



## **Summary of the Citizen Petition re Labeling and Advertisements for Aqueous-based Drugs for Inhalation**

The Citizen Petition (CP) is a formal mechanism for requesting the federal Food and Drug Administration (FDA) to take an action. The CP is written in a format and language that is consistent with FDA regulations and appropriate for formal advocacy before the agency. It is grounded in science and law.

### **The CP is significant:**

- Pharmacy businesses that promote and dispense unapproved CADIs without meeting the legal obligation to provide truthful and nonmisleading information about their products expose patients to unnecessary health risks.
- Patients, nurses, physicians and respiratory therapists have joined together to request that FDA address this issue.

### **The CP asks FDA to:**

- A. 1. Confirm that the law requires pharmacy businesses that promote or dispense CADIs to provide patients and healthcare professionals with information (material facts) necessary to make informed decisions when using or prescribing these products.
- A. 2. Make the general public aware of this requirement; ensure that patients and health care professionals know their rights to receive full disclosure of material facts; make compounding pharmacy businesses aware of their obligations to provide material facts; ensure health care professionals have the material facts in order to advise patients about the risks or benefits of using CADIs.
- A. 3. Write a regulation that specifies how the material facts are to be displayed and worded in product labeling and in advertisements.

In cases where the FDA has taken enforcement action against a pharmacy business that is operating in a manner that is more consistent with pharmaceutical manufacturing than with traditional pharmacy compounding, the CP asks FDA to:

- A. 4. Require the pharmacy business to provide material facts to patients who received CADIs within the last twelve months and to health care professionals who may have authorized the use of CADIs within the same period.

### **Basis for concern**

#### *Patients are not aware*

Without their knowledge, patients are increasingly exposed to unnecessary health risks associated with CADIs. Furthermore, their prescribers may sometimes not be fully aware that unapproved CADIs are being substituted for FDA-approved medications.

#### *Health risks are serious*

Patients with asthma, COPD and other respiratory conditions are vulnerable to respiratory infection caused by bacteria that have been found in CADIs that are not manufactured according to strict FDA guidelines for sterility. Furthermore, CADIs may contain known airway irritants such as ethanol (most commonly used to dilute budesonide) and other preservatives.

Resulting symptoms of coughing, wheezing, and shortness of breath cannot be differentiated from that of the diseases these medications are intended to treat. 15 patients die of asthma each day. 120,000 patients die of COPD each year. How many of these patients were using unproven CADIs? No one knows.

#### *Under the guise of traditional pharmacy compounding*

Americans generally trust that their prescriptions are filled with FDA approved medications. In rare cases, involving a medical condition for which no proven, commercially available medication exists, patients and their medical care professionals can turn to compounding pharmacists who will prepare (compound) individual doses specific to the patient's need. The patient, prescriber and pharmacist must assess the risks and benefits of using a CADI. The decision ultimately resides with the patient.

However, a new industry has emerged in recent years; mass manufacturing under the guise of traditional pharmacy compounding. Relying on lax state standards and arguing that federal standards do not apply, these companies manufacture millions of doses of aqueous-based medications each year and distribute products through a

network of smaller pharmacies, home health care companies and Internet pharmacies.

*The absence of disclosure in drug labeling and advertisements is misleading*

FDA approved medications must meet specific criteria for safety and efficacy. In the case of aqueous-based drugs for inhalation, there are special requirements for sterility. They must be labeled, packaged and dispensed in a manner that protects the patient from potential health risks. After a medication is introduced into the market, it is monitored for safety. Each package is labeled with a unique lot number that may be used to identify everything from the source of the raw ingredients used to make the drug to the pharmacy that dispenses it.

CADIs are not FDA-approved. They are not established generic equivalents of FDA-approved brand name medications. They are not proven to be safe or effective and do not meet FDA standards for sterility. The origin and quality of raw ingredients are not disclosed.

Medical experts agree that the need for a CADI in treating asthma, COPD, acute bronchitis and pneumonia patients is questionable because in most cases the risks of using unproven drugs manufactured outside of the parameters of FDA regulation outweigh the benefits of using FDA-approved medications.

The petitioners seek to ensure that compounding pharmacy manufacturers and distributors comply with the Food Drug and Cosmetic Act's requirement to disclose essential information to patients and prescribers in all CADI labeling and advertising.