FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

GREG WALDEN, OREGON
RANKING MEMBER

ONE HUNDRED SIXTEENTH 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

October 10, 2019

Brian S. Tyler, Ph.D.
Chief Executive Officer
McKesson Corporation
6555 State Highway 161
Irving, TX 75039

Dear Dr. Tyler:

As Members of the House Energy and Commerce Committee and leaders of an investigation into opioid distribution, we are following up on the status of recommendations directed to opioid distributors to address concerns outlined in the December 19, 2018 report, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*. This report was prepared by the then-Republican Majority Committee staff.

While this report focused on a series of missteps and missed opportunities that contributed to the worsening of the opioid epidemic in West Virginia, the report raised grave concerns about distributors' compliance programs nationwide. The report included recommendations to improve distributors' programs. In addition, the recently enacted SUPPORT for Patients and Communities Act included several provisions to respond to these concerns.

To assist our ongoing oversight and legislative efforts related to the opioid epidemic, we would appreciate your company providing a written summary of what actions it has taken or is taking to implement each of the following recommendations from the report that were directed to the distributors, as well as providing information on any barriers, legislative or otherwise, to the implementation of each recommendation:

- Distributors should perform, document, and maintain robust due diligence files for both prospective and existing customers.

- Distributors should perform due diligence on any customers that distributors may assume through acquisition of another wholesale distributor.

- Distributors should review and analyze any existing due diligence materials for a prospective customer pharmacy prior to rendering an onboarding decision regarding any such pharmacy's prospective customer application.

- As part of their prospective customer due diligence, and at regular intervals thereafter, distributors should require the production of dispensing data from a pharmacy, preferably in a manner that would enable a distributor to identify the pharmacy's prescribing physicians.

- Distributors should utilize a threshold system as part of their controlled substance monitoring programs, which would assist in identifying potentially suspicious orders and pharmacies.

- Distributors should document and verify all pharmacy threshold events, and increases or decreases to a pharmacy's threshold limits, including the reason for the increase or decrease and the reason for approval or denial of any threshold increase requests.

- Distributors should have policies limiting and delineating the instances in which blocked orders are not reported to Drug Enforcement Administration (DEA) as suspicious, for example, when an order is made in error. All other blocked orders should be reported to DEA as suspicious when discovered.

- Distributors' suspicious order reporting policies should provide guidance on warning signs or red flags, or other methods to identify suspicious orders beyond numeric algorithms.

- When red flags are raised and documented regarding a pharmacy, that pharmacy should be subject to heightened monitoring. Distributors' policies should specify the frequency and type of any such heightened monitoring.

- Distributors' policies should clearly require a proactive review of pharmacies that share common ownership with a pharmacy terminated for compliance reasons within a reasonable and determined amount of time.

Please provide this written summary by November 11, 2019. Your assistance is appreciated. If you have any questions, please contact Jennifer Barblan or Alan Slobodin of the Minority Committee staff at (202) 225-3641.

Sincerely,

Greg Walden
Republican Leader

Brett Guthrie
Republican Leader
Subcommittee on Oversight
and Investigations

David B. McKinley
Member of Congress