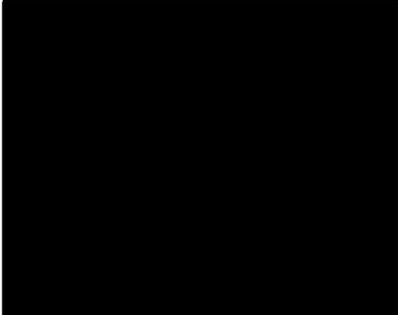

From: L.D. King [REDACTED]
Sent: Wednesday, January 07, 2009 1:40 PM
To: Sarah Dodge; 'Jennifer Goodrum'
Subject: obama

L.D. King, MBA
Executive Director, EVP

International Academy of Compounding Pharmacists



Save the date for IACP's Annual Meeting and Compounders on Capitol Hill
June 13-16, 2009

Protect Your Profession....Advance Your Practice

This email may contain information that is confidential. If you are not the intended recipient, please notify us immediately. Thanks.

Health Policy Stakeholder Meeting Template
(Administration Questions in Bold)
IACP Responses Below

In order to accurately capture and understand your organization's priorities for health care reform and other health care policy issues, we ask that you briefly detail your priorities as follows:

• **Health policy priorities/goals in the short term:**

The International Academy of Compounding Pharmacists (IACP) wishes to ensure the recognition of the importance of the practice and the services provided by compounding pharmacists to patients and their physicians ^{prescribed} by serving a critical void in the current healthcare system. Compounding pharmacists play an essential role in their patient's lives by providing the compounded medications ~~used by physicians who prescribe customized medication therapy~~ to best meet the needs of their patients. For the growing number of people with unique health care needs that cannot be addressed with commercially available products, a compounded product may be the only viable treatment option. Compounding enables a pharmacist to utilize their medication knowledge and expertise to produce individualized medications that meet a patient's needs. Compounding is also in great demand in the veterinary field (for treating animals) because of the relatively narrow selection of medications that are manufactured for them. ~~Sometimes the available dose of a medication does not suit the individual needs of a patient and the compounding pharmacist can fill this very vital role.~~ ^{Manufactured}

• **Health policy priorities/goals in the long term:**

^{wants} IACP wishes to ensure the continued availability of compounding services to patients who need these services and whose doctors' prescribe compounded medications for them. Increasingly, the federal government is creating an adversarial relationship between the relationship of the compounding pharmacist, patient, and prescribing physician. It is impractical for a manufacturer to make numerous, slightly different products to address the entire range of patients' needs. ~~Generally, only a few or even one dosage form will be commercially available.~~ Physicians and pharmacists recognize that the healthcare needs of some individuals do not always fall within the confines of commercially available dosage strength and formulations. Because large-scale manufacturers cannot tailor a medication for a single patient or even a handful of patients cost-effectively, many patients ~~need~~ ^{require} custom-made medication dosages ~~to solve specific medical problems.~~ ^{manufact.}

Examples of some of the most commonly compounded products include lotion ointments, creams, gels, suppositories, intravenously administered fluids and medications, total parenteral nutrition products, oral suspensions, and troches. Pediatric or geriatric patients may need extremely small doses. Cancer patients may need specific combinations of chemotherapy drugs to treat their disease, or special dosage forms may be necessary to care for patients with AIDS, chronic pain or other maladies. Some therapies, such as parenteral nutrition, can only be provided to ^{patusing} compounded dosage forms. Other patients need preservative-free products, liquids with special flavors or delivery systems that are not commercially available.

what is this word?

- The mechanisms for achieving the goal (i.e., executive order, regulation, guidelines, policy change or legislation)

IACP views the likely approach(es) to changing the current situation effectively as twofold:

1) A possible Executive Order to remedy the FDA's expansive overreach into the pharmacy community (over and above the state Boards of Pharmacy); and/or

2) A legislative/statutory (policy change) change to FDAMA law that will more definitively narrow the statute to clearly define and limit the FDA's jurisdiction into areas of manufacturing and not into pharmacy issues.

IACP has ample case evidence, as well as two disparate circuit court decisions, that support our call for action in this regard.

- Any budgetary or appropriations concerns or impact

If anything, the statutory and/or Executive Order would save the government (not expend) additional resources. A CBO cost estimate IACP believes would prove that ~~once a legislative proposal and/or Executive Order were proposed.~~

- Any other HHS related issue

Specific FDA activity with regard to estril and ~~their enforcement activity~~ in various ~~circuit court regions of the country~~ -- differing enforcement for differing circuit court regions; heavy handed tactics; questionable authority; and FDA hurting, not helping patients, doctors and pharmacists.

2 -> what are these?

Support this.

not correct

The Food, Drug, and Cosmetic Act to clarify that compounded preparations are not subject to the FDA approval process and manufacturing requirements that apply to the commercial manufacture of drug products