

Allergy & Asthma Network Mothers of Asthmatics
American Academy of Allergy, Asthma and Immunology
American Association for Respiratory Care
American College of Allergy, Asthma and Immunology
American Latex Allergy Association
American Partnership for Eosinophilic Disorders
Association of Asthma Educators
Asthma and Allergy Foundation of America
National Emphysema and COPD Association
COPD-ALERT

March 8, 2007

The Honorable Edward Kennedy
The Honorable Pat Roberts
The Honorable Richard Burr
Senate Committee on Health, Education, Labor & Pensions
428 Dirksen Office Building
Washington, DC 20510

Dear Chairman Kennedy, Senator Roberts and Senator Burr:

Thank you for your efforts in drafting the Safe Compounding Act of 2007. The proposed legislation speaks to the needs of patients and medical care providers for clarity about lawfully compounded medications.

In particular, we are gravely concerned about the increase in clandestine pharmacy businesses that mass manufacture inhalation medications under the guise of traditional pharmacy compounding and the network of home healthcare businesses and pharmacies that distribute these products to patients in place of prescribed FDA-approved medications.

These businesses are not registered with FDA to mass manufacture nebulizer medications. Their pharmacists are not part of the medical care team or involved in monitoring patient outcomes in the same manner that traditional pharmacy compounding requires. They have a foot in both worlds without regard for patient safety and medical professional liability.

Your legislation addresses our concerns about sterility and labeling. These are important issues from a patient and prescriber perspective – we have the right to know critical material facts about the medications we are using or prescribing. Additionally, medical care professionals are *required* to know about the medications patients are using. Without transparency and disclosure, prescribers unknowingly place patients at unnecessary health risk and face medical liability that puts their license to practice medicine at risk.

This legislation would not be necessary if State Pharmacy Board and federal laws, guidance documents and enforcement efforts were working. Despite warning letters, arrests and incarcerations, clandestine pharmacy businesses continue to flourish as a shadow industry while billing Medicare, Medicaid and other insurers for fraudulently made drugs. With the Safe Drug Compounding Act of 2007 comes the light necessary to expose these unlawful businesses and the activities of similar operations in every chronic disease state. It will protect patients and caregivers and eliminate unlawful mass manufacturing under the guise of traditional compounding. It will also impact those with a vested interest in blocking your legislation, i.e. illegal mass manufacturers, chemical and equipment suppliers and related trade associations.

Physicians are required to document the medical needs of patients for prescribed therapies. Your legislation clarifies that the prescription for a compounded medication does not provide sufficient evidence of medical need. From a liability standpoint, absence of such documentation in the medical records leaves the medical professional vulnerable to litigation.

The bill does not limit patient access to compounded medications or the physician's rights to prescribe them and use them in the office setting, hospital or at home. Sterile medications are addressed separately and with good cause. The bill eliminates any business from mass manufacturing medications if not registered and authorized to do so by FDA. And that is good for patients and prescribers.

Thank you for giving all stakeholders the opportunity to submit comments before introducing the bill. We hope our comments submitted to you on March 6th and this letter of support today are helpful.

As the bill moves forward, we are committed to keeping our respective memberships and constituents – a total of more than 50 million people – aware of your efforts on their behalf. And that includes the many pharmacists who support our efforts as well.

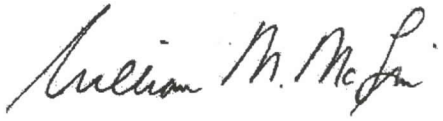
Sincerely,



Nancy Sander
President
Allergy & Asthma Network
Mothers of Asthmatics



American Academy of Allergy, Asthma
and Immunology



Asthma and Allergy Foundation of America



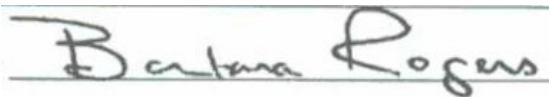
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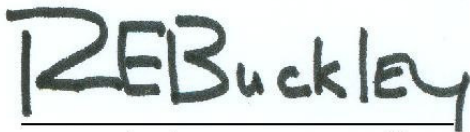
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