The FED UP! Coalition

A COALITION TO END THE OPIOID EPIDEMIC

A call for immediate, coordinated and comprehensive federal action to end the epidemic of opioid addiction and overdose deaths

Honorable Robert Drain
United States Bankruptcy Judge
United States Bankruptcy Court
Southern District of New York
300 Quarropas Street
White Plains, New York 10601-4140

December 8, 2020

Re: Purdue Pharma L.P., Case No. 19-23649 (RDD)

Dear Judge Drain:

In Docket No. 2045 (*Motion of Debtors for Entry of a Third Order Extending the Exclusive Periods Within Which to File a Chapter 11 Plan and Solicit Acceptances Thereof*) Purdue Pharma requested an extension of court deadlines to develop the "successor entity to which the Debtors' assets will be transferred." In Docket No. 2056, Physicians for Responsible Opioid Prescribing (PROP) wrote to the Court regarding that Motion. The FED UP! Coalition shares PROP's concern and respectfully offers to the Court its view regarding the "successor entity" to Purdue.

FED UP! is a coalition of organizations with a mission to end the opioid epidemic. The FED UP! Coalition was formed in 2012 when organizations from across the country joined forces. What brought us together was our shared concern that the federal government was failing to stem the rising tide of opioid addiction and overdose deaths. We are families who have been ripped apart by opioids. We have lost loved ones to death and addiction. We are medical experts and advocates who understand that the root cause of the problem is overprescribing. This is a grassroots coalition, all seeking action from the federal government to bring this public health crisis to an end. We accept no money from pharmaceutical companies or their affiliates. We are beholden to no one – except our lost loved ones, or our family members struggling with addiction. We have come together to save lives.

FED UP! Agrees with the views articulated by Physicians for Responsible Opioid Prescribing in their letter (Docket NO. 2056).

Purdue should be shut down. Purdue's business should not be preserved as a "public benefit" company to keep selling OxyContin or provide a legacy for the Sackler family. Many companies go out of business every year and are not rescued by the government. Purdue killed thousands of Americans. For our government to prop up Purdue and give the OxyContin business a special public status is the opposite of justice.

We are especially troubled by the idea that a new "public benefit" version of Purdue would be trusted with the responsibility to provide medicines to treat opioid use disorder or reverse opioid overdoses. Purdue and its employees have exploited, injured, blamed, and stigmatized people who are hurt by opioids. For some of those same Purdue employees to paint a new "public benefit" label on their headquarters and try to pose as a public health agency is offensive. They should be ashamed.

For recovery efforts to succeed, it is essential that people who have been hurt by opioids be able to trust the organizations that provide medicines and services for recovery. We would never trust a Public Benefit Company created from Purdue Pharma, and we cannot in good conscience ask people we care about to trust the new entity, no matter what "public benefit" label it says it has.

As Physicians for Responsible Opioid Prescribing wrote, the way to deal with Purdue is to sell off its assets to other pharmaceutical companies. Those companies can take a hard look at the risks of going into this dangerous business. Meanwhile, the important work of abating the opioid epidemic and supporting people in recovery should be kept far away from Purdue and its successor entity.

Thank you for considering our concerns. If you have any questions or if we can be of any assistance to the Court, please let us know.

Sincerely,

Emily Walden

Emily Walden[1]

[1] This letter is submitted on behalf of FED UP! Emily Walden is not acting in her individual capacity as a creditor and member of the Ad Hoc Committee on Accountability.

FED UP!
A COALITION TO END THE OPIOID EPIDEMIC

October 14, 2020

The Honorable William P. Barr
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Ave. NW
Washington, D.C. 20530

Dear Attorney General Barr:

We write to ask you to revise a proposed DOJ settlement agreement that reportedly would wrongly mandate that Purdue Pharma's infamous OxyContin business be preserved as a public trust. A business that killed thousands of Americans should not be associated with government. Instead, the business should be sold to private owners, so the government can enforce the law against it with the same impartiality as for any other company.

States sued Purdue Pharma and its billionaire owners, the Sacklers, because their illegal conduct caused much of the national opioid crisis. Their misconduct also forced the company into bankruptcy, and the States and DOJ are participating in the bankruptcy case with the shared goals of distributing Purdue's assets to compensate people who were injured and to abate the opioid epidemic.

A key issue in the bankruptcy is the future of Purdue's OxyContin business. Purdue and the Sacklers proposed that the government should step into their shoes and take over their business of selling OxyContin. They want their OxyContin company preserved as a family legacy and a "public trust." Purdue explained: "We're turning [the company] into a public trust organization … It sells a very valuable product called OxyContin."[1]

We rejected Purdue's proposal. We believe that Purdue's assets should be sold to new owners in the private sector. The role of government in any OxyContin business should be to enforce the law, just as against any other company. The public deserves assurance that no opioid business is given the special protection of being placed under a public umbrella. Although it may take time to find a private sector buyer, the public should be confident that public officials are seeking to avoid having special ties to an opioid company, conflicts of interest, or mixed motives in an industry that caused a national crisis.

In the recent bankruptcy of another notorious opioid company, the assets of Insys Therapeutics Inc. were sold to a private buyer, pursuant to court approval, and our governments were not forced to enter the opioid business.[2] That is a normal, lawful result in a bankruptcy, and the DOJ should encourage Purdue to follow that same path. Compared to Purdue's proposal, selling the

[1] Berkeley Lovelace Jr., *Purdue Pharma chair: Best Way To Fight Opioid Crisis Is For OxyContin Maker To Stay In Business*, CNBC, Sept. 16, 2019, at https://www.cnbc.com/2019/09/16/purdue-pharma-chairman-steve-miller-on-bankruptcy-of-oxycontin-maker.html.

[2] *See* Nate Raymond, *Drugmaker Insys Wins Bankruptcy Court Approval To Sell Off Opioid*, Reuters, Sept. 19, 2019, at https://www.reuters.com/article/us-insys-opioids-bankruptcy/drugmaker-insys-wins-bankruptcy-court-approval-to-sell-off-opioid-idUSKBN1W42KY.

business to a private owner may also deliver more upfront money that cities and States can use to abate the opioid epidemic. At least one potential buyer has already come forward to make a bid to buy Purdue's drug businesses, which would keep the businesses in private ownership. Qualified buyers should be permitted to bid for Purdue's assets.

Instead, the press has reported that DOJ intends to sign agreements that would purport to prohibit the sale of Purdue's businesses to private owners, and would require that Purdue be preserved as a "public benefit company" that will sell OxyContin on behalf of cities and state governments.[3]

We ask you to reverse that decision for three reasons. First, as we explained above, the Sacklers' proposal to cloak the OxyContin business in public ownership compromises the proper roles of the private sector and government. Thousands of Americans have died, and it is a top priority of every State to enforce the law against the perpetrators whose misconduct caused the opioid crisis. The last business our States should protect with special public status is this opioid company.

Second, even if DOJ disagrees with the principles that keep government out of the opioid business, DOJ should not impose its view on States, cities, families, and all other stakeholders in the bankruptcy. Instead, the relevant parties in the bankruptcy should be permitted to negotiate without DOJ putting its thumb on the scale.

