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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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August 2, 2018

Dr. Craig Landau
President and Chief Executive Officer
Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431

Dear Dr. Landau:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is continuing to investigate the opioid epidemic. According to the Centers for Disease Control and Prevention, 115 Americans die from an opioid overdose every day and more than 351,000 lives have been lost since 1999.[1]

For more than a year, the Committee has been investigating 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 researching and developing products for the consumer market as well as marketing such products after obtaining approval from the Food and Drug Administration (FDA).

While numerous companies are engaged in the manufacture and marketing of prescription opioids in the United States, Purdue Pharma stands apart for its development and subsequent marketing of the extended-release opioid, OxyContin, which received FDA approval in 1995 and was released to consumers the following year.[2] Since its release, OxyContin has

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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 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.

[2] Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, N.Y. TIMES, May 29, 2018, https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html.

proven to be commercially valuable for Purdue, reportedly accounting for more than $31 billion in sales.[3]

For more than five years after it was introduced, Purdue explicitly marketed OxyContin as carrying less of a risk of addiction and abuse than other commercially available pain medications.[4] Purdue has long maintained that it first became aware of instances of abuse of OxyContin in 2000. For example, in 2001, then-Executive Vice President and Chief Operating Officer Michael Friedman testified before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce on the abuse of OxyContin. Mr. Friedman's written testimony stated, "[i]t was early in April of 2000 that Purdue was first alerted to reports of abuse and diversion of OxyContin by accounts in Maine newspapers claiming that OxyContin was the subject of recreational use in Maine."[5] This assertion was echoed by Purdue's then-Executive Vice Present and General Counsel, Howard Udell, as well as the company's then-Senior Physician, Dr. Paul Goldenheim, both of whom also provided testimony at the hearing. Specifically, Dr. Goldenheim testified "[i]t was not until [2000], when OxyContin press became so prevalent, when we began investigating . . . that we learned that in addition to oral abuse, that OxyContin was also, on occasion, being crushed and used intravenously."[6]

Media reports, however, suggest that Purdue was aware of instances of OxyContin being abused as early as 1997—just one year after OxyContin was introduced into the market.[7] According to a recent *New York Times* article, Department of Justice "prosecutors found that the company's sales representatives used the words 'street value,' 'crush,' or 'snort' in 117 internal notes recording their visits to doctors or other medical professionals from 1997 through 1999."[8] Also in 1997, several Purdue executives, including the company's then-Chief Operating Officer, received an e-mail which stated that "references to OxyContin abuse on addiction chat sites were 'enough to keep a person busy all day.'"[9] In 1998, Purdue was reportedly aware of a study published in the Journal of the Canadian Medical Association which found that MS Contin, a predecessor of OxyContin also manufactured by Purdue, had the highest street value of any prescription opioid—a 30-milligram tablet that cost $1 in a pharmacy cost $40 on the black market.[10] An accompanying editorial stated, "[i]t has been argued previously that controlled-release preparations might be less desirable as drugs of abuse than immediate-release pharmaceuticals. The relatively high street price of controlled-release opioid analgesics reported in this study clearly indicates that these drugs are coveted. This should ring alarm bells."[11] It has been reported that federal prosecutors also alleged that in 1999, Richard Sackler, then-President

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[3] Harriet Ryan, *Senator calls for investigation of Purdue Pharma following Times story on OxyContin*, L.A. TIMES, May 27, 2017, http://www.latimes.com/projects/la-me-oxycontin-full-coverage/.
[4] *See United States v. The Purdue Frederick Company*, Agreed Statement of Facts, ¶ 20 (W.D. Va. 2007) *available at* http://i.bnet.com/blogs/purdue-agreed-facts.pdf.
[5] *OxyContin: Its Use and Abuse, Hearing Before Subcomm. on Oversight and Investigations of the H. Comm on Energy and Commerce*, 107 Cong. Serial No. 107-54 (2001).
[6] *Id.*
[7] Meier, *supra* note 2.
[8] *Id.*
[9] Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, FORTUNE, Nov. 9, 2011, http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/.
[10] Meier, *supra* note 2.
[11] Brian Goldman, M.D., *The news on the street: prescription drugs on the black market*, Canadian Med. Ass'n J., July 28, 1998, *available at* http://www.cmaj.ca/content/cmaj/159/2/149.full.pdf.

of Purdue, was told of internet chat room discussions among individuals who described snorting OxyContin.[12] If Purdue personnel were in fact aware of reports of OxyContin being abused prior to 2000, then that may call into question testimony company executives provided to Congress, including before this Committee.

