

**STATE OF TENNESSEE**

OFFICE OF THE  
**ATTORNEY GENERAL**  
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March 28, 2006

Opinion No. 06-057

Legality of Provisions of H.B. 2501 Permitting Distribution of Expired Legend or Prescription  
Drugs Through Non-Profit Organizations

**QUESTION**

Whether a proposed state law allowing the donation of expired legend or prescription drugs to non-profit organizations which would distribute those drugs to low income recipients violates federal law?

**OPINION**

Yes. Federal law specifically prohibits the distribution of expired legend or prescription drugs even when those drugs are donated to non-profit organizations for the ultimate use of low income recipients who have a medical need for the drug.

**ANALYSIS**

Tennessee law currently prohibits the sale or distribution of any legend drug which has passed its stated expiration date. Tenn. Code Ann. § 53-10-106(a)(1); *see also* Tenn. Comp. R. & Regs. §§ 1140-9-.05(1)(c); 1140-3-.11. The term “legend drug” is synonymous with “any item that federal law prohibits dispensing without a prescription from a licensed doctor, dentist, optometrist or veterinarian.” Tenn. Code Ann. § 53-10-101(a).

House Bill 2501 proposes to legalize the donation of legend drugs that are beyond their expiration dates by one year or less to certain non-profit organizations for later distribution to low income persons who have a medical need for the drug. Federal regulations, however, set specific standards for the storage and handling of expired legend drugs. 21 C.F.R. §§ 205.50(a)(3), 205.50(e)(1), 205.50(g)(4). The provision of House Bill 2501 which would allow the distribution of expired drugs directly conflicts with these federal standards.

The Federal Food and Drug Administration requires that all licensed distributors of legend drugs must quarantine outdated drugs in a specific storage area and either destroy those drugs or return them to the drug manufacturer. *Id.* Federal regulations allow the donation of drug samples to charitable institutions under certain conditions but such drug samples must not be expired. 21 C.F.R. § 203.39(c)(1). Charitable institutions that accept donations of drug samples must also destroy expired samples or return them to the drug manufacturer. 21 C.F.R. § 203.39(d).

While researching this issue, our Office has found several instances in which other states have established drug repository programs for unused prescription drugs. Yet, in all of those instances, such programs are prohibited from either accepting or distributing drugs that have expired.<sup>1</sup>

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Requested by:

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<sup>1</sup> Ala. Code §§ 20-3-3(a)(1)(d), 20-3-3(a)(2)(d); Ark. Code Ann. § 17-92-1104(c)(9); Colo. Rev. Stat. § 25-35-103(3)(b); Ga. Code Ann. § 26-4-116(g); Minn. Stat. § 151.55(5)(b)(2); and, 59 Okl. St. Ann. § 367.4(3).