Third, the States will continue to oppose the Sacklers' plan. When a plan is proposed in the bankruptcy, States and all other creditors can vote against a plan they believe is wrong. Even after that, because the Sacklers seek extraordinary releases of the States' claims for their individual, personal liability, States have powerful arguments to challenge the confirmation of the Sacklers' plan in the Bankruptcy Court and every court above it.[4]

There is no need for DOJ to require a special status for the Sackler's OxyContin business. If DOJ insists that the Sacklers get their way and their OxyContin business is elevated into a public trust, Americans will question whether billionaires bought special treatment in this case, while working families across the country suffered.

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[3] Mike Spector & Jessica DiNapoli, *OxyContin Maker Purdue Nears Guilty Plea Agreement In U.S. Criminal Probe - Sources*, Reuters, Oct. 7, 2020, at https://www reuters.com/article/us-purdue-pharma-investigations-opioids/exclusive-oxycontin-maker-purdue-nears-guilty-plea-agreement-in-u-s-criminal-probe-sources-idUSKBN26S1P2 ("The Justice Department is prepared to waive a large portion of its $2 billion forfeiture claim as long as Purdue meets certain conditions. The first is that Purdue steer significant financial sums for combating the opioid epidemic to U.S. communities suing it over the crisis, two people said. The other is that it receive court approval for a reorganization plan transforming it into a 'public benefit company' run on behalf of those communities and no longer controlled by the Sacklers."). The same article also reported that details of the proposed settlement "remain in flux."

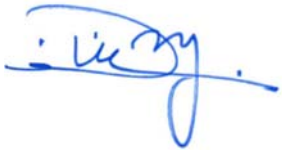
[4] States and the DOJ agree that bankruptcy courts should never force governments to release these claims. *See* Brief for the United States as Amicus Curiae at 12, *Lynch v. Mascini Holdings, Ltd. (In re Kirwan Offices S.a.R.L.)*, Case No. 18-3371 (2d Cir. Oct. 7, 2019) ECF No. 119 ("third-party releases are impermissible"); *id.* at 15 n.3 ("Moreover, the government's view is that, even assuming that releases may be appropriate in certain circumstances, no such releases should ever apply to the government, as its interests are distinct from those of ordinary creditors or other outsiders who may have claims against participants in the bankruptcy process. For example, no bankruptcy court order should release non-debtors from their obligations under criminal laws, tax laws, environmental laws, or other public health and safety laws….").

We ask you to work with us to keep the OxyContin business in the private sector, secure money to abate the crisis, and hold the perpetrators accountable.

Respectfully,

XAVIER BECERRA
California Attorney General

PHILIP J. WEISER
Colorado Attorney General



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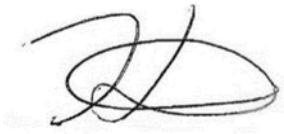

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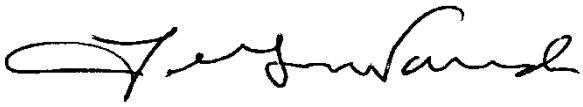

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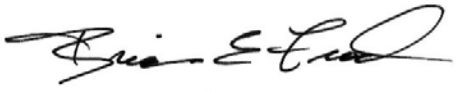

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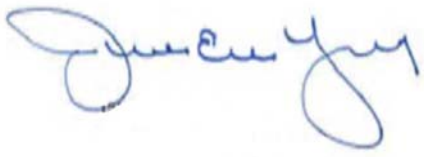

JANE E. YOUNG
New Hampshire Deputy Attorney General

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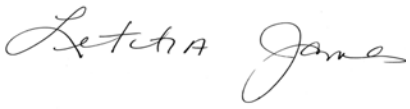
New Jersey Attorney General



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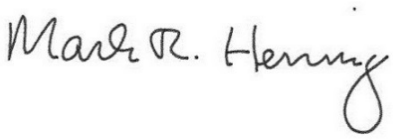

MARK R. HERRING
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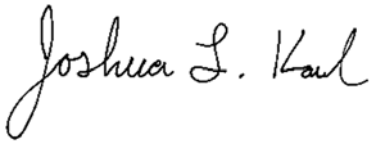

JOSHUA L. KAUL
Wisconsin Attorney General

Congress of the United States
Washington, DC 20515

November 10, 2020

The Honorable William Barr
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Ave. NW
Washington, D.C. 20530

Dear Attorney General Barr:

We write today to express our serious concerns with the Department of Justice's (DOJ) recently announced settlement with Purdue Pharma and members of the Sackler family. While we have several concerns about the adequacy of the entire settlement, we strenuously object to the provision that would convert Purdue Pharma into a so-called "public benefit company" and urge you to ensure this provision is not included in any final settlement agreement to be approved by the courts.

The idea to convert Purdue Pharma into some form of public trust originated with the Sackler family as a way to artificially inflate the size of their punishment by counting the public trust's future sales of OxyContin as part of the value the Sacklers must forfeit. There is no better example of the success of this public relations strategy than the Department of Justice's own settlement announcement. While headlines announced Purdue's $8 billion settlement, nearly a quarter, or $1.775 billion, of this figure is actually a "credit" DOJ is providing Purdue "[b]ased on the value that would be conferred to State and local governments" through the public benefit company.[1] In other words, this proposal is a mirage designed to help the Sacklers keep billions in ill-gotten gains by deceiving the American people into believing they have already been severely punished.

Granting the Sacklers' wish to convert their company into some form of a public trust has no precedent in American history. The Chairman of the Board of Directors for Purdue Pharma has suggested this proposal is similar to when the federal government took an ownership interest in AIG following the 2008 financial crisis.[2] But that temporary arrangement, the functional equivalent of a loan, was only to ensure the federal government was repaid for the taxpayer-funded financial assistance provided to AIG. Once repayment occurred, the ownership interest was terminated. In contrast, the Sackler/DOJ proposal would permanently transfer the ownership of Purdue Pharma to a trust operated for the benefit of state and local governments in order to

[1] United States Department of Justice press release. *Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family*. October 21, 2020.
[2] Steve Miller. *Here's what critics of the Purdue Pharma settlement get wrong*. The Washington Post. October 27, 2020.

resolve Purdue's financial liability for intentionally addicting hundreds of thousands of unsuspecting Americans to powerful opioids for profit.

Another important contrast is that in 2008 the federal government imposed the ownership interest obligation on itself. Here the federal government is attempting to resolve Purdue's financial liability to the federal government by forcing state and local governments to assume an indefinite obligation to direct the operations of an opioid manufacturer.

On October 14, 2020, 25 state Attorneys General wrote to you explicitly asking DOJ not to mandate that Purdue be preserved as a public benefit company. As policymakers, we agree with the states' argument that the public trust proposal creates the potential for, or at the least the appearance of, a conflict of interest between a state's ownership interest in the public trust and its law enforcement obligations. The proper role of government in the production of prescriptions opioids is to enforce regulatory compliance, prevent diversion, and hold perpetrators liable for violations. An ownership interest in the production of OxyContin would mean that states may be forced to balance these enforcement interests with their interest in the products or revenue produced by the public trust. Moreover, entangling government with this company may also create conflicts and doubts regarding the government's ability to regulate other companies in the industry that are its suppliers, customers, and competitors. This apparent conflict will undermine the public's faith in state enforcement activity.

Never in American history have federal courts used the bankruptcy process to achieve this outcome. That is why there is so much confusion and uncertainty about how this public benefit corporation will operate. No one knows the answers to simple questions like: Who would sit on the board of directors? Who would receive the profits from the sale of OxyContin? How would profits be distributed? These are questions of policy that must be resolved by Congress, not the courts. But Congress has never addressed these issues because state ownership of private business has never been considered an appropriate outcome of bankruptcy proceedings. To force the court to create this new bankruptcy outcome would set a dangerous precedent.

