

Destroying Unused, Unopened Prescription Drugs at Taxpayer Expense: An Update

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It's most frequently a dramatic device seen in B-movie Westerns. The sunburned hero is found crawling among the cacti of some parched desert by the villain – more often than not playing the part of the local sheriff. Overcome by thirst and the elements, the hero squints up into the mirrored sunglasses of The Law and asks – pleads – begs for water. A smarmy grin spreads across the face of the sheriff as he produces a canteen beading with condensation. The hero, meanwhile, watches with outstretched hands as The Law pours the water onto the sand.

In a way, up until recently, this melodrama was being played out in real life in nursing homes around the country. While millions of Americans could not adequately afford their prescription medications, long-term care facilities were throwing away millions of dollars worth of prescription drugs. This was because states felt bound by a well-intentioned Food and Drug Administration (FDA) policy that instructed nursing homes and other long-term care facilities to destroy unused and unopened prescription drugs after a specific period of time.¹ This policy, issued in the early 1980s, was not, as one might expect, to protect nursing home residents from potentially harmful or ineffective expired drugs (these drugs were, for the most part, yet to reach their expiration dates). Instead, the policy was intended to protect pharmacists from legal liability for restocking drugs that had left the pharmacists' possession and then returned. It was also to protect future consumers from drugs that were no longer "known" to be safe because they had left a pharmacist's watchful eye for a spell. Who knew what beastly horrors might lie in that bottle of pain medicine? This was, after all, the decade that brought us tampered Tylenol™ riddled with cyanide.

But technology then rendered moot some of the earlier worries evident in the FDA policy. Tamper-evident packaging – a direct response to the Tylenol™ terrorism of the early 1980s – became much better at assuring the cleanliness of drugs than a strict "chain of custody" policy. Nonetheless, the FDA policy remained in place and was followed for roughly 20 years

Commentators and state legislators eventually began to see that the policy was unnecessarily prohibitive and the cause of too much waste. Taxpayer-funded Medicaid and Medicare were footing the bill for millions of dollars of unused, unopened, perfectly safe and effective prescription drugs to be, quite literally, flushed down the toilet. As Joseph Wang from the University of Houston Law Center's Health Law & Policy Institute said in a Health Law Perspectives article in 2000, "[i]t seems wasteful, imprudent, and unethical to destroy quality drugs that could benefit so many individuals."² Indeed, in times when access to pharmaceuticals for the poor and uninsured continues to be sub-par, the wholesale destruction of so much medicine is shameful.

¹ U.S. FOOD AND DRUG ADMINISTRATION, COMPLIANCE POLICY GUIDE § 7132.09, available at http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-300.html.

² Joseph J. Wang, *Unopened, Unused Prescription Drugs Destroyed at Taxpayer Expense*, HEALTH LAW PERSPECTIVES (2000), at <http://www.law.uh.edu/healthlaw/perspectives/Food/001129Unopened.html>. Note that, as an update on the state of the law, this Health Law Perspectives article supersedes Mr. Wang's.

As well one might imagine, the already high cost of prescription medicines brings with it a concomitantly high cost for public health. A recent study revealed that about 1.3 million adults with disabilities did not take their prescriptions as prescribed due to their cost.³ These patients either did not get their prescriptions filled, did not fill their prescriptions completely, failed to refill their prescriptions or used their medicine less often than prescribed because of cost.⁴ More than half of these respondents subsequently reported increased health problems as a result.⁵ What's worse is that respondents who characterized themselves as having fair or poor health were more likely to be noncompliant than were those who described themselves as having good health. Severe disability, low income, lack of insurance and a high number of prescriptions were all found to increase the odds of cost-related noncompliance as well.⁶ It is these health care consumers, the sick poor, who are the most wounded by the wasteful FDA policy requiring nursing homes to destroy the medicine that was prescribed but never dispensed due to the intended patient's transfer or death.

Thankfully, State legislatures are finally doing something about the destruction of expensive medicines. Since articles like that of Joseph Wang focused light on this issue, many states including Texas have redesigned their laws to allow for nursing homes to return unused drugs as long as they are sealed in unopened, tamper-evident packaging.⁷ The pharmacy or manufacturer then reimburses Medicaid or Medicare for the drugs wherever appropriate. And while there are substantial qualifications for the drugs that may be recycled (for example, controlled substances like Valium™ and Tylenol™ with Codeine must be destroyed instead of returned, and the returned drugs cannot have less than 120 days before expiration), there are a great many drugs that now have the potential to be rescued and returned for resale or charitable use.

However, while these laws generally *allow* a consulting pharmacist to return unused, unopened prescription drugs to a pharmacy or manufacturer, they don't usually *require* pharmacists to be conservationists⁸ even though laws like that of Texas limit the liability of pharmacists who recycle drugs with care and good faith.⁹ The Texas law also does not require pharmacies to accept or restock returned drugs even when they comply with all FDA and state requirements.¹⁰

Considering the permissive nature of these laws, and the possible fear of liability and additional work involved in returning unused prescription drugs, it remains an interesting question whether and to what extent the State laws will impact the drug destruction problem in the future. It also remains to be seen whether these medicines will ultimately find their way to the indigent and infirm or, like our thirsty hero, whether the sick poor will witness the waste of their most-needed commodity.

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³ Jae Kennedy & Christopher Erb, *Prescription Noncompliance due to Cost Among Adults With Disabilities in the United States*, 92 AM. J. PUB. HEALTH 1120 (2002).

⁴ *Id.* at 1121.

⁵ *Id.* at 1122.

⁶ *Id.* See also Jay M. Pomerantz, *Special Article: Recycling Expensive Medication: Why Not?*, MEDSCAPE (2004), available at <http://www.medscape.com/viewarticle/472851>.

⁷ TEX. OCC. CODE ANN. § 562.1085.

⁸ TEX. OCC. CODE ANN. § 562.1085(a).

⁹ TEX. OCC. CODE ANN. § 562.1086(a).

¹⁰ TEX. OCC. CODE ANN. § 562.1085(c).