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# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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March 21, 2019

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

Dear Mr. Landau:

We are writing to request documents relating to reports that members of the Sackler family, who purchased Purdue Pharma in 1952 and continue to own a controlling share of the company, sought to drive up sales of OxyContin and other addictive painkillers while simultaneously expanding the market for medications to treat addiction—even after the company settled criminal charges that it had misled regulators, doctors, and patients about OxyContin's potential for misuse.[1]

Despite knowing about "significant" abuse shortly after OxyContin's introduction in 1996, Purdue reportedly continued to market the painkiller as less prone to abuse and addiction than other prescription opioids.[2] The recently unsealed transcript of an August 28, 2015, deposition of Richard Sackler—the former president and co-chairman of Purdue—suggests an email exists showing that he was complicit in the company's efforts to downplay OxyContin's potential for misuse. According to the transcript, in May 1997, Purdue's former head of sales and marketing wrote in an email to Mr. Sackler: "We are well aware of the view held by many physicians that oxycodone is weaker than morphine. ... I do not plan to do anything about that." In response, Mr. Sackler wrote: "I agree with you."[3]

In addition, documents obtained by *60 Minutes* reveal that Purdue pressured the Food and Drug Administration (FDA) to expand the designation on OxyContin's labeling to cover "daily, around-the-clock, long-term" use. In 2001, FDA made this change to OxyContin's labeling—despite a lack of scientific justification—and sales of the painkiller tripled shortly after.

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[1] *In Guilty Plea, OxyContin Maker to Pay $600 Million*, New York Times (May 10, 2007) (online at www.nytimes.com/2007/05/10/business/11drug-web.html).

[2] *Origins of An Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, New York Times (May 29, 2018) (online at www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html).

[3] Commonwealth of Kentucky, ex rel. v Purdue Pharma L.P., et al., Deposition of Richard Sackler, M.D. (Aug. 28, 2015) (online at www.documentcloud.org/documents/5745056-Depo-022019.html).

According to internal documents, Purdue executives celebrated "enormous opportunities" created by FDA's action.[4]

The Department of Justice (DOJ) conducted a four-year investigation into Purdue's marketing and sales practices. According to the *New York Times*, at the conclusion of the investigation in 2006, federal prosecutors recommended that three of Purdue's top executives be indicted on felony charges, including conspiracy to defraud, for their involvement in the company's marketing of OxyContin. Political appointees at DOJ under President George W. Bush reportedly rejected the prosecutors' recommendations, deciding instead to settle for misdemeanor charges of "misbranding."[5]

As part of this settlement, Purdue agreed to pay $600 million in fines to federal and state agencies, patients, and plaintiffs. In a news release following the settlement, Purdue accepted responsibility for "past misstatements" made regarding OxyContin and stated that it had implemented changes to its training, monitoring, and compliance systems "that seek to assure that similar events do not occur again."[6]

However, the Massachusetts Attorney General's Office alleges that eight members of the Sackler family "directed deceptive sales and marketing practices deep within Purdue" and aggressively pushed company officials to drive up sales of its highly addictive painkillers from 2007 through 2018.[7] According to new documents and other information obtained by the Attorney General's Office:

> They directed the company to hire hundreds more sales reps to visit doctors thousands more times. They insisted that sales reps repeatedly visit the most prolific prescribers. They directed reps to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered staff to use them.[8]

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[4] *Did the FDA Ignite the Opioid Epidemic?*, CBS News (Feb. 24, 2019) (online at www.cbsnews.com/news/opioid-epidemic-did-the-fda-ignite-the-crisis-60-minutes/).

[5] *Origins of An Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, New York Times (May 29, 2018) (online at www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html).

[6] *Purdue Pharma Admits Lies Over OxyContin Painkiller Risks*, Pharma Times (May 11, 2007) (online at www.pharmatimes.com/news/purdue_pharma_admits_lies_over_oxycontin_painkiller_risks_989853).

[7] Plaintiff's Pre-Hearing Memorandum (Jan. 15, 2019) *Commonwealth of Massachusetts v. Purdue Pharma L.P., et al*, Suffolk County Superior Court (No. 1884 CV 01808) (online at https://int.nyt.com/data/documenthelper/569-purdue-pharma-documents/abbd666f51f9fae8bd7a/optimized/full.pdf); Plaintiff's First Amended Complaint and Jury Demand (Jan. 31, 2019) *Commonwealth of Massachusetts v. Purdue Pharma L.P., et al*, Suffolk County Superior Court (No. 1884 CV 01808) (online at www.mass.gov/files/documents/2019/01/31/Massachusetts%20AGO%20Amended%20Complaint%202019-01-31.pdf).