Finally, injecting this novel and confusing issue into an already complex bankruptcy process will only further delay the financial assistance state and local governments need to respond to the harms caused by Purdue's illegal actions. Final resolution of Purdue's bankruptcy will be delayed, not only by forcing the court to create an entirely new legal framework for the operation of a public benefit corporation, but also by the appeals that will inevitably flow from the opposition of half the states.

The solution to this problem is simple: reject the Sackler family's public relations strategy to fabricate a novel legal solution and allow the court to conclude the bankruptcy process by selling Purdue Pharma to a new private owner. While following established bankruptcy law may reduce the settlement headlines, it will hasten financial assistance to the victims of the Sackers' crimes, it will prevent states from maintaining an indefinite association with OxyContin, it will ensure impartiality in government enforcement actions, and it will help maintain the public's trust that the rules were not bent to protect billionaires.

Thank you for your attention to this important matter.

Sincerely,

Katherine Clark
Member of Congress

Hal Rogers
Member of Congress

Ann McLane Kuster
Member of Congress

David Trone
Member of Congress

Gilbert R. Cisneros, Jr.
Member of Congress

Barbara Lee
Member of Congress

Ayanna Pressley
Member of Congress

James P. McGovern
Member of Congress

Stephen F. Lynch
Member of Congress

Jahana Hayes
Member of Congress

Joseph P. Kennedy, III
Member of Congress

André Carson
Member of Congress

Brian Fitzpatrick
Member of Congress

Peter Welch
Member of Congress

Bill Foster
Member of Congress

Mark DeSaulnier
Member of Congress

Rosa L. DeLauro
Member of Congress

David B. McKinley, P.E.
Member of Congress

Marcy Kaptur
Member of Congress

Jim Himes
Member of Congress

Joe Courtney
Member of Congress

Joe Neguse
Member of Congress

John P. Sarbanes
Member of Congress

John B. Larson
Member of Congress

William R. Keating
Member of Congress

Jason Crow
Member of Congress

Lori Trahan
Member of Congress

Lucille Roybal-Allard
Member of Congress

Bobby L. Rush
Member of Congress

Peter A. DeFazio
Member of Congress

Jan Schakowsky
Member of Congress

Kathy Castor
Member of Congress

Katie Porter
Member of Congress

Madeleine Dean
Member of Congress

Chris Pappas
Member of Congress

Zoe Lofgren
Member of Congress

Angie Craig
Member of Congress

David N. Cicilline
Member of Congress

Max Rose
Member of Congress

Jackie Speier
Member of Congress

Gerald E. Connolly
Member of Congress

Pramila Jayapal
Member of Congress

Tony Cárdenas
Member of Congress

Ted W. Lieu
Member of Congress

Raja Krishnamoorthi
Member of Congress

Suzanne Bonamici
Member of Congress

United States Senate
WASHINGTON, DC 20510

November 10, 2020

The Honorable William Barr
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Ave. NW
Washington, D.C. 20530

Dear Attorney General Barr:

We write to raise concerns about a key element of the Department of Justice's (DOJ) settlement agreement with Purdue Pharma (Purdue) announced on Wednesday, October 21, 2020. We ask that you defer court approval of the proposed agreement until the appropriate stakeholders have addressed public policy concerns associated with the agreement which all but requires Purdue to emerge from bankruptcy as a public benefit company (PBC), to function "entirely in the public interest," with proceeds directed toward State and local governments.[1] This arrangement ignores the objections of many of the States themselves, who have no interest in owning or operating a company that has devastated their communities with dangerous opioids, and raises significant public policy concerns. [2]

Purdue and the Sackler family are the driving force behind the inclusion of the PBC in the agreement, and had proposed that it be included during the company's ongoing bankruptcy proceedings.[3] Allowing Purdue to emerge from bankruptcy as a PBC would enable it to shed its liability while continuing to manufacture and sell opioids, with its creditors—including state and local governments who have sued Purdue for the harms it caused—owning a stake in its profits.

This proposal was rejected by Attorneys General from 25 States because "the public deserves assurance that no opioid business is given the special protection of being placed under a public umbrella."[4] These States are adamant that Purdue should be sold to a private buyer—which is the regular result of bankruptcy proceedings.

[1] Department of Justice, Office of Public Affairs. "Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family". 21 October 2020. *Accessible at*: https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid

[2] Mike Spector. "U.S. states oppose settlement being negotiated by OxyContin maker Purdue and Justice Department: letter". Reuters. 14 October 2020. *Accessible at*: https://www.reuters.com/article/us-purdue-pharma-opioids-investigations/u-s-states-oppose-settlement-being-negotiated-by-oxycontin-maker-purdue-and-justice-department-letter-idUSKBN26Z2WJ

[3] Berkley Lovelace Jr., Purdue Pharma chair: Best Way To Fight Opioid Crisis Is For OxyContin Maker to Stay in Business, CNBC, 16 September 2019, *accessible at*: https://www.cnbc.com/2019/09/16/purdue-pharma-chairman-steve-miller-on-bankruptcy-of-oxycontin-maker.html

[4] Becerra et al. "Letter to Attorney General Barr". Attorneys General from CA, HI, CO, ID, CT, IL, DE, IA, DC, ME, MD, MA, OR, PA, MN, RI, NV, NH, VT, VA, NJ, WA, NY, WI, NC. 14 October 2020. *Accessible at*: https://www.mass.gov/doc/october-14-2020-letter-to-attorney-general-barr/download

Despite these objections, DOJ moved forward with its proposed settlement, which would allow Purdue to withdraw from the agreement—including retracting its criminal pleas—if it does not become a PBC. In doing so, DOJ is effectively imposing these terms on all of the stakeholders in the bankruptcy proceeding.

This is an inappropriate use of federal authority, and DOJ's decision to acquiesce to Purdue's PBC proposal is puzzling for several reasons.

First, Purdue is in bankruptcy because it has been sued for its illegal conduct and its role in the ongoing opioid crisis. In fact, a review of internal company documents makes quite clear that the company's primary goal was to maximize its profits by selling as many addictive opioids as possible, regardless of the harm to patients or laws standing in the way.[5] DOJ's own plea agreement with Purdue corroborates this view of the company's goals.[6] Nevertheless, DOJ is forcing this unorthodox arrangement on objecting states, even though it is unclear how a company with such a history will be transformed into "function[ing] entirely in the public interest."

Second, DOJ is not serving the interests of the public by agreeing to Purdue's proposal. The plan allows Purdue to inflate the value of the settlement by relying on its own rosy analysis of the company's value and promising to pay the terms of a settlement out of the future profits of the company. States would get less money immediately and, because these profits are uncertain, may never recover the full value of the settlement. At a minimum, the PBC also creates the appearance of a conflict of interest, as citizens may wonder whether their government will effectively regulate a company in which it has a financial interest. In a worst case, aligning the financial interests of States with the increasing sale of opioids, which is the very reason the lawsuit was brought against Purdue in the first place, could significantly and, negatively impact public health.

Finally, the PBC provision, and other aspects of the proposed plea agreement are unusual and highly favorable to Purdue. When Insys Therapeutics declared bankruptcy due to its role in fueling opioid epidemic, the company was not restructured as a PBC, but sold to a private buyer.

