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ONE HUNDRED FIFTEENTH 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
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August 2, 2018

Mark Trudeau
President and Chief Executive Officer
Mallinckrodt Pharmaceuticals
675 McDonnell Blvd.
St. Louis, MO 63042

Dear Mr. Trudeau:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is continuing to investigate the opioid epidemic in the United States, which has claimed the lives of more than 351,000 people since 1999.[1] Tragically, an average of 115 Americans die from opioid overdoses every day as part of this ongoing crisis.[2]

For more than a year, the Committee has examined potential breakdowns in the controlled substances supply chain which may have contributed to the nation's opioid epidemic. Pharmaceutical manufacturers play a unique and critical role in this supply chain by both researching and developing products for the consumer market and marketing these products after approval from the Food and Drug Administration (FDA).

Mallinckrodt is one of the largest manufacturers of generic oxycodone[3] and was active in the controlled substances industry when the opioid epidemic took hold in the United States. Under the Controlled Substances Act (CSA), manufacturers of controlled substances are required to register with the Drug Enforcement Administration (DEA)[4] and are subject to certain legal obligations designed to combat drug diversion. All legitimate handlers of controlled substances,

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[1] Centers for Disease Control and Prevention, *Understanding the Epidemic, Opioid Overdose* (last updated Aug. 30, 2017) *available at* https://www.cdc.gov/drugoverdose/epidemic/index.html and Centers for Disease Control.
[2] Centers for Disease Control and Prevention, *Data Brief 294. Drug Overdose Deaths in the United States, 1999-2016*, *available at* https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4.
[3] Press Release, U.S. Dep't of Justice, Mallinckrodt agrees to pay record $35 million settlement for failure to report suspicious orders of pharmaceutical drugs and for recordkeeping violations (July 11, 2017) *available at* https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.
[4] 21 U.S.C. § 822.

including distributors and manufacturers, must obtain a DEA registration and, as a condition of maintaining such registration, take reasonable steps to ensure their registration is not used as a source of diversion.[5] DEA requires registrants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and to inform the agency of any suspicious orders as soon as they are detected.[6] DEA has defined suspicious orders as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[7] As of June 2018, 580 entities are registered with DEA as manufacturers of controlled substances.[8]

Even with these regulations in place, Americans' use of opioid painkillers has skyrocketed and drug diversion has fueled trafficking and abuse of controlled substances. Opioid prescribing rates increased dramatically throughout the 1990s and 2000s, eventually peaking in 2012 when more than 255 million prescriptions were written.[9] Drug manufacturers' sales of prescription opioid products similarly spiked, growing from less than $1 billion in 1992 to $8 billion in 2015.[10]

It was against the backdrop of rising opioid addiction and overdose rates[11] that DEA first raised questions about Mallinckrodt's adherence to CSA regulations. DEA officials reportedly met with Mallinckrodt executives in August 2011 to review concerns regarding Mallinckrodt's oxycodone sales.[12] According to *The Washington Post*, DEA investigators became concerned about the large amount of Mallinckrodt's oxycodone pills sent to Florida – the epicenter of the nation's opioid crisis in the mid-2000s. DEA subpoenaed Mallinckrodt twice for information related to its controlled substance sales, requesting information about the company's suspicious order monitoring programs in November 2011, and again in October 2012.[13] Federal prosecutors later alleged that between 2008 and 2011, Mallinckrodt "supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[14] Investigators reportedly identified nearly 44,000 orders they believed Mallinckrodt should have reported to DEA as suspicious.[15] According to *The Washington Post*, investigators believed more than 500 million oxycodone pills manufactured by Mallinckrodt ended up in Florida between 2008 and 2012 – or roughly 66 percent of all oxycodone sold in the state during that time.[16]

