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**FDA Warning Letters to Pharmacies Ignore Patient Safety and Law,  
Aimed Instead at Protecting Manufacturers**

**MISSOURI CITY, Texas** – *On October 31, 2006, the Food and Drug Administration (FDA) issued warning letters to two N.J.-based pharmacies, both members of the International Academy of Compounding Pharmacists (IACP). Regarding the letters, the following statement should be attributed to L.D. King, IACP's executive director.*

“The FDA appears to be using warning letters as a tool to press its position – recently rejected by a U.S. district court – that compounded medicines are ‘new, unapproved drugs’ and illegal. This is a threat to all compounding pharmacists and the patients and prescribers they serve.

“From pediatric patients who need cherry flavoring to help the medicine go down to hospice patients who need tailored pain management medications to allow them to die in dignity, millions of Americans have individual, medical needs that one-size-fits-all medicines cannot meet. For them, doctors often prescribe customized, compounded medicines that are prepared by trained, licensed and state-regulated pharmacists.

“To justify its broad authority to regulate compounded medicines, FDA has concocted a legal theory that all compounded medicines are illegal but that it will selectively enforce its position. Yet whether enforcement is selective or not, pharmacists and physicians cannot be expected to treat their patients freely if the government says that what they are prescribing and preparing is illegal.

“The FDA relies heavily on internal policy guidelines to justify taking action against these pharmacies. The FDA unilaterally developed these guidelines in 2002 and 2003 to draw a line between what it considers acceptable (though still illegal) and unacceptable compounding. These guidelines are poorly conceived and legally unenforceable. When they were issued, physicians, pharmacists and lawmakers expressed serious concern because FDA broke with tradition and did not allow for public comment before releasing them. Since then, FDA has agreed repeatedly and publicly to revise and reissue the guidelines for public comment. Four years later, it still has failed to do so.

“FDA writes in both letters that there is ‘substantial judicial authority’ to support its claim that all compounded drugs are unapproved and illegal, yet it ignores the only federal court case to rule squarely on the issue. On August 30, 2006, U.S. District Court Judge Robert Junell ruled in *Medical Center Pharmacy v. Gonzalez* that compounded medicines are not ‘new, unapproved drugs’ subject to the new drug requirements of the Food, Drug, and Cosmetic Act of 1938. Judge Junell wrote: ‘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.’

“State boards of pharmacy regulate compounding and license trained pharmacists to practice it. State pharmacy laws require pharmacists to prepare medications responsibly, and prohibit the dispensing of medications that are sub-standard or are not explicitly prescribed by a licensed healthcare practitioner. FDA’s attempt to usurp this authority not only duplicates what states are doing, but it will harm underserved patients who rely on compounded medicines prescribed by their physicians.”

For more information, please visit [www.iacprx.org](http://www.iacprx.org) and [www.compoundingfacts.org](http://www.compoundingfacts.org).

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