A 2003 study conducted by the Government Accountability Office (GAO) at the request of this Committee and the Committee on Appropriations found that Purdue's aggressive direct marketing of OxyContin for non-cancer pain resulted in nearly a tenfold increase in prescriptions for the drug over a 6-year period.[13] According to the GAO, the Drug Enforcement Administration (DEA) considered Purdue's marketing of OxyContin to have been "overly aggressive."[14] The National Institute on Drug Abuse (NIDA) has stated that the nation's opioid crisis can be traced back to the increased prescribing rates seen in the late 1990s, which, according to NIDA, were a product of assurances received from pharmaceutical companies and ultimately led to "widespread diversion and misuse of these medications[.]"[15] A 2009 article, appearing in the *American Journal of Public Health*, and citing Purdue Pharma internal documents, stated that a cornerstone of Purdue's marketing plan for OxyContin was to target physicians among the country's highest prescribers for opioids, and that the company would offer patients a starter coupon for OxyContin, providing them with a free prescription for a 7-to-30 day supply of the drug.[16]

Purdue also promoted OxyContin through indirect means as well, conducting more than 40 national pain management and speaker training conferences between 1996 and 2001.[17] Purdue used these conferences to recruit and train practitioners to participate in the company's "speaker bureau" – a network of healthcare practitioners, compensated by Purdue to speak to colleagues about the appropriate use of opioids, including OxyContin.[18] In addition, during the first seven years that OxyContin was on the market, Purdue also funded more than 20,000 pain-related educational programs, including programs designed to educate hospitals and practitioners on how to comply with the newly-developed pain management standards issued by the Joint Commission on Hospital Accreditation.[19] For many hospitals, maintaining accreditation from the Joint Commission is necessary to retain eligibility to participate in the Medicare and Medicaid programs.[20] According to the GAO, Purdue may have increased its access to hospitals through an

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[12] Meier, *supra* note 2.
[13] U.S. Gov't Accountability Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110 (Dec. 2003) *available at* https://www.gao.gov/new.items/d04110.pdf.
[14] *Id.*
[15] Nat'l Inst. On Drug Abuse, *Opioid Overdose Crisis* (last updated March 2018) *available at* https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-*crisis*.
[16] Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health, 221 -227 (2009) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.
[17] *Id.*
[18] U.S. Gov't Accountability Office, *supra* note 13 and Patrick Radden Keefe, *The Family that Built an Empire of Pain*, THE NEW YORKER, OCT. 30, 2017, https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.
[19] U.S. Gov't Accountability Office, *supra* note 13.
[20] In order to participate in the Medicare program, a hospital must meet minimum federal standards, otherwise known as the Conditions of Participation (CoPs). *See* 42 U.S.C. 1395x. Pursuant to Section 1865 of the Social Security Act, hospitals may demonstrate their compliance with the CoPs through achieving accreditation by an Accrediting Organization that has been approved by the Centers for Medicare and Medicaid Services. *See* 42 U.S.C.

agreement the company reached with the Joint Commission whereby Purdue was the only company allowed to distribute educational videos and a book about pain management to the 4,211 hospitals accredited by the Joint Commission at the time.[21] The Joint Commission also published these materials on its website.[22]

In January 2003, FDA sent a warning letter to Purdue related to its advertisements for OxyContin, advising the company that it was in violation of the Federal Food, Drug, and Cosmetic Act and that its "advertisements omit and minimize the serious safety risks associated with OxyContin, and promote it for uses beyond which have been proven safe and effective."[23] FDA had previously ordered that a "black box warning" be added to OxyContin's label, which is FDA's strictest warning label for approved medications.[24]

Over seven million Americans have reportedly abused OxyContin since Purdue first introduced the medication in 1996.[25] In 2007, Purdue, along with former company executives, pleaded guilty to misbranding OxyContin, with the intent to defraud or mislead, through its misrepresentations regarding the drug's risks and were forced to pay more than $634 million in criminal and civil penalties.[26] However, a former Purdue employee has questioned whether, following the company's guilty plea, Purdue did in fact discontinue misrepresenting OxyContin's potential for addiction.[27] Media reports have similarly cast doubt on Purdue's claim that it ceased downplaying OxyContin's potential for addiction following the 2007 plea agreement.[28] In February of this year, Purdue announced plans to restructure its sales operations

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1395bb. According to CMS' most recent report to Congress, in Fiscal Year (FY) 2015, 89 percent of hospitals—3,500 hospitals in total—chose to demonstrate compliance with the CoPs through accreditation, with the Joint Commission being the predominant Accrediting Organization. *See* U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services, Review of Medicare's Program for Oversight of Accrediting Organizations and the Clinical Laboratory Improvement Validation Program – Fiscal Year 2016, 16 (July 28, 2017), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-40.pdf.