Similarly, while the Sackler family reportedly extracted as much as $13 billion from the company and placed it into a web of personal accounts and trusts, some in offshore tax havens, DOJ has agreed to settle its federal civil claims against them for only $225 million. The low settlement amount is particularly troubling because the investigation into the Sackler family's misconduct is ongoing, and scheduled depositions of several members of the Sackler family may reveal additional information about the scope of their scheme.

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[5] House Committee on Oversight and Government Reform. "Maloney and DeSaulnier Release Documents Following DOJ Settlement with Purdue and Sackler Family". Press Release. 27 October 2020. *Accessible at*: https://oversight.house.gov/news/press-releases/maloney-and-desaulnier-release-documents-following-doj-settlement-with-purdue

[6] Department of Justice. "Re: Plea Agreement with Purdue Pharma L.P.". United States Attorney, District of New Jersey. 20 October 2020. Accessible at: https://www.justice.gov/opa/press-release/file/1329576/download

The agreement also appears consistent with the troubling practice of this Administration of timing public actions in major cases to have maximum political benefit to the President. These facts suggest that the government is not entitled to a presumption of regularity in these proceedings.

Regrettably, DOJ's position appears consistent with the historical leniency it has shown to Purdue and members of the Sackler family. Some of us have raised these concerns in previous letters, without receiving a satisfactory response.

DOJ should not require the States, who are attempting to rectify the harm Purdue has done to their communities, to lead Purdue's public benefit "repurposing" campaign and take part in an enterprise that has contributed to thousands of American deaths. Given that this plan originated with Purdue and its owners, the Sackler family, it is more likely that its transformation to a PBC will function as a rebranding opportunity for the company and the family's public image. This is not justice for the families that have lost loved ones.

We therefore ask that you defer court approval of the proposed agreement until the appropriate stakeholders have addressed these public policy concerns. Such an arrangement—requiring States to own and operate a felonious company they are currently suing—is a misuse of federal authority.

Sincerely,

Tammy Baldwin
United States Senator

Sheldon Whitehouse
United States Senator

Margaret Wood Hassan
United States Senator

Elizabeth Warren
United States Senator

Jeanne Shaheen
United States Senator

Charles E. Schumer
United States Senator

Richard Blumenthal
United States Senator

Dianne Feinstein
United States Senator

Richard J. Durbin
United States Senator

Edward J. Markey
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Mazie K. Hirono
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Amy Klobuchar
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Tina Smith
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CHARLES D. BAKER
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KARYN E. POLITO
LIEUTENANT GOVERNOR

November 9, 2020

The Honorable William P. Barr
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Ave. NW
Washington, D.C. 20530

Dear Attorney General Barr:

As Governor of Massachusetts, I write to express my concern and opposition to the Department of Justice's proposed settlement with Purdue Pharma and the Sackler Family. Under the terms of this settlement, as I understand were proposed by the Sackler family, Purdue would be converted into a public benefit company owned by state and local governments, which would make these governments the beneficiaries of the company's continuing sale of OxyContin. The settlement also does not require the Sackler family to admit any wrongdoing.

Throughout the Commonwealth, I have met countless families whose lives have been ruined by the drug that the Sackler family made their fortunes on. It has caused immeasurable harm to the infants and children who lost a parent to addiction, and to the parents and families who have lost their children and loved ones. Massachusetts has been hit particularly hard by the opioid epidemic. Opioid-related death have increased more than 500% since 2000. In 2014, Massachusetts had one of the highest rates of deaths from opioids in the nation and one of the highest incidences of infants born with Neonatal Abstinence Syndrome and Substance Exposed Newborn. Addiction continues to be the primary reason why children enter our state's child welfare system.

Much of this harm can be traced directly back to Purdue Pharma and its aggressive and deceptive promotion "of opioids to health care providers that the company knew were prescribing opioids for uses that were unsafe, ineffective and medically unnecessary, and that often led to abuse and diversion," in the words of the Department of Justice's settlement announcement. The Massachusetts Attorney General has shown that at least 670 Commonwealth residents prescribed Purdue opioids died of overdose. This settlement, which does not require the Sackler family to admit any wrongdoing, would not do justice for their losses.

I join the Massachusetts Attorney General and 24 other Attorney Generals in their opposition to your proposal to convert Purdue into a public benefit company. Under this scheme, the Commonwealth's compensation and restitution for all of the harms that Purdue wrought on our communities and citizens depends on the continuing sales of the addictive drug that caused them in the first place. This means that governmental entities that are looking for resources to invest in treatment, recovery, and prevention would essentially be rooting for more sales of OxyContin, in the United States and abroad. Such a resolution is counterproductive and perverse, resulting in more families suffering as their loved ones battle opioid addiction.

I join with Attorney General Healey in asking you, in the interest of justice and accountability, to reconsider the terms of your settlement.

Sincerely,

Charles D. Baker
Governor

Cc: Attorney General Maura Healey

PROP
Physicians for Responsible Opioid Prescribing

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December 2, 2020

Honorable Robert Drain
United States Bankruptcy Judge
United States Bankruptcy Court
Southern District of New York
300 Quarropas Street
White Plains, New York 10601-4140

Re: Purdue Pharma L.P., et al, Case No. 19-23649 (RDD)

Dear Judge Drain:

In Doc. No. 2045 (*Motion of Debtors for Entry of a Third Order Extending the Exclusive Periods Within Which to File a Chapter 11 Plan and Solicit Acceptances Thereof*) Purdue Pharma requested an extension, in part, to develop the "contours of the structure and governance of the successor entity to which the Debtors' assets will be transferred[.]"[1] Physicians for Responsible Opioid Prescribing (PROP) is respectfully submitting a letter to the Court regarding this successor entity.

At the last hearing, the Court directed the parties to "negotiate a plan that has an appropriate exit structure" and indicated that the "guiding imperative" for such a plan is the "public interest" and "resolving the opioid crisis."[2] PROP is writing to share our perspective with the Court on the potential negative public health impact of preserving Purdue's business as a public benefit company (PBC).

PROP is a non-profit professional organization founded in 2010 to address the opioid crisis. Our education and advocacy efforts are focused on reducing opioid-related morbidity and mortality by promoting more cautious opioid prescribing. Our members include clinicians and researchers in the fields of Primary Care, Pain Medicine, Addiction Medicine, Anesthesiology, Emergency Medicine, Public Health, Internal Medicine, Rheumatology and other specialties.

Purdue Pharma has argued that the new entity it proposes would positively impact the opioid crisis by making buprenorphine for opioid addiction treatment more accessible. We disagree. The primary barrier to opioid addiction treatment with buprenorphine has little to do with the cost of the medication. Rather, it is a lack of clinicians eligible to prescribe buprenorphine that is impeding access to treatment. Only about 5% of eligible clinicians have obtained the federal waiver required to treat

[1] Purdue Pharma L.P., et al, Case No. 19-23649 (RDD). Doc. No. 2045 (*Motion of Debtors for Entry of a Third Order Extending the Exclusive Periods Within Which to File a Chapter 11 Plan and Solicit Acceptances Thereof*); Page 2.
[2] Purdue Pharma L.P., et al, Case No. 19-23649 (RDD). Hearing transcript from November 17, 2020; Page 247.

opioid addiction with buprenorphine.[3] Free buprenorphine provided by a PBC would not impact this barrier.

