

In Victory for Patients, Federal Court Rules that Compounded Medicines are Legal

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Missouri City, Texas - The International Academy of Compounding Pharmacists today applauded the ruling from U.S. District Court Judge Robert Junell that compounding is legal. The Court's written opinion follows an initial ruling from the bench issued on May 25, 2006.

"The Court's ruling is a precedent-setting victory for millions of patients, their doctors who prescribe compounded medicines for them and the compounding pharmacists who prepare their medications," said L.D. King, executive director of IACP. "Congress, the U.S. Supreme Court, and each of the 50 state boards of pharmacy that regulate compounding have long recognized the value of pharmacy compounding, yet the FDA has contended for nearly 20 years that compounded medications are illegal. This ruling affirms what the rest of the government and medical establishment have long held - compounding is vital and it is legal."

The case - Medical Center Pharmacy, et al. v. Gonzalez, et al., No. MO-04-CV-130, in the United States District Court for the Western District of Texas, Midland-Odessa Division - was filed in September 2004 by 10 pharmacies against the Food and Drug Administration and addressed a number of issues affecting the practice of pharmacy compounding.

First, the Court ruled that "compounded drugs do not fall under the new drug definitions" and, as a result, are legal. Judge Junell explained: "If compounded drugs were required to undergo the new drug approval process, the result would be that patients needing individually tailored prescriptions would not be able to receive the necessary medication due to the cost and time associated with obtaining approval. ... It is in the best interest of public health to recognize an exemption for compounded drugs that are created based on a prescription written for an individual patient by a licensed practitioner."

Second, the Court ruled that pharmacies are exempt from the requirement to submit to an FDA inspection of their records unless FDA can demonstrate that the pharmacy is not compliant with applicable state laws and does not operate as a retail pharmacy. The Court also ruled that each of the 10 plaintiffs met the requirements for exemption.

Third, the Court ruled that compounding from bulk pharmaceutical ingredients for non-food animals is legal. This is an important issue for animal owners and their veterinarians who prescribe compounded medications to treat a variety of conditions,

many of which require medications that are only available by compounding bulk pharmaceutical ingredients. Without them, animals may needlessly suffer or even die. Until now, FDA asserted that prescribing and preparing these treatments was illegal.

The plaintiffs were represented by the Austin, Texas, law firm of Hance, Scarborough, Wright, Woodward & Weisbart.

IACP was not a plaintiff in the case but filed Amicus Curiae briefs supporting them. IACP's March 2005 brief can be downloaded directly from <http://www.iacprx.org/midlandamicus> and its May 2006 brief from <http://www.iacprx.org/midlandamicus2>.

About IACP

The International Academy of Compounding Pharmacists (IACP) is a non-profit association founded in 1991 to protect, promote and advance the compounding pharmacy profession. We represent more than 1,800 pharmacists, physicians, technicians and patients who are committed to the safe practice of pharmacy compounding. We are committed to ensuring the rights of physicians to prescribe, of pharmacists to prepare and of patients to take customized medications that meet their unique, individual needs. Visit <http://www.iacprx.org/> to learn more about pharmacy compounding.

Resources

[Midland District Court Order](#) (.pdf)