S T A T E O F T E N N E S S E E
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April 20, 2009

Opinion No. 09-61

Distribution of Recently Expired Prescription Drugs

QUESTION

In light of several additional materials -- including news reports, an e-mail message from the United States Food and Drug Administration, and information about other states' drug donation laws -- should Op. Tenn. Att'y Gen. 06-057 be reconsidered?

OPINION

No, the additional materials provide no legal basis to change our previous opinion that the distribution of expired prescription medication is expressly prohibited by federal law.

ANALYSIS

In 2006, we issued an opinion concluding that 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 drugs. Op. Tenn. Att'y Gen. 06-057 (March 28, 2006). We based this conclusion upon federal regulations that: (1) require all licensed distributors of legend drugs to quarantine outdated drugs in a specific storage area and either destroy those drugs or return them to the drug manufacturer; (2) allow the donation of drug samples to charitable institutions under certain conditions but such drug samples must be not be expired; and (3) require charitable institutions that accept donations of drug samples to destroy expired samples or return them to the drug manufacturer. 21 C.F.R. §§ 203.39(c)(1), 203.39(d), 205.50(a)(3), 205.50(e)(1), 205.50(g)(4). Later in 2006, in response to a request that we reconsider the opinion, we issued a letter stating that we had found no legal reason to change our conclusions.

We have reviewed additional materials with which we have been provided. The materials include two 2008 news reports describing, respectively, nursing home employees' flushing of "brand new" medicine left over from patients and a Pennsylvania Amish-owned salvage grocery store's discounted sales of dinged food items and over-the-counter ("OTC") medicines that are, in some cases, past their expiration or sell-by dates. We have also been provided with a copy of a November 3, 2008, e-mail message from a press officer of the United States Food and Drug Administration. In response to several questions, the message states, in pertinent part:

> The Food, Drug and Cosmetic Act does not permit the sale of either expired OTC or expired prescription drugs. . . [P]rovisions in the Act apply to both prescription and non-prescription medications.
>
> Further, there are regulations at 21 CFR 205.50 that describe minimum requirements for the states regarding the storage and handling of prescription drugs. These regulations address outdated prescription drugs and state, among other requirements, that they be separated from other drugs until destroyed or returned to the supplier.
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> . . .
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> We were unaware of the sale of the expired medications by the Amish salvage stores. However, as a matter of policy, we would generally defer enforcement at the retail level to local state authorities.

Finally, we have been asked to take into consideration other states' drug donation laws, including those of Iowa, Wyoming, and Rhode Island. We have looked at those Iowa, Wyoming and Rhode Island statutes and note that they prohibit acceptance and/or redispensing of donated drugs that have passed their expiration dates. *See* Iowa Code Ann. § 135M.4 (1)(b); Wyo. Stat. § 35-7-1603(b)(iv) (as amended by 2009 Wyo. Sess. Laws Chap. 166); R.I. Gen. Laws § 23-25.4-5(3).

We appreciate the work of charitable organizations, such as those described in the opinion request, that provide medical assistance to the medically underserved. We cannot overlook, however, the clear prohibition contained in federal law and its preemptive effect on state law. Accordingly, we must conclude that the additional materials provide no legal basis to change our previous opinion that the distribution of expired prescription medication is expressly prohibited by federal law.

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