 803 would correct an unconstitutional regulation of the Board of Pharmacy by explicitly authorizing pharmacists and pharmacies to promote specific compounded drug products that the pharmacy or pharmacist dispensed or delivered.

The bill would alert pharmacists and others that they lawfully could provide notice to more people about the availability and benefit of compounded drugs. Patients with drug allergies, patients who cannot tolerate particular drug delivery systems, patients requiring special drug dosages, and others often rely on compounded drugs for relief they otherwise could not obtain. As a result, the bill properly could help more people achieve better health through the special properties of compounded drugs.

**OPPONENTS
SAY:**

SB 803 would enact unnecessary law and would encourage the growth of an underregulated pharmaceutical practice — drug compounding — thus potentially risking public health. Because the U.S. Supreme Court’s *Thompson* decision made the state’s nonconforming regulation unenforceable, pharmacists and pharmacies already can promote specific compounded drug products lawfully.

Although the U.S. Constitution may protect a pharmacist’s right to promote compounded drugs, the state should not encourage this activity with new legislation. Drug compounding can involve combining ingredients in new and untested ways that might cause serious side effects, including death. Yet compounded drugs made by pharmacists do not undergo the Federal Drug Administration’s rigorous approval process before becoming available to consumers. These drugs therefore carry a special risk of causing unintended harm, and the state should not facilitate their use.