



FDA's Questionable Jurisdiction and Prescription Compounding Need for Senate Oversight Hearings

The International Academy of Compounding Pharmacists (IACP) and the U.S. Food and Drug Administration (FDA) continue to disagree regarding the FDA's jurisdiction to regulate pharmacy compounding of prescription medicines. An ongoing and troublesome example of this pertains to pharmacists' ability to use pure chemicals for veterinary compounding for nonfood animals. While IACP respects the FDA's proper and legal regulation of pharmaceutical manufacturers, state laws specifically state that State Boards of Pharmacy are responsible for regulating pharmacy compounding (including veterinary compounding). IACP has approached both the Senate and the House of Representatives repeatedly to resolve this dispute, and although members from both chambers have written the FDA and the agency has agreed to discuss resolution (even promising certain specific actions), the FDA has yet to act. The FDA's refusal to respond in a timely and appropriate manner to both constituent and Congressional inquiry is well documented.

IACP now requests Senate Oversight Hearings to resolve this issue.

- **July 2003:** Without warning, the FDA published a new Compliance Policy Guideline (CPG) concerning veterinary compounding, in which compounding from bulk ingredients for nonfood animals was forbidden. CPGs are technically internal guidelines, not laws, but they are enforced by the FDA as if they were law. The CPG significantly overstepped the legal jurisdiction of the FDA outlined by Congress in the Animal Drug Use Control Act of 1994 (AMDUCA) and subsequent laws. The FDA did not follow its own policies and failed to publish a draft for public review and comment.
- **June 2004:** Responding to inquiries from pharmacists and constituent patients, more than 70 members of Congress wrote the FDA, requesting either the withdrawal or the revision of the CPG after providing for an appropriate public comment period. The FDA responded by assuring IACP that a new CPG would be issued and subjected to public comment. The FDA did neither.
- **June 2005:** In response to one year of inaction on the part of the FDA, 113 members of Congress signed letters requesting justification. The FDA did not reply.
- **April 2010:** After several years of status quo, the FDA filed a permanent injunction against a compounding pharmacy in Ocala, Florida, for compounding from pure drug chemicals. As a result, this dispute is no longer rhetorical. Patients' lives and the pharmacy profession will be affected. Congressional oversight hearings must be held to clarify the FDA's jurisdiction and action over veterinary compounding.

IACP, its 2,000 pharmacist members, and 87,000 patient members urge the U.S. Senate to schedule and hold oversight hearings that investigate the legislative intent of AMDUCA and the FDA's resultant jurisdiction over veterinary compounding from bulk ingredients.

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