

FDA To Take Action Against Pharmacies That Compound Drugs As If They Were Drug Manufacturers

American Society of Interventional Pain Physicians
"The Voice of Interventional Pain Medicine"
2831 Lone Oak Road, Paducah, KY 42003
Tel.: (270) 554-9412; Fax : (270) 554-8987 E-mail:drm@asipp.org

From: Laxmaiah Manchikanti, M.D.
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Courtesy of: William Sarraille, J.D., Arent Fox

In June 2002 the U.S. Food and Drug Administration ("FDA") published a new section in its Compliance Policy Guide ("CPG") Manual, CPG 460.200, outlining the Agency's enforcement policy on pharmacy compounding. The Guidance details the types of compounding that could be the subject of FDA enforcement action following to the recent Supreme Court decision in *Thompson v. Western States Medical Center*. **POLICY** In general, the FDA will consider enforcement action when the scope and nature of a pharmacy's actions resemble those normally associated with drug manufacturing.

Specifically, the Agency said that it will take enforcement action when a pharmacy engages in:

- * Compounding drugs before actual receipt of a valid prescription;
- * Compounding drugs that were removed from the market for safety concerns;
- * Compounding drugs from ingredients that are not components of FDA approved drugs without an investigational new drug application;
- * Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that they were made in an FDA-registered facility;
- * Receiving, storing, or using drug components not guaranteed to meet official compendia requirements.
- * Compounding drugs using commercial-scale equipment;
- * Compounding drugs for resellers who sell to individuals or who offer the drugs wholesale;
- * Compounding drugs that are copies of FDA-approved drugs (in certain cases FDA may permit pharmacies to compound a small quantity of a drug if it is slightly different than an approved drug); and/or
- * Activities that violate state pharmacy laws.

Enforcement action could include any or all of the following: warning letter, seizure, injunction, and/or criminal prosecution.

BACKGROUND

In 1992 the FDA issued a CPG, formerly designated CPG 7132.16, which detailed the FDA's enforcement policy on pharmacy compounding. In 1997, President Clinton signed into law the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), which added section 503A to the Federal Food, Drug, and Cosmetic Act ("the Act"). Pursuant to section 503A, drug products compounded by a pharmacist or physician on a customized basis for individual patients were exempted from the Act's adulteration provisions concerning compliance with current good manufacturing practices, misbranding provisions requiring adequate directions for use on labeling, and new drug provisions. Section 503A also prohibited compounders from soliciting prescriptions for compounded drugs and prohibited compounders from advertising specific compounded drugs. FDAMA's compounding provisions superceded FDA's 1992 CPG.

In November 1998 seven compounding pharmacies filed suit in a Nevada District Court and claimed that the solicitation and advertising provisions of section 503A violated the First Amendment because the provisions were impermissible restrictions of commercial speech. The U.S District Court ruled in favor of the pharmacies. The FDA appealed the District Court's decision to the U.S. Court of Appeals for the Ninth Circuit. In February 2001 the Court of Appeals declared not only that the solicitation and advertising provisions of section 503A were unconstitutional, but that the entire section, which allowed compounding under certain circumstances, was unconstitutional (*Western States Medical Center v. Shalala*). The government appealed the adverse decision to the U.S. Supreme Court. In April 2002 the Supreme Court upheld the Ninth Circuit's finding that section 503A was an unconstitutional restriction on commercial speech (*Thompson v. Western States Medical Center*). Therefore, presently section 503A in its entirety is invalid. In response, FDA published CPG 460.200 in an effort to clarify the time at which the Agency will take enforcement action against compounders.