[8] Plaintiff's First Amended Complaint and Jury Demand, 63 (Jan. 31, 2019) *Commonwealth of Massachusetts v. Purdue Pharma L.P., et al.*, Suffolk County Superior Court (No. 1884 CV 01808) (online at www.mass.gov/files/documents/2019/01/31/Massachusetts%20AGO%20Amended%20Complaint%202019-01-31.pdf).

Members of the Sackler family, including Richard Sackler, reportedly pressured company executives to increase sales during this time and were aware of the company's strategy to boost revenue by encouraging doctors to prescribe higher doses of their drugs.[9]

At the same time, other members of the Sackler family were involved in efforts to expand the company's business to include treatments for substance use disorders. Kathe Sackler, a Purdue Board member and cousin of Richard Sackler, was involved in the development of Project Tango, Purdue's plan to become "an end-to-end pain provider" by developing products to treat people after they become addicted to opioids like OxyContin.[10] In materials provided to Ms. Sackler regarding Project Tango, company officials described the "vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction" as "an attractive market."[11]

In January 2018, a Purdue subsidiary obtained a patent for a new form of buprenorphine, a drug used in medication-assisted treatment to ease withdrawal symptoms.[12] The patent lists Richard Sackler as one of six inventors.[13] Just last week, Purdue announced that FDA had granted Fast Track designation for its new opioid overdose reversal drug, nalmefene hydrochloride.[14]

Purdue has pledged that it will not profit from sales of its new products.[15] However, the Sackler family has already realized significant personal profit from Purdue's commercial enterprise. The Sacklers voted on dozens of occasions to pay out Purdue's profits to themselves, and between 2007 and 2018, Purdue compensated members of the Sackler family more than $4 billion.[16]

The United States is in the midst of its greatest public health crisis in decades. Due in part to the aggressive over-prescribing of opioids like OxyContin, millions of Americans are in

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[9] *Id.* at 74.

[10] *Id.* at 152.

[11] *Id.* at 151 and 154.

[12] Patent and Trademark Office, *Buprenorphine-Wafer for Drug Substitution Therapy* (online at http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=98,61,628.PN.&OS=PN/98,61,628&RS=PN/98,61,628) (accessed Oct. 3, 2018).

[13] *Id.*

[14] Purdue Pharma, *FDA Grants Purdue Pharma's Nalmefene HCI Injection Fast Track Designation for the Emergency Treatment of Known or Suspected Opioid Overdose* (Mar. 13, 2019).

[15] *Id.*

[16] Plaintiff's First Amended Complaint and Jury Demand, 79 (Jan. 31, 2019) *Commonwealth of Massachusetts v. Purdue Pharma L.P., et al.*, Suffolk County Superior Court (No. 1884 CV 01808) (online at www.mass.gov/files/documents/2019/01/31/Massachusetts%20AGO%20Amended%20Complaint%202019-01-31.pdf).

the grip of drug addiction. According to the Centers for Disease Control and Prevention, more than 200,000 people died from prescription opioid overdoses between 1999 and 2017.[17]

For these reasons, the Committee requests that you produce by April 4, 2019, the following documents for the time period of January 1, 2007, to the present:

1. A list of all members of the Sackler family that have served on the Board of Directors, as corporate officers, or in any other capacity for Purdue Pharma or its subsidiaries, to the present, and their titles and dates of service;

2. All internal and external presentations, analyses, or other documents prepared for or provided to any member of the Sackler family referring or relating to sales or marketing strategies for each of Purdue's and its subsidiaries' prescription opioid products and substance use disorder treatments;

3. All communications between employees or officers of Purdue and its subsidiaries and members of the Sackler family regarding sales and marketing for each of Purdue's and its subsidiaries' prescription opioid products and substance use disorder treatments; and

4. All internal and external presentations, analyses, or other documents, including email and other communications, concerning FDA labeling for OxyContin.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X.

An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Committee staff at (202) 225-5051.

Thank you for your attention to this matter.

Sincerely,

Elijah E. Cummings
Chairman

Mark DeSaulnier
Member of Congress

Enclosure

[17] Centers for Disease Control and Prevention, *Prescription Opioid Data* (online at www.cdc.gov/drugoverdose/data/prescribing.html) (accessed on February 13, 2019).

cc: The Honorable Jim Jordan, Ranking Member

## Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

## Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term "including" shall be construed broadly to mean "including, but not limited to."

5. The term "Company" means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term "identify," when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; (b) the individual's business or personal address and phone number; and (c) any and all known aliases.

7. The term "related to" or "referring or relating to," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term "employee" means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term "individual" means all natural persons and all persons or entities acting on their behalf.