[21] U.S. Gov't Accountability Office, *supra* note 13 and U.S. Gov't Accountability Office, *Medicare: CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals*, GAO-04-850 (July 2004) *available at* https://www.gao.gov/assets/250/243477.pdf.

[22] U.S. Gov't Accountability Office, *supra* note 13.

[23] Warning Letter from Thomas W. Abrams, R.Ph., Dir., Division of Drug Marketing, Advertising, and Communications, U.S. Food and Drug Admin. to Michael Friedman, Exec. Vice President and Chief Operating Officer, Purdue Pharma L.P., Jan. 17, 2003 *available at* https://web.archive.org/web/20030625221000/http://www.fda.gov/cder/warn/2003/oxycontin11400.pdf.

[24] U.S. Food and Drug Admin., Timeline of Selected FDA Activities & Significant Events Addressing Opioid Misuse & Abuse (last accessed June 21, 2018) available at https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM332288.pdf.

[25] Harriet Ryan, Lisa Girion, and Scott Glover, *'You Want a Description of Hell?' Oxycontin's 12-Hour Problem*, L.A. Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

[26] *United States v. The Purdue Frederick Company*, Opinion and Order, Case No. 1:07CR00029 (W.D. Va. 2007) *available at* http://www.vawd.uscourts.gov/OPINIONS/JONES/107CR00029.PDF.

[27] CBS News, *Purdue Pharma continued deceptive sales practices for OxyContin after 2007, whistleblower says*, June 20, 2018, https://www.cbsnews.com/news/oxycontin-*purdue*-whistleblower-says-drug-maker-continued-deceptive-sales-practices/.

[28] *See* Jonathan Mattise, *Unsealed lawsuit: Opioid firm placed profits over people*, Associated Press, July 6, 2018, https://www.apnews.com/a29f8be3c99944deb8c2ec9e597f5226.

and that the company would no longer promote its opioid products to prescribers.[29] The company later announced that it planned to discontinue promoting its products to prescribers altogether.[30]

To assist the Committee's understanding of Purdue Pharma's role in the opioid epidemic in the United States, please provide the following information as well as scheduling a briefing on these matters by August 16, 2018:

1. According to the *New York Times,* federal prosecutors were in possession of 117 notes from Purdue Pharma sales representatives that were authored following visits to medical practitioners between 1997 and 1999 and referenced "street value," "crush," or "snort," with respect to OxyContin.

    a. What is the meaning of these references by sales representatives with respect to OxyContin?

    b. What attempts, if any, did Purdue make to follow-up on the references to abuse of OxyContin in the notes of its sales representatives between 1997 and 1999?

    c. Please provide all documents to or from Purdue Pharma sales representatives between 1996 and 2000 referring or relating to the abuse, or potential for abuse, of OxyContin.

    d. Has Purdue conducted any internal or independent reviews regarding the abuse of OxyContin and when the company should have become aware of the abuse of OxyContin? If so, please provide a copy of any such review.

2. According to the *New York Times*, Purdue Pharma was aware of a 1998 study published in the Canadian Medical Association Journal regarding the street value of prescription drugs and an accompanying editorial.

    a. When did Purdue first become aware of the high street price of controlled-release opioid analgesics?

    b. When and how did Purdue first become aware of the 1998 study in the Canadian Medical Association Journal?

    c. Given OxyContin's controlled-release formulation, what actions did the company take in response to the 1998 study and accompanying editorial?

    d. Please provide all communications from 1998 referring or relating to the study published in the Canadian Medical Association Journal.

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[29] Press Release, Purdue Pharma L.P., Purdue Pharma L.P. Issues Statement on Opioid Promotion (Feb. 9, 2018) *available at* http://www.purduepharma.com/news-media/2018/02/purdue-pharma-l-p-issues-statement-on-opioid-promotion/.

[30] Stephen Singer, *Stamford's Purdue Pharma Axes Remaining Sales Force*, Hartford Courant, June 20, 2018, http://www.courant.com/business/hc-biz-purdue-pharma-jobs-20180619-story.html.

e. Given the study and editorial's implications regarding the safety of OxyContin, why did Purdue choose not to share this information with FDA?

