



January 12, 2009

President-Elect Barack Obama
United States of America
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

The Honorable Tom Daschle
Department of Health and Human Services
The Atlantic Building
950 F Street, N.W.
Washington, D.C. 20004

Dear President-Elect Obama and Senator Daschle,

I am writing to you both on behalf of the International Academy of Compounding Pharmacists (IACP) and in advance of a Transition Team Leader meeting on January 13, 2009. IACP would like to wish you the best this coming year, and we look forward to working with your Administration and staff.

IACP is one of a number of recognized authorities for information, expertise, and practice standards with regard to pharmacy compounding. IACP represents more than 2,000 compounding pharmacists nationwide. In addition, we want to highlight the importance of compounding pharmacists to patient care in the country.

The Food and Drug Administration, the U.S. Supreme Court, Congress, and virtually every major association of healthcare professionals have recognized the value of compounding pharmacists. Unfortunately, misguided efforts by the FDA to alter the regulatory landscape threaten pharmacists' ability to practice compounding. Subsequently, physician and patient access to these medication choices is threatened. IACP is fighting in courts, in Congress and in the public arena to raise awareness of the value of compounding and to maintain states' historically established authority over the practice of pharmacy compounding.

Compounding pharmacists play an essential role in their patients' lives by providing the compounded medications prescribed by physicians to best meet the needs of their patients. Because every patient is different and has different needs, access to customized, compounded medications is a vital part of quality medical care.

For the growing number of people with unique health care needs that cannot be addressed with commercially manufactured products, a compounded medication may be the only viable treatment option. Examples of some of the most commonly compounded medications 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. 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 with compounded dosage forms. Other patients need preservative-free medications, liquids with special flavors or delivery systems that are not commercially available.

Compounding is also in great demand in the veterinary field (for treating non-food producing animals) because of the relatively narrow selection of medications that are manufactured for them. Veterinary compounding often requires more flavors, dosages and potency levels than commercially available medications supply.

It is impractical and not economically feasible for drug manufacturers to make numerous, slightly different products to address the entire range of patient needs. Physicians and pharmacists recognize that the health care needs of some individuals do not always fall within the confines of commercially manufactured dosage strengths and formulations. Because large-scale manufacturers cannot tailor a medication for a single patient or even a handful of patients cost-effectively, many patients require custom-made medication dosages provided by compounding pharmacies.

The basis of the profession of pharmacy has always been the "triad," the patient-physician-pharmacist relationship. In fact, some estimate about 38 million prescriptions are compounded and dispensed each year by community pharmacy alone and that nearly all hospitals provide compounding services to their doctors and patients.

It is essential to ensure the continued availability of compounding services to patients who need these services and to doctors who prescribe compounded medications. Increasingly, the federal government is placing a barrier to that access to compounded medications and creating an adversarial relationship by interfering in the pharmacist, patient, and physician relationship. Currently, patients face the risk of losing access to their compounded medications because of unwarranted FDA regulation.

IACP has ample case evidence, as well as two disparate circuit court decisions, that support the need to clarify the FDA's regulatory authority of manufacturers versus pharmacies. The two conflicting circuit court decisions occurred in the 9th District Circuit Court¹ and in the 5th District Circuit Court² over the

¹ 9th District Circuit Court Case:
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

WESTERN STATES MEDICAL CENTER, a Nevada corporation; WOMEN'S INTERNATIONAL PHARMACY, a Wisconsin corporation; HEALTH PHARMACY, a Wisconsin corporation; APOTHECURE, a Texas corporation; COLLEGE PHARMACY, a Colorado corporation; LAKESIDE PHARMACY, a Tennessee corporation; WEDGEWOOD VILLAGE PHARMACY, a New Jersey corporation, DAE (RLH)

Plaintiffs-Appellees,

v.

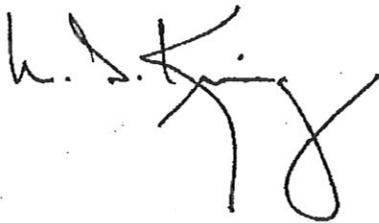
DONNA E. SHALALA, in her official capacity as Secretary, United States Department of Health and Human Services; JANE E. HENNEY, M.D., in her official capacity as Commissioner, Defendants-Appellants.

Appeal from the United States District Court for the District of Nevada
David A. Ezra, District Judge, Presiding

applicability of Section 503A of the Food and Drug Administration Modernization Act of 1997, which clarified that pharmacy compounded preparations are exempt from the FDA approval process and manufacturing requirements, if certain conditions are met.

We look forward to the opportunity to discuss these issues with you further in our upcoming meeting with the Transition Team staff. In advance, we thank you for your time and efforts on behalf of us and all Americans

Sincerely,



L.D. King
Executive Director and Executive Vice President

Argued and Submitted
December 12, 2000—San Francisco, California
Filed February 6, 2001

Before: Mary M. Schroeder, Chief Judge, Cynthia Holcomb Hall, and William A. Fletcher, Circuit Judges.
Opinion by Judge Hall

² *5th District Circuit Court Case:*
Civil Action No. 7:04-cv-130

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS
MIDLAND-ODESSA DIVISION
MEDICAL CENTER PHARMACY, ET AL.,
PLAINTIFFS
v.
JOHN ASHCROFT, ET AL.