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[5] 21 U.S.C. § 823.
[6] 21 C.F.R. 1301.74(b).
[7] *Id.*
[8] U.S. Drug Enforcement Admin., *Registrant Population by Business Activity*, (last visited July 15, 2018) *available at* https://apps.deadiversion.usdoj.gov/webforms/jsp/odrReports/odrBusActReportSelect.jsp.
[9] Centers for Disease Control and Prevention, *U.S. prescribing rate maps,* (last updated July 31, 2017) *available at* https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.
[10] U.S. Food and Drug Admin., *FDA Analysis of Long-Term Trends in Prescription Opioid Analgesic Products: Quantity, Sales and Price Trends,* (Mar. 1, 2018) *available at* https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM598899.pdf.
[11] Centers for Disease Control and Prevention, *supra* note 2.
[12] Lenny Bernstein and Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, WASH. POST, Apr. 2, 2017, https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.795e8103bc73.
[13] *Id.*
[14] U.S. Dep't of Justice, *supra* note 3.
[15] Lenny Bernstein and Scott Higham, *supra* note 12.
[16] *Id.*

In July 2017, Mallinckrodt settled DEA's allegations for $35 million.[17] According to a memorandum of agreement signed by both Mallinckrodt and DEA, Mallinckrodt agreed that certain aspects of its system to monitor and detect suspicious orders did not always meet standards outlined by DEA.[18] According to the Justice Department, the case also alerted federal authorities to the practice of "chargebacks," through which a drug manufacturer gives a discount to a drug wholesale distributor in exchange for the distributor providing their direct customer sales data to the manufacturer.[19] Through these programs, manufacturers collect information about the pharmacies and other registrants that ultimately buy their products. As part of the settlement agreement, Mallinckrodt is now required to analyze the data it collects through the chargeback program and to alert DEA when it detects any downstream registrants that may pose a risk for drug diversion.[20]

The 2017 agreement did not end federal authorities' interest in the company. In August 2017, the very next month, Mallinckrodt disclosed that it received a subpoena from the Justice Department related to its promotional practices and sales involving opioid products including Exalgo and Xartemis XR.[21] In January 2018, the drug maker also received a federal grand jury subpoena from the Southern District of Florida related to its marketing and sale of oxymorphone generic products.[22]

Given the company's history in the opioid market, the Committee has questions about Mallinckrodt's past and current efforts to prevent drug diversion, employees' understanding of their responsibility to report suspicious orders to DEA, and the company's marketing practices as they relate to the sale of prescription opioids. To assist the Committee in its investigation, we request that you please provide the Committee with the following information as well as scheduling a briefing on these matters by August 16, 2018.

1. Please describe Mallinckrodt's suspicious order policies and procedures and define under what circumstances the company reports orders to DEA as suspicious.

    a. Please provide all policies and procedures regarding suspicious orders and suspicious order reporting.

2. When did the company begin receiving chargeback data from drug distributors? Please describe how and why this policy was adopted and how the company uses this data.

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[17] U.S. Dep't of Justice, *supra* note 3.
[18] U.S. Dep't of Justice, Drug Enforcement Admin. and Mallinckrodt, *Administrative Memorandum of Agreement*, July 7, 2017, *available* at https://www.justice.gov/usao-edmi/press-release/file/986026/download.
[19] U.S. Dep't of Justice, *supra* note 3.
[20] U.S. Dep't of Justice, Drug Enforcement Admin. and Mallinckrodt, *supra* note 18.
[21] Press Release, Mallinckrodt Pharmaceuticals, Mallinckrodt Statement on U.S. DOJ Subpoena Related to Opioid Products Aug. 2, 2017) *available at* https://www.mallinckrodt.com/about/news-and-media/2291309.
[22] Nate Raymond, *U.S. subpoenas Mallinckrodt for information on opioid painkillers* Reuters, Feb. 27, 2018, https://www.reuters.com/article/us-malinckrodt-opioids/u-s-subpoenas-mallinckrodt-for-information-on-opioid-painkillers-idUSKCN1GB37S.

a. Please provide all policies and procedures regarding Mallinckrodt's chargeback data collection, or other programs by which Mallinckrodt receives information from direct customers about downstream pharmacies and other registrants that ultimately buy controlled substances manufactured by Mallinckrodt.

3. Please provide copies of the suspicious order reports, if any, Mallinckrodt submitted to the DEA regarding orders for any of its opioid products for each year between 2006 and 2017.

    a. Of the suspicious order reports provided to DEA, please indicate how many and which suspicious orders were reported to DEA based on an analysis of chargeback data.

4. Please provide a list of Mallinckrodt's top 10 downstream customers for its opioid products for each year since the company began using chargeback data to identify downstream customers.

    a. For each customer, please also include the amount of opioid products purchased each year, expressed in dosage units.

