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Congress of the United States
House of Representatives

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The Honorable Dr. Andrew C. von Eschenbach
Commissioner
United States Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857


Dear Commissioner von Eschenbach,

We were recently contacted by representatives from the Allergy and Asthma Network – Mothers of Asthmatics with a number of concerns about the distribution of respiratory drugs that are subpotent, including serious concerns about ambiguity in the distinction between legal pharmacy compounding and illegal pharmacy manufacturing. We are aware of the Food and Drug Administration's interest in this issue, and that the FDA recently warned Lincare/Reliant, Rotech/Pulmodose and CCS Medical to stop manufacturing compounded respiratory medications, and are interested to know to how Congress might better support the FDA's ability to regulate these activities

Our discussions on this issue have raised a variety of questions, both about the practice of compounding pharmacy and the FDA's current ability and inclination towards regulating it. First and foremost, what is the current operating distinction between legal pharmacy compounding and illegal pharmacy manufacturing? Has the FDA recently issued regulatory guidance in this regard? Does the FDA have an official position on the regulation of compounding pharmacy? Second, what, if any, additional resources would the FDA need to effectively regulate these practices, and pursue action against individuals and corporations engaged in illegal manufacturing of compounded medications?

We appreciate your attention to this serious issue, and look forward to your response. We value the principle of compounding pharmacy, when it is medically appropriate and when the doctor, patient and compounding pharmacist are engage in meaningful dialogue throughout the process. In light of the recent deaths of three individuals in Oregon from illegally manufactured medications and the scope of the manufacturing practices engaged in by the companies recently warned by the FDA, however, the need to better regulate this industry seems pressing, and we look forward to working with you to preserve the safety of our prescription drug supply.

Sincerely yours,


James P. Moran


Patrick Kennedy


Lois Capps

JPM/srk