

下

**Citizen Petition re Labeling and  
Advertisements for Compounded,  
Aqueous-Based Drugs for Inhalation**

**EXHIBITS**

# **EXHIBIT 1**

For Immediate Release

Release Date: 03-10-03

Contact: Kevin Kinkade 573/751-0093 or

Jim Grebing 573/751-9065

### **Missouri Board of Pharmacy Takes Action Against Kansas City Company**

The Missouri Board of Pharmacy has received a temporary restraining order against a Kansas City pharmacy for failing to comply with state law in its actions in recalling contaminated drugs.

The Platte County Circuit Court issued the injunction today against Med 4 Home Pharmacy, located at 10800 North Congress in Kansas City; John P. Byrnes, president of Lincare Holdings, Inc. of Clearwater, FL, owner of the pharmacy; and Julian "Marty" Williams, pharmacist-in-charge of Med 4 Home.

Med 4 Home has approximately 250 employees at its Kansas City location.

The petition states that the pharmacy "has engaged in practices that pose a threat of immediate and irreparable injury, loss, or damage to patients and presents a probability of serious danger to the health, safety or welfare of the residents of the state."

On Wednesday (March 5), an inspector for the pharmacy board was denied access to the compounding areas of the pharmacy, a violation of state law.

The temporary restraining order will remain in full force until March 21 at 10 a.m. At that time a hearing will be held in Platte County Circuit Court on whether a preliminary injunction should be issued.

Kevin Kinkade, executive director of the State Board of Pharmacy, said the court action was sought after board investigators determined that Med 4 Home had not followed proper recall and notification procedures for a batch of Albuterol/Ipratropium solution it had compounded. The product is an inhalant solution distributed nationwide and used to treat a variety of pulmonary disorders, such as asthma.

Quality assurance tests conducted by the pharmacy revealed contamination in at least two lots of the product. The contaminant in one lot was identified as Burkholderia cepacia (B.cepacia), formerly known as Pseudomonas cepacia. The contaminant in the other lot has not yet been identified.

As of February 10 over 19,000 patients had been contacted concerning the recall and 600 had not. Over 2,500 patients have been identified as having the suspect vials.

Kinkade explained that Med 4 Home recalled only partial batches of the product, based on the machines that filled the vials. "We believe this recall was inadequate and that the entire batch should have been recalled," he said.

"In its recall to patients, they did not identify what the problem was. They did not tell them they had potentially contaminated products, only that it was a quality assurance problem. The company also failed to notify prescribers of the problem."

In addition, Budesonide, another inhalant solution compounded by the pharmacy, utilizing the same type

of vials, may have also been contaminated. Kinkade said the company quarantined the product, but failed to recall what had already been shipped out to patients.

"This is a serious public health issue," said Kinkade. "Through this legal action we want to make sure anyone who has received potentially contaminated products are notified and advised of the potential risks, that procedures to protect the public be implemented before further compounding occurs at the facility, our inspectors must have access to the pharmacy and its records, and those records must be preserved."

The U.S. Food and Drug Administration was contacted by the board and subsequently initiated their own inspection of this facility. In addition, FDA experts testified at today's hearing.

Anyone who believes they may have this product should contact their prescribing physician, Kinkade said.

The Missouri Board of Pharmacy is a professional licensing board within the Division of Professional Registration, which is a regulatory agency under the Missouri Department of Economic Development. The board works in conjunction with other state and federal agencies, such as the Food and Drug Administration (FDA) and the federal Drug Enforcement Administration (DEA) to enforce drug laws. A part of the board's mission is to enforce minimum standards of practice and licensure for the practice of pharmacy and to protect consumers against incompetent or illegal practices.