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Landmark Pharmacy Compounding Court Decision Issued

U.S. District Court rules in favor of pharmacy compounding for veterinary patients.

HOUSTON (September 13, 2011): Judge Timothy Corrigan of the US District Court for the Middle District of Florida has issued his ruling in *US v. Franck's Lab, Inc.* This lawsuit, brought by the Food & Drug Administration against Paul Franck, RPh, FIACP of Franck's Lab in Ocala, Fla., alleged that the use of active pharmaceutical ingredients (APIs) in compounding veterinary preparations for non-food producing animals was illegal. The FDA stated in its case that Franck's Lab, Inc. – and all other pharmacists involved in compounding veterinary preparations with APIs – were in direct violation of AMDUCA, the FDA's CPG, and the entire Food Drug and Cosmetic Act because those preparations are “new drugs” and subject to FDA review and approval.

Judge Corrigan's ruling states:

- The FDA does not have jurisdictional authority over the compounding of medications by a licensed pharmacy so long as the pharmacy's activities are not manufacturing. That rests with individual state Boards of Pharmacy.
- Congress did not give FDA jurisdictional authority when it enacted the FDCA in 1938 to take enforcement action against a pharmacy that is engaged in the traditional practice of compounding.
- The FDA cannot use its CPG for veterinary compounding issued in 2003 as the basis for enforcement action.

- The regulations enacted by the FDA based upon AMDUCA are in error – AMDUCA did not give FDA authority to prohibit the use of bulk APIs in veterinary compounding.
- Size and scope of compounding does not mean a pharmacy is a manufacturer.
- The use of bulk APIs in compounding for humans and the prohibition of bulk APIs for compounding for non-food producing animals is an illogical position for the FDA to take and contraindicated by its own actions over the past 50+ years.

“This ruling is a significant victory for compounding pharmacists and the veterinary patients and practitioners they serve,” says, **IACP President John Herr, RPh, FIACP**. “Not only does it clearly refute the FDA’s attempts to exert unauthorized jurisdiction over compounding, it is sharply critical of the FDA’s approach towards veterinary compounding in particular. Judge Corrigan correctly ruled that Congress never intended the FDA to prohibit the use of APIs in veterinary compounding. He also clearly stated what IACP has said for years – the FDA does not have jurisdiction over the traditional practice of pharmacy compounding. That is the sole authority of the state Boards of Pharmacy,” says Herr. “Even more important to IACP members is Judge Corrigan’s outright dismissal of the FDA’s arguments that compounds prepared for an individual patient on the order of that patient’s prescriber are ‘new drugs’ and should be subject to FDA’s oversight.”

“For more than six years, IACP has worked with our supporters and allies in Congress to have the FDA address its ill-founded 2003 Compliance Policy Guideline on veterinary compounding,” explained **David G. Miller, RPh, IACP Executive Vice President & CEO**. “Multiple Congressional inquiries, letters, phone calls... all of them ignored by a regulatory agency so sure of its ‘rightness’ in claiming that compounders were violating laws. Well, today, they were proven wrong by the courts. The tireless efforts of our members and our staff, the courage of Paul Franck to fight the FDA itself, and the commitment of IACP to its mission of the art and science of compounding has paid off.”

Judge Corrigan’s ruling cites a number of landmark court cases and decisions affecting IACP members in addition to addressing the specific issue of APIs in veterinary compounding. The document numbers more than 80 pages and provides an exceptional summary of the case as well as the FDA’s attempts to grant itself authority that Congress never intended it to have. To read the entire decision, go to the IACP homepage at www.iacprx.org.

About IACP

The International Academy of Compounding Pharmacists (IACP) is a professional association founded in 1991 to protect, promote and advance personalized medication solutions. The association represents more than 2,070 pharmacists and pharmacist technicians located throughout North America, South America, Europe, Australia and

Asia, who are committed to the safe and ethical practice of pharmacy compounding. In addition, IACP represents more than 154,800 patients, physicians, nurse practitioners and veterinarians through its ally grassroots organization, Patients & Professionals for Customized Care (P2C2). IACP is committed to ensuring the rights of physicians to prescribe, of pharmacists to prepare, and of patients to take personalized medication solutions that meet their unique, individual health needs.

IACP offers a Pharmacist Locator Service which can be accessed toll free at 800/927-4227 or via IACP's website at www.iacprx.org.

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