

ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

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January 13, 2020

Mr. Mark Trudeau
President and CEO
Mallinckrodt Pharmaceuticals
675 McDonnell Boulevard
St. Louis, MO 63042

Dear Mr. Trudeau:

We are continuing our work investigating the causes and effects of the opioid epidemic. Last Congress, the Committee on Energy and Commerce began bipartisan investigations into fentanyl, opioid manufacturing, opioid distribution, and the substance use disorder treatment industry. We write today to reactivate the investigation started on August 2, 2018, that examined potential breakdowns in the controlled substances supply chain, which may have contributed to the nation's opioid epidemic, and the role of certain opioid manufacturers in such potential breakdowns.

Last year, we sent a letter to Mallinckrodt Pharmaceuticals requesting information and documents (see attached). In response to this letter, Mallinckrodt Pharmaceuticals produced information and documents in response to the letter. We would appreciate Mallinckrodt making appropriate personnel available to discuss questions arising from the responses and documents that were provided.

Since the August 2, 2018 letter, we have become aware of additional issues of concern. To assist our oversight of these matters, we would request that Mallinckrodt Pharmaceuticals respond to the following by February 13, 2020:

1. In a January 2019 deposition,¹ Mallinckrodt's former senior manager of controlled substance compliance testified that she alerted Mallinckrodt management in 2008 that their suspicious order monitoring (SOM) system was faulty and needed to be

¹ See Deposition of Karen Harper, In re: National Prescription Opiate Litigation, No.1:17-md-02804 (N. D. Ohio, July 23, 2019), available at <https://www.docketbird.com/court-documents/In-re-National-Prescription-Opiate-Litigation/Exhibit-34-Depo-Excerpts/ohnd-1:2017-md-02804-01957-034>.

upgraded. However, company executives declined to hire an outside vendor to enhance the system.² Mallinckrodt's September 12, 2018, response to the Committee indicated that your company believed that its SOM system complied with all available (DEA) guidance and that Drug Enforcement Administration (DEA) praised Mallinckrodt's SOM program after reviewing it "in detail." Does Mallinckrodt acknowledge that Mallinckrodt management was alerted in 2008 by its senior manager of controlled substance compliance that the SOM system was faulty and needed to be upgraded? If so, did Mallinckrodt act on these concerns? If not, why not? Please provide unredacted documents that substantiate your responses.

2. The former senior manager of controlled substance compliance also testified during her deposition that, in 2010, the company changed an algorithm for flagging "peculiar" orders—from those twice as large as the average from the previous year to those three times as large—because there were too many orders to review.³ A November 2, 2010, memorandum from Mallinckrodt's outside consultant (a former DEA official) to the compliance manager confirms the use of algorithms and raised concerns that Mallinckrodt's numeric formula was problematic because a suspicious or excessive order could meet and not exceed criteria, and thus would theoretically be filled through normal processing without further question.⁴ As a result, "Mallinckrodt would be unnecessarily exposing itself to potential liability."⁵

Why did Mallinckrodt change the algorithm from twice as large from the previous year to those three times as large? For what time period did Mallinckrodt use this algorithm for flagging "peculiar orders" and, if no longer in use, why was this algorithm discontinued? In the November 2, 2010, memorandum, the outside consultant recommended the immediate revision of SOP No. C/S Comp 3.0. Did Mallinckrodt implement this recommendation?

If you have any questions, please contact Jen Barblan or Alan Slobodin of the Minority Staff at (202) 225-3641. Thank you for your prompt attention to this matter.

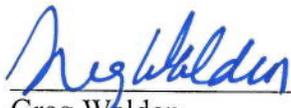
² Eliza Ronalds-Hannon *et al.*, *Mallinckrodt Mulls Restructuring as a Major Opioid Trial Nears*, BLOOMBERG NEWS (Sept. 5, 2019) available at <https://www.bloomberg.com/news/articles/2019-09-04/opioid-maker-mallinckrodt-taps-restructuring-firms-as-suits-loom>. See also Sari Horowitz *et al.*, *Newly unsealed exhibits in opioid case reveal inner working of the drug industry*, WASH. POST (July 23, 2019) available at https://www.washingtonpost.com/investigations/newly-unsealed-exhibits-in-opioid-case-reveal-inner-workings-of-the-drug-industry/2019/07/23/acf3bf64-abe5-11e9-8e77-03b30bc29f64_story.html.

³ Washington Post, *supra* note 2.

⁴ See Memorandum from Howard Davis to Karen Harper, In re: National Prescription Opiate Litigation, No. 1:17-md-02804 (N. D. Ohio, July 23, 2019) available at <https://www.docketbird.com/court-documents/In-re-National-Prescription-Opiate-Litigation/Exhibit-41-Memo/ohnd-1:2017-md-02804-01957-041>.

⁵ *Id.*

Sincerely,



Greg Walden
Republican Leader



Brett Guthrie
Republican Leader
Subcommittee on Oversight
and Investigations



H. Morgan Griffith
Member of Congress

Attachment