We are deeply concerned that the proposed PBC would receive funding from ongoing sales of opioid analgesics because this creates a conflict of interest that is harmful to public health. Despite a recent trend toward more cautious opioid use, the United States continues to consume far more prescription opioids per capita than other countries.[4] Organizations with a mission to address the opioid crisis should work to reduce overprescribing of opioids. If the proposed PBC benefits financially from ongoing opioid sales it would have a perverse incentive to maintain a high volume of opioid sales.

PROP fully supports the sale of Purdue Pharma's pharmaceutical assets to other pharmaceutical companies, such that proceeds from the sale of these assets are made available for abating the opioid crisis. However, we would oppose an asset sales agreement that relies on royalty payments from ongoing opioid analgesic sales because this would create a conflict of interest between the need for funds to address the crisis and the need to reduce opioid analgesic consumption. The medical community and the public should be able to trust that efforts to address the opioid crisis are not impeded by potential conflicts of interest.

Thank you for considering our concerns. If you have any questions or if we can be of any assistance to the Court, please let us know.

Sincerely,

Andrew Kolodny, MD
Executive Director
Physicians for Responsible Opioid Prescribing

[3] Haffajee RL, Bohnert ASB, Lagisetty PA. Policy pathways to address provider workforce barriers to buprenorphine treatment. Am J Prev Med. 2018;54:S230-S242; Andrilla CHA, Moore TE, Patterson DG, Larson EH. Geographic distribution of providers with a DEA waiver to prescribe buprenorphine for the treatment of opioid use disorder: A 5-Year Update. J Rural Health. 2019;35:108-112.

[4] Kaafarani HMA, Han K, El Moheb M, et al. Opioids After Surgery in the United States Versus the Rest of the World, Annals of Surgery: December 2020 - Volume 272 - Issue 6 - p 879-886.

University at Buffalo
The State University of New York
College of Arts and Sciences
Department of History

December 12, 2020

Honorable Robert Drain
United States Bankruptcy Judge
United States Bankruptcy Court
Southern District of New York
300 Quarropas Street
White Plains, New York 10601-4140

Re: Purdue Pharma L.P., et al, Case No. 19-23649 (RDD)

Dear Judge Drain:

Purdue Pharma has requested an extension of the deadline for submission of a bankruptcy plan in Doc. No. 2045 (Motion of Debtors for Entry of a Third Order Extending the Exclusive Periods within Which to File a Chapter 11 Plan and Solicit Acceptances Thereof). At a previous hearing the Court instructed the parties to "negotiate a plan that has an appropriate exit strategy" and that "resolving the opioid crisis" and "the public interest" should be the guiding principles of such a plan. We respectfully submit this letter regarding the development of this plan.

We are both historians who have written extensively on the pharmaceutical industry, drug addiction, and related topics. David Herzberg is Associate Professor at the University at Buffalo-State University of New York. Joseph M. Gabriel is Associate Professor at the Florida State University College of Medicine. Our scholarship has won national awards and has been widely recognized as both deeply researched and innovative. Between us we have published four books and more than twenty-five scholarly articles and book chapters on the history of pharmaceuticals and related topics. The Court recently referred to Herzberg's book *White Market Drugs* as "the most comprehensive and up-to-date history on this issue."[1]

We are honored that the Court has consulted the work of pharmaceutical historians, and we agree that greed in the pharmaceutical industry has been the primary cause of a long series of public health crises. As noted by the Court, our scholarship has led us to believe that nationalization or other far-reaching

[1] David Herzberg, *White Market Drugs: Big Pharma and the Hidden History of Addiction in America* (University of Chicago Press, 2020). See also David Herzberg, *Happy Pills in America: From Miltown to Prozac* (The Johns Hopkins University Press, 2010); Matthew Crawford and Joseph M. Gabriel, eds., *Drugs on the Page: Pharmacopeias and Healing in the Early Modern Atlantic World* (University of Pittsburgh Press, 2019); Joseph M. Gabriel, *Medical Monopoly: Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry* (University of Chicago Press, 2014).

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reforms should be considered as ways to minimize the malign effects of this greed. We do not, however, believe that turning Purdue Pharma into a public benefit corporation will be effective in mitigating the opioid crisis or promoting the public interest.

History suggests that the proposed transformation of Purdue will not advance the public interest for two main reasons:

- First, historical precedent suggests that the new Purdue is unlikely to thrive and produce the desired revenue. Systemic changes in pharmaceutical markets over the past century have made it unlikely that a declining company remade into a public benefit corporation will survive.
- Second, transforming one relatively small company will not address the systemic problems in the pharmaceutical industry that enabled—or even encouraged—Purdue's bad behavior. History makes clear that Purdue is not an outlier; its practices have been all too common among other companies. Transforming Purdue will not meaningfully address these broader problems.

In this letter we provide evidence and reasoning for these two propositions. In the interest of being constructive, we also respectfully submit for the Court's consideration several historically-informed ways that Purdue's assets might be directed towards strategies that will promote the public interest in abating the opioid crisis—and preventing the next one.

PURDUE'S MISDEEDS, AND THE OPIOID CRISIS MORE GENERALLY, ARE A CONSEQUENCE OF PHARMACEUTICAL COMPANIES' INCREASING PRIORITIZATION OF PROFIT OVER THE COURSE OF THE 20TH CENTURY

Reputable pharmaceutical companies have not always risked public health in pursuit of profit. The origins of today's pharmaceutical industry lie in the 19th century with a small group of drug companies who defined themselves by their commitment to the AMA's Code of Medical Ethics. Historians refer to these companies as "ethical" drug manufacturers. Following the Code, these companies sold only known, proven, unpatented drugs and did not advertise to the public. This ethical restraint restricted their share of a drug market dominated by hyper-advertised "patent" medicines, and thus limited their profits, but it deepened their connection to professional medicine and scientific research undertaken for public benefit.[2]

Over the course of the 20th century, "ethical" pharmaceutical companies increasingly prioritized profits and drug marketing became a core business strategy. In the 20th century, "ethical" pharmaceutical manufacturing developed into a highly competitive and regulated market in which success depended on developing new products likely to return high profits. This raised the value of "me-too" drugs that were not always well-matched with a social need and which often did not bring significant new clinical benefit. Indeed, sometimes "innovative" products were substantially *worse* than similar products already on the market.[3] Unable to produce a steady stream of miracles, the industry invested in the next best thing: a

[2] Joseph M. Gabriel, *Medical Monopoly: Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry* (University of Chicago Press, 2014).
[3] Jonathan J. Darrow and Aaron S. Kesselheim, "Nearly One-Third of New Drugs are No Better than Older Drugs, and Some are Worse" *Health Affairs* (Oct. 6, 2016); Milton M. Silverman and Philip R. Lee, *Pills, Politics, and*

deluge of marketing. Most of this marketing targeted physicians and other clinicians through "detailing," direct mail advertising, sponsorship of conferences, and other means. Some of it has also been directed at the general public.[4] Over the course of the 20th century, the imperatives of marketing have crept ever earlier in the research and development process, shaping medicines' trajectory from the first moments of interaction between scientists and molecules.[5]

Drug marketing increases drug risks. The ancient Greek word "pharmakon" can be translated as both "remedy" and "poison." Even useful medicines can be dangerous and expose patients (and in the case of opioids, their friends and families) to significant risk. Marketing intensifies those risks: evidence suggests that the more a drug is advertised the greater the iatrogenic (medically-caused) harm.[6] This has been borne out by a series of preventable public health crises linked to drug marketing over the course of the 20th century, both in the United States and across the world. One infamous example is the sale of the tranquilizer/anti-nausea drug thalidomide in the late 1950s and early 1960s, which led to the deaths of about 2,000 children and serious birth defects in more than 10,000 children worldwide (the drug was only prevented from entering the US market due to the heroic efforts of FDA employee Frances Kelsey).[7] Thanks in part to continued expansion of pharmaceutical marketing, harms related to use of prescription drugs are a major public health problem in the U.S. today.[8]

Profits (University of California Press, 1974). For the early twentieth-century, see Gabriel, *Medical Monopoly*, esp. Chapt. 6.

