

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

December 7, 2012

Mr. Scott Karolchyk
President
Board of Directors
International Academy of Compounding Pharmacists
4638 Riverstone Blvd.
Missouri City, TX 77459

Dear Mr. Karolchyk:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the facts surrounding the recent outbreak of fungal meningitis linked to contaminated steroids made and distributed by the New England Compounding Center (NECC).

According to an October 2012 *New York Times* report, the International Academy of Compounding Pharmacists “tutored pharmacists on how to sidestep [U.S. Food and Drug Administration] requests” for samples related to FDA’s assessment of the quality of compounded drugs.¹ Specifically, the *Times* stated that your association told its members: “We do not compound or distribute ‘samples’ of any of our prescription medications to anyone. And if a compounded drug was on the premises...a pharmacist should say it was awaiting pickup by a patient.” Allegations that your association may have encouraged compounding pharmacists to attempt to impede the FDA from evaluating the efficacy and safety of their products, if true, raise serious concerns about your actions.

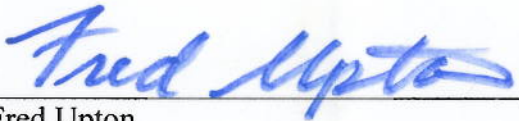
To assist the Committee in understanding your role in assisting compounding pharmacists in their interactions with Federal and State authorities, please provide the following documents and information, from January 1, 2002, to the present, by no later than December 20, 2012:

¹ *U.S. Concern Over Compounders Predates Outbreak of Meningitis*, New York Times (Oct. 22, 2012).

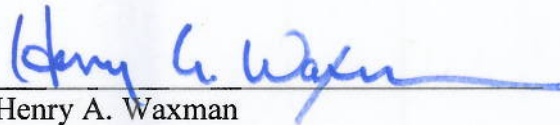
1. All documents, including internal communications and communications to your members, referring or relating to the provision of samples to FDA officials; responding to FDA requests for records or other materials or information; or FDA inspections of compounding pharmacies.
2. All documents containing communications with any owners, pharmacists, or employees of the New England Compounding Center (NECC); Ameridose, LLC; or Alaunus, LLC, including, but not limited to, Barry J. Cadden.

An attachment to this letter provides additional information about how to respond to the Committee's request. Should you have any questions, please contact John Stone or Brian Cohen with the Committee staff at (202) 225-2927.

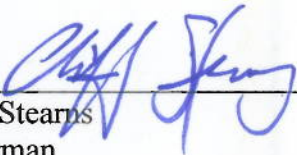
Sincerely,



Fred Upton
Chairman



Henry A. Waxman
Ranking Member



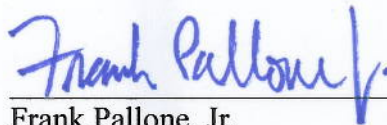
Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations



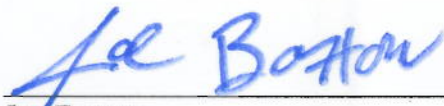
Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations



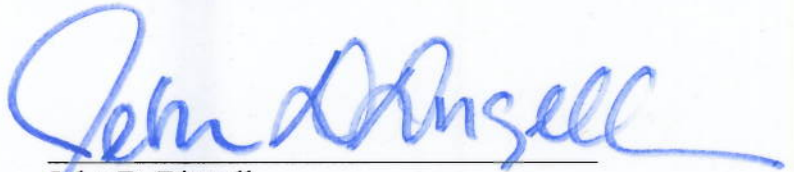
Joseph Pitts
Chairman
Subcommittee on Health



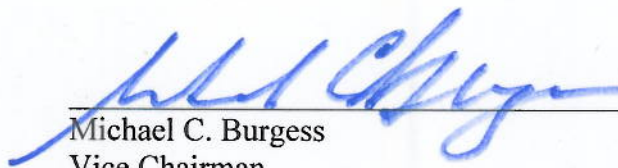
Frank Pallone, Jr.
Ranking Member
Subcommittee on Health



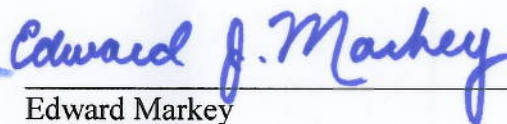
Joe Barton
Chairman Emeritus



John D. Dingell
Chairman Emeritus



Michael C. Burgess
Vice Chairman
Subcommittee on Health



Edward Markey
Member
Subcommittee on Oversight and Investigations

Attachment