3. In February 2018, Purdue Pharma announced that it would no longer promote its opioid products to consumers, and in June 2018, Purdue Pharma eliminated its sales division and "ended its sales force engagement with prescribers for all of its medicines."[31]

   a. Please describe Purdue's previous practices with respect to "sales force engagement with prescribers."

   b. From 1996 through 2002, Purdue had a co-promotional agreement with Abbott Laboratories to promote and distribute OxyContin. What other co-promotional agreements, if any, did Purdue engage in with regards to OxyContin?

   c. Why did Purdue decide to make these changes to its marketing practices in 2018, over 10 years after the 2007 settlement?

   d. Is Purdue continuing to indirectly market OxyContin, such as through conducting or sponsoring conferences or educational programs?

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

   e. What other direct or indirect marketing efforts, if any, is Purdue currently engaged in with regards to OxyContin?

   f. With the elimination of the sales division, which division at Purdue will be responsible for managing product sales?

4. Does Purdue Pharma currently provide funding to outside organizations or finance grants related to pain management?

   a. If so, please provide all policies and procedures referring or relating to any such funding.

5. With respect to its opioid products, did Purdue Pharma 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 Purdue paid its employees, broken down by year, under any such policies or programs.

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[31] Purdue Pharma, *supra* note 29; Singer, *supra* note 30.

6. Has Purdue conducted any internal or independent reviews related to the company's marketing of OxyContin?

    a. If so, please provide a copy of any such review.

    b. If not, why not?

7. Please provide copies of the minutes from any meeting of Purdue Pharma's Board of Directors or Committees where the abuse, or potential for abuse, of OxyContin and/or MS Contin was discussed since January 1, 1996.

8. The *New York Times* referenced an email written by former Purdue Pharma General Counsel Howard R. Udell, stating in part, "[w]e have in fact picked up references to abuse of our opioid products on the internet[.]"[32]

    a. Please provide this email and all documents between January 1, 1996, and April 1, 2000, referring or relating to the abuse, or potential for abuse, of OxyContin.

9. The *New York Times* stated that then-President Richard Sackler was told in 1999 about discussions in Internet chat rooms where drug abusers described snorting OxyContin.[33] Please provide all documents to or from Richard Sackler in 1999 related to the abuse of OxyContin.

10. Please provide an unredacted copy of the deposition, and any exhibits attached thereto, of Richard Sackler, taken in relation to the case, *Commonwealth of Kentucky, ex rel. Jack Conway, Attorney General v. Purdue Pharma, L.P., et al.*, Pike County Circuit Court Division II Case No. 07-CI-01303.

11. Please provide all documents from Purdue Pharma sales representative Jim Speed related to illegal prescriptions of OxyContin or other opioids, and/or OxyContin abuse potential.

12. Please provide all documents from Purdue Pharma executive, Dr. J. David Haddox related to a crisis-response plan for illegal prescriptions or abuse of OxyContin.

13. Please provide all documents from Purdue Pharma Chief Executive Michael Friedman related to a crisis-response plan for illegal prescriptions or abuse of Oxycontin.

14. Please provide all documents from Purdue Pharma sales representative Mark Ross related to his concerns about a doctor's office filled with drug seekers.

15. Purdue Pharma admitted in 2007 that it trained sales representatives to tell doctors that OxyContin was less addictive and prone to abuse than competing opioids, claims that did

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[32] Meier, *supra* note 2.
[33] *Id.*

not have FDA approval.[34] Please provide all documents Purdue Pharma provided its sales representatives referring or relating to OxyContin's potential for abuse or addiction.

a. Please provide all training materials pertaining to OxyContin that Purdue provided to its sales representatives between 1996 and 2017.

b. What information did Purdue have in 2007 about Oxycontin's abuse risks compared to the abuse risks of other opioids?

16. Please provide copies of the suspicious order reports, if any, Purdue Pharma submitted to the DEA regarding orders for any of its opioid products placed between 2000 and 2017.

17. Please provide a list of all wholesale distributors, physicians, or pharmacies that Purdue Pharma terminated as customers for opioid products since January 1, 2000.

18. Please provide all memoranda referring or relating to meetings between Purdue Pharma and the DEA related to OxyContin's potential for abuse or addiction.

19. Please provide all memoranda referring or relating to meetings between Purdue Pharma and FDA related to OxyContin's potential for abuse or addiction.

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

[34] *United States v. The Purdue Frederick Company*, *supra* note 4.

Morgan H. Griffith
Vice Chairman
Subcommittee on Oversight
and Investigations

Kathy Castor
Vice Ranking Member

Attachment