[4] Jeremy A. Greene and David Herzberg, "Hidden in Plain Sight: Marketing Prescription Drugs to Consumers in the Twentieth Century" *American Journal of Public Health* 100 (2010), 793-803.

[5] Bennett Harvey Holman, *The Fundamental Antagonism: Science and Commerce in Medical Epistemology* (Ph.D. dissertation, University of California, Irvine, 2015); Jean-Paul Gaudilière and Ulrike Thomas (eds.), *The Development of Scientific Marketing in the Twentieth Century: Research for Sales in the Pharmaceutical Industry* (New York: Routledge, 2016); Jean-Paul Gaudilière, "From *Propaganda* to Scientific Marketing: Schering, Cortisone, and the Construction of Drug Markets," *History and Technology* 29 (2013): 188-209; Jeremy Greene, *Prescribing by Numbers: Drugs and the Definition of Disease* (Baltimore: The Johns Hopkins University Press, 2006).

[6] Howard Brody and Donald Light, "The Inverse Benefit Law: How Drug Marketing Undermines Patient Safety and Public Health," *American Journal of Public Health* 101 (2011): 399-404.

[7] Carpenter, *Reputation and Power*, Chapter Four. Another example is the early broad spectrum antibiotic chloramphenicol in the 1950s, which caused severe and fatal aplastic anemia in some patients. Scott Podolsky, *The Antibiotic Era: Reform, Resistance, and the Pursuit of a Rational Therapeutics* (Johns Hopkins University Press, 2015). More recent examples include the Fen-phen (fenfluramine/phentermine) tragedy of the 1990s and the Vioxx (rofecoxib) tragedy of the early 2000s. See Harlan M. Krumholz, Joseph S. Ross, Amos H. Presler, and David S. Egilman, "What Have We Learned from Vioxx?" *BMJ* 324 (2007), 120 - 123; Tom Nesi, *Poison Pills: The Untold Story of the Vioxx Drug Scandal* (St. Martin's Press, 2008); Alicia Mundy, *Dispensing with the Truth: The Victims, the Drug Companies, and the Dramatic Story Behind the Battle Over Fen-Phen* (St. Martin's Press, 2001).

[8] Some studies suggest that just the medically-approved use of prescription drugs (i.e., not including un-approved use such as opioid pills used by friends or family of the person to whom they were prescribed) is between the fourth and sixth leading cause of death in America; see Brian Chen, John Restaino, and Elizabeth Tippett, "Key Elements in Adverse Drug Reactions Safety Signals: Application of Legal Strategies" *Cancer Policy: Pharmaceutical Safety* (Springer, 2019); Donald Light, Joel Lexchin, and Jonathan J. Darrow, "Institutional Corruption and the Myth of Safe and Effective Drugs," *Journal of Law, Medicine, & Ethics* 41 (2013): 590-600; J. Lazarou, B.H. Pomeranz, and P. N. Corey, "Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-Analysis of Prospective Studies" *JAMA* 279:15 (1998), 1200-5.

Addiction has long been one of the risks tied to drug marketing. This has been the case with addictive drugs over the course of the twentieth-century. As Herzberg documents in *White Market Drugs*, the U.S. has suffered three major waves of marketing-driven addiction crises. The first involved pharmaceutical opioids and cocaine from the late 19th century to the early 20th century; the second involved pharmaceutical sedatives (barbiturates, benzodiazepine tranquilizers) and stimulants (amphetamine) from the 1930s to the 1970s; and the third involved pharmaceutical sedatives, stimulants, and opioids in the late 20th and early 21st centuries. In all three waves, aggressive marketing spurred dangerous overuse of addictive medicines with catastrophic consequences. As we describe below, unethical and illegal forms of marketing have also been a significant part of this broader process. The Sackler family has been a pioneer of all kinds of pharmaceutical marketing since the end of World War II, but they did not invent it and nor were they its sole practitioners.

UNETHICAL DRUG MARKETING HAS ALSO INCREASED DURING THE 20th CENTURY AND HAS HARMED THE PUBLIC INTEREST

Pharmaceutical companies increasingly engaged in unethical or fraudulent marketing practices over the course of the 20th century. As "ethical" pharmaceutical companies intensified their marketing campaigns, they increasingly engaged in unethical and sometimes illegal forms of drug promotion.[9] The Sackler family has been a leader in this trend, pushing the boundary on acceptable marketing practices and helping to ignite not only the current opioid crisis but also an earlier crisis of tranquilizer addiction and overdose in the 1960s and 1970s (a period during which Valium was the leading cause of drug-related ER visits and fatal overdose).[10] However, the Sacklers did not stand alone. Rather, they were unusually successful examples of broader problematic developments, as evidenced (for example) by the large number of criminal and civil complaints against pharmaceutical companies over the past thirty years.[11]

Unethical and illegal tactics for promoting medicines have corrupted medical knowledge and practice. Numerous physicians, scholars, investigative journalists, and other researchers have described how pharmaceutical manufacturers bend clinical decision making to their own ends through aggressive efforts to promote their goods, sometimes by corrupting the scientific process.[12] Not all of these efforts are illegal, or even necessarily unethical, but many are. These activities can be grouped into the following three broad categories: illegal marketing and other illegal behaviors; ethically dubious but not necessarily illegal marketing; and legal but unethical manipulation of scientific practice and publishing (Appendix

[9] Joseph M. Gabriel and Bennett Holman, "Clinical Trials and the Origins of Pharmaceutical Fraud: Parke, Davis & Company, Virtue Epistemology, and the History of the Fundamental Antagonism" *History of Science* (2020)
[10] Patrick Radden Keefe, "The Family that Built an Empire of Pain," *New Yorker*, October 23, 2017; David Herzberg, *Happy Pills in America: From Miltown to Prozac* (Johns Hopkins University Press, 2009), Chapter Four.
[11] According to Public Citizen, between 1991 and 2017 alone drug makers entered into more than 400 federal and state settlements resulting in criminal and civil penalties totaling $38.6 billion. A large portion of these settlements were related to illegal forms of marketing and promotion. Sammy Almashat, Ryan Lang, Sidney M. Wolf, and Michael Carome, *Twenty-Seven Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2017* (Public Citizen, 2018)
[12] There is an extensive literature documenting this. Two excellent overviews are Ben Goldacre, *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients* (New York: Farrar, Straus and Giroux, 2013) and Carl Elliot, *White Coat Black Hat: Adventures on the Dark Side of Medicine* (Boston: Beacon Press, 2010)

provides a list for each category). Commenting on the deleterious effect of these activities, in 2009 a former editor-in-chief of the *New England Journal of Medicine* lamented that "it is no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative guidelines."[13]

