

Direct Dial: 216.348.5839
E-mail: rblake@mcdonaldhopkins.com

June 19, 2018

(Sent via Regular and Electronic Mail)

Ali Fulling
Legislative Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115
Ali.Fulling@mail.house.gov

Re: Dr. Joseph Mastandrea – Miami-Luken, Inc.

Dear Ms. Fulling:

Please accept these responses pursuant to Congressman Harper's letter dated May 31, 2018. Should you have additional questions, please direct them to my attention.

The Honorable Gregg Harper

1. Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?

Response: Miami-Luken no longer sells any controlled substances to retail customers.

2. In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?

Response: Miami-Luken no longer sells any controlled substances to retail customers.

3. As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?

Response: Miami-Luken no longer sells any controlled substances to retail customers.

4. Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?

Response: Miami-Luken no longer sells any controlled substances to retail customers.

5. In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?

Response: Miami-Luken no longer sells any controlled substances to retail customers.

6. As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?

Response: Miami-Luken no longer sells any controlled substances to retail customers.

The Honorable Michael C. Burgess

1. While your companies seem to have put forth effort to improve your system of flagging possible drug diversion, there remains work to be done. In February, the Drug Enforcement Administration announced that it would begin sharing select data it collects on controlled substance prescriptions with drug distributors. Have your companies been able to access that data, and if so, has it been useful?

Response: We have not been provided access to any data from the DEA.

Chicago | Cleveland | Columbus | Detroit | Miami | West Palm Beach

www.mcdonaldhopkins.com

2. What is the largest hurdle you face as your companies scale up your diversion prevention on activities? Is data-sharing, or lack thereof, the primary challenge?

Response: Miami-Luken no longer sells any controlled substances to retail customers.

3. Throughout each of your written testimonies, you mentioned your efforts to report suspicious orders to the DEA, and in cases that exceed the volume threshold, you stop the orders entirely. Where is the line drawn between drug manufacturers and the DEA in responding to suspicious orders? Does the DEA take enforcement action after you report the suspicious order?

Response: The DEA does not share its enforcement actions with us and therefore we are not privy to this information.

4. Distributors and other pieces of the drug supply chain have a responsibility to help prevent diversion. What can Congress do legislatively to strengthen oversight of that supply chain?

Response: Federal and state agencies need to work better with industry. We also need laws that are consistent from state to state and uniform enforcement of those laws. There also needs to be sharing of data in all states across the full supply chain.

The Honorable David B. McKinley

1. As a Wholesale Distributor of prescription opiates, do you agree that you owe a duty under federal law to monitor, detect, investigate, refuse and report suspicious orders? 21 U.S.C. § 823, 21 CFR 1301.74

Response: Yes.

2. Do you agree that the foreseeable harm of a breach of this duty is the diversion of prescription opiates for nonmedical purposes?

Response: Not necessarily.

3. In other words, if you ship a suspicious order, it is likely that prescription opiates will be diverted into the illicit market. Agree?

Response: Not necessarily.

4. Do you concur that filling suspicious orders is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality?

Response: Not necessarily.

5. Do you agree the United States is in the midst of a prescription opiate epidemic?

Response: Yes.

6. Do you concur that filling suspicious orders is a direct and proximate cause of the prescription opiate epidemic plaguing our country?

Response: It is a contributing factor.

7. Do you believe the prescription opiate epidemic is an immediate hazard to public health and safety?

Response: Yes.

8. Do you believe the prescription opiate epidemic is a public nuisance?

Response: Yes.

9. Are you aware of your company's efforts to detect, address, and report suspiciously large orders in West Virginia?

Response: Miami-Luken no longer sells any controlled substances to retail customers.

10. Are you aware that for years your company never followed West Virginia's law by reporting all suspicious orders to the West Virginia Board of Pharmacy?

Response: No, we are unaware of this.

11. Did your company have a policy that orders had to be less than 50% controlled substances to be filled?

Response: No, such a policy did not exist.

The Honorable Frank Pallone, Jr.

1. The Committee asked Miami-Luken for copies of all suspicious order reports that MiamiLuken submitted to DEA since 2008. According to what your company provided, it does not appear that Miami-Luken submitted any suspicious order reports to DEA earlier than 2015. Miami-Luken also provided the Committee with its due diligence files for several pharmacies. These files show that Miami-Luken supplied the Sav-Rite pharmacy in Kermit, WV, population 400, with over 5.7 million opioids between 2005 and 2011. Why did Miami-Luken not submit any suspicious order reports for any of its sales to SavRite?

Response: As Miami-Luken has previously informed the DEA and this Subcommittee, the company's prior management did not maintain an effective suspicious order monitoring system at that time. Although prior management did take steps to address suspicious orders and were instructed by the Board to do so, its efforts were not effective.

2. You told the Committee that you wished Miami-Luken had had a suspicious order monitoring system in place sooner, and that your failure to do so resulted in high distribution to at least one pharmacy. However, DEA sent letters to all distributors in 2006 and 2007 reminding them that federal regulations expressly require distributors to identify and report suspicious orders of controlled substances, and laying out examples about how to do so. After receiving letters from the DEA advising you to report suspicious orders, why did your company not have a robust program in place to make this happen, especially when it was well known that the opioid crisis was growing?

Response: As Miami-Luken has previously informed the DEA and this Subcommittee, the company's prior management did not maintain an effective suspicious order monitoring system at that time. Although prior management did take steps to address suspicious orders and were instructed by the Board to do so, its efforts were not effective.

The Honorable Jan Schakowsky

1. Does your company buy the drugs from the manufacturers, take title and move pallets to and from your warehouse? Or are you like brokers, working on consignment, arranging sales to pharmacies and then taking a percentage of the sale price?

Response: Miami-Luken purchases product from manufacturers and such product is moved to and from its warehouse.

2. In setting prices to pharmacies, is your markup more like a flat rate (for example, selling \$5 more than the price at which you bought), or is your markup more like a percentage (for example, selling for 5% higher than the price at which you bought)?

Response: Branded products are generally sold at a discounted percentage to Wholesale Acquisition Cost, while generics are priced to market.

3. Is it possible that even if your company pays a higher price to get those drugs in stock, you end up making more money on those sales where your acquisition prices are higher? And would the same be true for your consignment/broker sales?

Response: No. Miami-Luken is a market price taker, not a market price setter.

Thank you again.

Very truly yours,



Richard H. Blake