5. A *Washington Post* report indicates DEA met with Mallinckrodt executives on August 23, 2011, to discuss concerns about the company's opioid sales and the amount of the company's drugs being recovered on the street.[23]

    a. Please provide all documents including, but not limited to, communications and memoranda Mallinckrodt has on file regarding this meeting.

    b. What, if any, action did the company take to address the concerns raised by DEA?

    c. What, if any, changes were made to the company's compliance program?

6. Please describe any additional instruction or guidance Mallinckrodt received since January 1, 2006, from DEA regarding its responsibility to report suspicious orders. If Mallinckrodt received the instruction or guidance in writing, please provide these documents.

    a. What, if any, additional meetings or calls were conducted with DEA on this topic?

7. *The Washington Post* report indicates a DEA Supervisor recommended in 2009 that Mallinckrodt conduct an audit of drug distributor Sunrise Wholesale after a Tennessee drug task force sting operation recovered oxycodone that Mallinckrodt had sold the distributor.

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[23] Lenny Bernstein and Scott Higham, *supra* note 12.

a. Did Mallinckrodt conduct an audit of Sunrise Wholesale? If so, when was such audit conducted, and what were the findings? Please provide a copy of any written reports.

b. If not, please explain why Mallinckrodt did not conduct an audit.

8. The same media report also indicates that DEA was concerned with shipments of Mallinckrodt drugs made by Ohio-based KeySource Medical.

a. Did DEA communicate its concern about KeySource drug shipments to Mallinckrodt and was any audit of the customer conducted by Mallinckrodt? If so, when was such audit conducted, and what were the findings? Please provide a copy of any written reports.

b. If not, please explain why Mallinckrodt did not conduct an audit.

9. Please provide minutes from any meeting since January 1, 2006, of Mallinckrodt's Board of Directors during which suspicious orders, or the potential for abuse of the company's opioid products was discussed.

10. Does Mallinckrodt currently market opioids directly to practitioners? If so, please provide all relevant marketing, training, and sales materials related to marketing opioids to practitioners. If not, was this previously a practice employed by the company? When and why was this practice discontinued?

a. Is Mallinckrodt continuing to indirectly market opioid products, such as through conducting or sponsoring conferences or educational programs?

i. If so, please provide all policies or procedures regarding Mallinckrodt's involvement in any such programs.

b. What other direct or indirect marketing efforts, if any, is Mallinckrodt currently engaged in with regards to its opioid products?

11. With respect to its opioid products, did Mallinckrodt ever make use of sales quotas, base employee remuneration on sales, or utilize any other sales-based incentive program for its employees?

a. If so, please provide the year(s) any such policies were in effect, along with a description of said policies and the total amount Mallinckrodt paid its employees, broken down by year, under any such policies or programs.

b. If so, please provide copies of any policies regarding sales quotas and employee salary and bonuses.

12. *The Washington Post* report states that when DEA investigators began investigating the large amount of Mallinckrodt's oxycodone pills sent to Florida, the manufacturer's "blue 30-milligram oxycodone tablets had become so popular among drug users and dealers that they had a street name — 'M's,' for the company's distinctive block-letter logo." Did the company ever conduct any internal or independent reviews regarding the risk of abuse of its opioid products?

    a. If so, please provide copies of any such reviews or reports.

    b. What if any steps has the company taken to develop abuse-deterrent opioid drugs?

    c. Please indicate which of Mallinckrodt's opioid drugs have abuse-deterrent formulations.

13. Starting with 2006, please provide an annual breakdown of the types of opioid drugs Mallinckrodt manufactured as well as a chart detailing the amount of dosage units of each type of opioid drug sold each year.

An attachment to this letter provides additional information about responding to the Committee's request. If you have any questions, please contact Alan Slobodin, Christopher Santini or Andrea Noble of the Majority staff at (202) 225-2927 or Kevin McAloon of the Minority staff at (202) 225-3641. Thank you for your prompt attention to this matter.

Sincerely,

Greg Walden
Chairman

Frank Pallone, Jr.
Ranking Member

Gregg Harper
Chairman
Subcommittee on Oversight
and Investigations

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

Morgan H. Griffith
Vice Chairman
Subcommittee on Oversight
and Investigations

Kathy Castor
Vice Ranking Member

Attachment