There is abundant evidence that illegal and ethically dubious forms of drug promotion harms patients.[14] Off-label drug use and adverse drug reactions are correlated, for example, raising concerns about illegal advertising intended to increase off-label prescriptions.[15] The manipulation of the scientific process, including the publication of misleading ghostwritten articles, undermines the reliability of the clinical literature and also harms patients. One recent independent re-analysis of the raw data from a clinical trial of antidepressants in adolescents concluded that neither of two major drugs (paroxetine and imipramine) were more effective than placebo, and that both increased harms. The original ghostwritten publication discussing SmithKline Beecham's now-infamous Study 329 said the exact opposite. This deceptive article has been cited at least 796 times and has not been retracted.[16]

HISTORY SUGGESTS TURNING PURDUE INTO A PUBLIC BENEFIT CORPORATION WILL NOT ADDRESS THESE PROBLEMS

Because Purdue's greatest misdeed was to pioneer the use of these unethical and illegal activities in the promotion of a powerful opioid, true abatement requires correcting these corrupt practices, not just changing Purdue's behavior. Purdue's main innovation was the application of unethical and/or illegal marketing strategies to promote a powerful opioid. The company infamously deployed deceptive advertising, cultivated KOLs, manipulated professional practice guidelines, and otherwise bent scientific medicine to its own ends.[17] As Purdue racked up profits, other opioid manufacturers quickly joined in, following the same playbook. In other words, Purdue did not just sell dangerous products; it also sold a way of selling dangerous products. Abating the opioid crisis means addressing both of Purdue's misdeeds: abating the harms from the over-promotion of opioids, and abating the corrupt practices involved in over-promoting opioids. We do not think transforming Purdue into a public benefit corporation will accomplish these goals, for four reasons:

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[13] Marcia Angell, "Drug Companies & Doctors: A Story of Corruption" *New York Review of Books* (Jan. 15, 2009)

[14] Donald Light, Joel Lexchin, and Jonathan J. Darrow, "Institutional Corruption and the Myth of Safe and Effective Drugs," *Journal of Law, Medicine, & Ethics* 41 (2013): 590-600; Donald W. Light, ed., *The Risks of Prescription Drugs* (Columbia University Press, 2010).

[15] Antle Neubert, Harald Dormann, Jutta Weiss, Tobias Egger, Manfred Criegee-Rieck, Wolfgang Rascher, Kay Brune, and Burkhard Hinz, "The Impact of Unlicensed and Off-Label Drug Use on Adverse Drug Reactions in Paediatric Patients" *Drug Safety* 27 (2004), 1059-1067.

[16] Joanna Le Noury, John M. Nardo, David Healy, Jon Jueidini, Melissa Raven, Catalin Tufaru, and Elia Abi-Jaoude, "Restoring Study 329: Efficacy and Harms of Paroxetine and Imipramine in Treatment of Major Depression in Adolescence" *BMJ* 351 (2015), h4320. The original results were published as MArk B. Keller, et. al., "Efficacy of Paroxetine in the Treatment of Adolescent Major Depression: A Randomized, Controlled Trial" *Journal of the American Academy of Child & Adolescent Psychiatry* 40:7 (2001), 762-772. See also Leemon B. McHenry and Jon N. Jureidini, "Industry-Sponsored Ghostwriting in Clinical Trial Reporting: A Case Study" *Accountability in Research* 15:3 (2008), 152-67.

[17] Sergio Sismondo, *Ghost-Managed Medicine: Big Pharma's Invisible Hands* (Mattering Press, 2018), 1-39.

First, Purdue is no longer an influential force in opioid markets. Transforming the company into a public benefit corporation will have little impact on the market or on the behavior of other opioid manufacturers. Purdue's days of being an influential industry leader are almost certainly over. It is a relatively small and declining company (several major health insurance companies have recently dropped coverage of OxyContin, for example--a leading indicator of shrinking market share).[18] Purdue had an outsized role in the opioid crisis because it pioneered applying the pharmaceutical industry's dubious promotional practices to sell an opioid. Once other companies followed suit, however, the opioid market became crowded and highly competitive; Purdue's OxyContin was a significant but not dominant player (16% market share by some measures[19]). On top of that, the company's role in the opioid crisis has inflicted significant reputational harm that transforming it into a public benefit corporation is unlikely to repair. In short, even a reformed Purdue will not be able to undo the damage inflicted to industry ethics.

Second, the new public benefit corporation would be unlikely to generate the promised revenue. Based on historical examples, such as the failed experiment with Metopon detailed in *White Market Drugs*, we believe that non-commercial products are unlikely to succeed in a market organized around competition, promotion, and profit. Metopon was an opioid developed and marketed by the Federal Bureau of Narcotics in 1946 "follow[ing] principles of science and therapeutic reform rather than to hunt for profit." There was no splashy advertising, just sober pronouncements of the drug's qualities in peer-reviewed medical journals. Despite the support of the Federal Bureau of Narcotics and leading pharmacologists at the National Research Council, Metopon made no headway against better-advertised competitors. Sales were so disappointing that by 1950 the Bureau relinquished the patent to the public and ended the experiment.[20] We see little reason that the new public benefit corporation would not meet a similar fate. In fact, we suspect that it is likely to fail as a business enterprise not long after it is begun.

Third, Purdue's plan to remake itself as a provider of addiction treatment drugs such as buprenorphine is unlikely to succeed. Unlike other drugs such as insulin, cost has never been a significant barrier to patients' use of addiction treatment drugs. Thus, any savings created by public benefit corporation manufacturing (itself a dubious proposition in a market suffused with generics) would have little impact on treatment availability. The main barriers to greater availability of addiction treatment drugs has been skepticism, stigma, and fear on the part of policymakers, medical authorities, and the recovery community. Having a company with Purdue's bad reputation associated with addiction treatment drugs would worsen, not improve, those barriers.

Finally, transforming Purdue will send the wrong message to other pharmaceutical companies that the profits to be earned from bad behavior will exceed even the worst punishments. For nearly thirty years, pharmaceutical companies appear to have factored in settlements with the Department of Justice, states, and other parties as a cost of doing business. By protecting Sackler family assets, and by inviting the family company to continue to do business and indeed to rehabilitate its name, the proposed settlement shows that even the most egregious behavior will not result in consequences comparable in scope to the

[18] Blake Farmer, "Insurer to Purdue Pharma: We Won't Pay for OxyContin Anymore," Nashville Public Radio / Kaiser Health Network News, https://khn.org/news/insurer-to-purdue-pharma-we-wont-pay-for-oxycontin-anymore/
[19] David Armstrong and Jeff Ernsthausen, "Purdue Pharma touts data that downplay its role in the opioid epidemic, new analysis shows" *STAT* (Sept. 9, 2019).
[20] Herzberg, *White Market Drugs*, 115-120.

immense profits that can be made through illegal and unethical promotion and the manipulation of the clinical literature.

In sum, turning Purdue into a public benefit corporation will not serve the public interest, either in the narrow sense of abating the opioid crisis or in the broader sense of abating the pharmaceutical industry's long-standing ethical crisis.

RECOMMENDATIONS FOR ADDRESSING SYSTEMIC PROBLEMS

In an effort to be constructive, and after careful consideration of historical precedent, we believe that the following ideas would serve the purposes articulated by the Court to abate the opioid crisis and to promote the public interest by minimizing the influence of greed in the pharmaceutical industry.

Any settlement should include a significantly higher financial penalty for the Sackler family. As noted earlier, past financial penalties have not been large enough to deter the industry from unlawful and unethical behavior. The Sackler's penalty would be even less because the settlement allows them to shield most of their considerable fortune by shifting costs to the supposed future earnings of an unpromising company. Numerous people serve long prison sentences for crimes resulting in far less harm than what this family has done; their financial penalty should match their misdeeds.

The settlement should dissolve the company. While a company still exists, so does hope for success, future profit, and vindication. Eliminating Purdue ensures that it will remain as an infamous symbol of past misdeeds and consequential justice—a strong deterrent to bad behavior by other companies.

A portion of the settlement funds should be used to abate industry corruption of medical science and clinical decision making. We agree with the Court that we cannot eliminate greed but we can minimize its effects. The best way to do so, we contend, is to create strategies that move the industry closer to its original "ethical" behavior and sensibilities. Some promising ideas for doing so include the development of alternative models for incentivizing innovation, mandatory licensing of third parties for unduly expensive medications, and public manufacturing of essential medicines such as opioids. A variety of efforts along these lines are being considered or underway by states and other parties.[21]

Although such big picture solutions may be beyond the scope of the Court, we believe that decisions about Purdue's assets should be made with an eye towards these long-term goals. A crucial step, we believe, is to address the corrosive influence of illegal and unethical marketing on scientific practice and medical decision making. We therefore urge the parties who may be involved in abatement planning,

[21] Marisa Fernandez, "California Could Become First State to Produce Generic Drugs" *Axios* (Sept. 2, 2020); State of California Department of Justice, "Attorneys General Becerra and Landry Lead Bipartisan Coalition Urging Federal Government Action to Increase Access and Affordability of Remdesivir" (Aug. 4, 2020); "Vitale, Pou, Sweeney Bill to Limit Copayments for Insulin Advances" *InsiderNJ* (Nov. 16, 2020); "Fair Pharma? Intermountain's New Generic Drug Company" *NEJM Catalyst* (Feb. 1, 2018); Thomas Pogge, Matthew Rimmer, and Kim Rubenstein, *Incentives for Global Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, 2010)

including the Court, state Attorneys General, the federal government, cities and towns, and all others involved, to consider these and similar ideas:

- Support efforts to build robust alternatives to industry marketing
    - Support studies and pilot initiatives of academic detailing, an evidence-based form of clinical outreach conducted by noncommercial entities such as universities.
    - Fund pilot programs that connect local communities of clinicians to the best available sources of information through the development of collaborative relationships with medical libraries.
- Support efforts to build robust alternatives to industry-funded medical education and Continuing Medical Education by establishing funds for educational events that require receiving institutions to develop and implement robust conflict of interest policies.
- Support the development of solutions to dubious industry-academic relations by providing financial support for research units at universities dedicated to the study and resolution of industry-academic problems, including exploration of legal repercussions for academic physicians and other researchers who participate in corrupt activities.

Finally, it is critical that the emails and other documents held by Purdue over the course of its history enter the public domain. A portion of the settlement should be used to establish an archive of industry documents that scholars and other researchers can analyze in the future. Research on the tobacco industry, the oil industry, the lead industry, and other powerful industries has benefited tremendously from having access to internal industry documents, many of which have been made available through litigation.[22] Research on the pharmaceutical industry has benefitted as well. Industry documents that have entered the public domain as a result of legal settlements have revealed important information about product safety, industry advertising, and efforts by drug manufacturers to distort science toward their own ends.[23]

We believe that *the single most important asset Purdue possesses is the documentary evidence of its past behavior.* In our view any settlement should ensure that the public has full access to this record.

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[22] Lisa Bero, "Implications of the Tobacco Industry Documents for Public Health and Policy" *Annual Review of Public Health* 24 (2003), 267-288; Robert Proctor, *Golden Holocaust: Origins of the Cigarette Catastrophe and the Case for Abolition* (University of California Press, 2012); Naomi Oreskes and Erik M. Conway, *Merchants of Doubt: How a Handful of Scientists Obscured the Truth on Issues from Tobacco Smoking to Global Warming* (New York: Bloomsbury, 2010); Gerald Markowitz and David Rosner, *Lead Wars: The Politics of Science and the Fate of America's Children* (University of California Press, 2013). See also American Medicine and Public Health Historians and the Organization of American Historians, *Brief of* Amici Curiae *in Support of a Settlement Agreement Including Broad Transparency Provisions in the Interest of Future Research*, Case No. 1:17-MD-2804, U.S. District Court, Northern District of Ohio, "In re: National Prescription Opiate Legislation."

[23] For one important example, see Jon N. Jureidini, Jay D. Amsterdam, and Leemon B. McHenry, "The Citalopram CIT-MD-18 Pediatric Depression Trial: Deconstruction of Medical Ghostwriting, Data Mischaracterisation and Academic Malfeasance" *International Journal of Risk & Safety in Medicine* 28 (2016): 33-43. Jureidini et. al. examined more than 750 internal company documents related to Forest Pharmaceuticals' fraudulent marketing of two antidepressants in the early 2000s that were made available through litigation. The evidence demonstrates that the company made untruthful claims about the efficacy, and downplayed the risks, of citalopram in at least one ghostwritten article. The industry documents they analyzed can be found here: https://www.industrydocuments.ucsf.edu/drug/ For another example, see Michael A. Steinman, Lisa A. Bero, Mary-Margaret Chren, and Seth Landefeld, "The Promotion of Gabapentin: An Analysis of Internal Industry Documents," *Annals of Internal Medicine* 145 (2006): 284-293.

CONCLUSION

As historians of the pharmaceutical industry we have spent many years researching the behavior of companies that manufacture and sell medicines. Our work contributes to a large body of scholarship that explores how greed within the industry has led to significant harm, and that evaluates the successes and failures of past efforts to contain or minimize the impact of that greed. Based on our knowledge of this past record, we do not support transforming Purdue into a public benefit corporation. We do not believe it will accomplish the goals of abating the current opioid crisis or advancing the public good. We therefore urge the Court and the parties to seek a resolution that begins to address broader, systemic problems in the pharmaceutical industry exacerbated by Purdue's misdeeds. And finally, we would be happy to speak with the Court or with any interested parties about our scholarship or these suggestions.

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APPENDIX: EXAMPLES OF UNETHICAL AND ILLEGAL MARKETING

Illegal marketing and other illegal practices such as:

- Deceptive claims about safety and effectiveness
- Failing to disclose risks in advertising
- Providing kickbacks to physicians
- Promoting drugs for off-label use

Ethically dubious - but not necessarily illegal - marketing such as:

- Cultivating and financially supporting "key opinion leaders" (KOLs) through consulting payments and other means
- Paying physicians to speak about company products, sometimes providing company-written powerpoint presentations and other materials for their use
- Secret funding of patient advocacy groups to increase support for widespread use of products
- Investing in Continuing Medical Education (CME) and other "educational" activities

Unethical - but not necessarily illegal - manipulation of the scientific process such as:

- Manipulating scientific evidence to demonstrate effectiveness and conceal risks
- Manipulating the scientific literature through ghostwriting, declining to publish negative results, other means
- Funding clinical research primarily for advertising purposes
- Manipulating standards of care and other evidence-based treatment guidelines