



Purdue Pharma L.P.

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**Testimony of Dr. Craig Landau
CEO of Purdue Pharma L.P.**

Before the

**United States House of Representatives
Committee on Oversight and Reform**

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Chairwoman Maloney, Ranking Member Comer, distinguished members of the Committee: Thank you for the opportunity to be here today. I would also like to thank you and your staff for the professionalism of this investigation and for your willingness to accommodate Purdue with a different hearing date in light of our scheduled bankruptcy hearing earlier this week.

My name is Craig Landau. Since June 2017, I have been the President and CEO of Purdue Pharma L.P. (“Purdue”), a company that develops and manufactures prescription medications—including opioid pain medicines—as well as consumer health products. As a physician, I am acutely aware of both the life-changing relief that opioid medicines can provide patients debilitated by pain, and the terrible ravages of opioid use disorder.

I appreciate the Committee’s role in investigating matters of significant public interest, and I welcome the opportunity to discuss the opioid crisis and the steps Purdue is taking to help address it. I will answer your questions to the best of my ability, but first I would like to take a moment to acknowledge the awful toll the opioid crisis has taken on many individuals, families, and communities across America. Every death, every case of addiction, is an unspeakable tragedy for the victims, their families, and our society. Looking forward, I pledge that I will do everything I can to ensure that Purdue’s assets are used to deliver as much relief as possible, as soon as possible, to the victims of this public health crisis.

As members of this Committee know, three weeks ago, Purdue pled guilty to three felonies in federal district court. While I personally did not participate in, and was not at the time aware of, the problematic conduct that forms the basis of the company’s guilty plea, I want to speak in the clearest of terms: those actions were wrong, and, on behalf of Purdue, I am profoundly sorry. At all times, a careful balance must be struck between the effective care of patients with pain and the serious risks presented by opioid medicines. On this crucial point, Purdue fell short. The company accepts full responsibility for its past wrongdoing.

During my tenure as CEO, Purdue has taken a series of decisive steps, including, as outlined below, the elimination of the company’s entire opioid sales force and the discontinuance of opioid promotion and the last of the company’s opioid-related speakers programs. The company has also agreed to a broad voluntary injunction prohibiting a wide range of promotional and lobbying activities, with compliance overseen by an independent monitor. And we are working aggressively towards a plan that will lead to the creation of a new public benefit company focused on providing relief from the opioid epidemic.

My Background

I am an anesthesiologist by training. I spent my early career practicing medicine and treating patients in both the private practice and academic settings. During that time I also served as a physician in the U.S. Army Reserve Medical Corps for more than 14 years. My last deployment, in 2004 as part of “Operation Enduring Freedom,” was to Wuerzburg, Germany, where I provided clinical anesthesia and pain management care at the 67th Combat Support Hospital, in support of American forces serving in Iraq and Afghanistan.

Early on in my career, I was drawn to clinical research and the opportunity offered by the pharmaceutical industry to develop new medicines and address the needs of broad patient populations. Given my specialty training, experience, and interest, chronic pain was my primary focus. In 1999, after a brief stint helping develop medicines at another pharmaceutical company, I joined Purdue’s clinical research team as an Associate Medical Director in the research and development (“R&D”) department. Purdue had recruited me to assist in the development of an injectable non-opioid medication that, had Purdue been able to successfully develop it and obtain approval by the U.S. Food and Drug Administration (“FDA”), could have significantly reduced the need for opioid medication following surgery.

Over the next 14 years, my responsibilities within R&D expanded to include other disciplines, including Regulatory Affairs, Epidemiology, and R&D Innovation. Notable initiatives that I contributed to, led, or supervised include obtaining the approval by the FDA of Butrans (a buprenorphine transdermal patch), as well as reformulated OxyContin (a controlled-release formulation of oxycodone), which was designed to deter abuse by the intranasal and intravenous routes. The addition of abuse-deterrent features to opioid medicines was widely welcomed as an important advance. For example, in a March 11, 2013 letter to the FDA, 48 state and territorial attorneys general recognized that “[a]dding new physical and chemical features to prescription opioids to deter abuse could reduce misuse of these drugs and the sometimes deadly consequences,” thanked the FDA for its efforts to establish clear standards for manufacturers developing abuse-deterrent opioid medicines, and encouraged the FDA to assure that not only branded opioids but also generics are designed with abuse-deterrent features.

Additionally, I oversaw first-of-their-kind epidemiological studies, which ultimately demonstrated that, relative to the original formulation of OxyContin, the reformulation meaningfully reduced abuse by snorting and injection. I also played a leadership role in an industry working group that interfaced with the FDA, resulting in the creation and implementation of a drug safety program—called a Risk Evaluation and Mitigation Strategy (“REMS”)—for the class of extended-release and long-acting opioid medications. In that role, dating back to 2010, I supported mandatory training for all opioid prescribers, linked to Drug Enforcement Administration (“DEA”) registration.

In July 2013, I became President and CEO of Purdue Pharma in Canada, a separate entity from the U.S. entity, with separate management.

Four years later, in late June 2017, I returned to Purdue in the U.S. to serve as its President and CEO. My aim was to take a clear-eyed view of the serious challenges faced by the company and chart the best path forward, guided at all times by a commitment to doing the right thing. And indeed, during my tenure as CEO, the company has made many significant changes to its operations, including: assembling a new management team, accepting the resignations of the Sackler family from the Board of

Directors, ending the promotion (also known as “detailing”) of opioids by sales representatives to prescribers, eliminating the company’s opioid sales force, discontinuing the last of the company’s speaker programs relating to opioids, and ceasing sponsorship of all outside pain groups.

Other actions and initiatives I have directed since becoming CEO of the U.S. company include a significant reduction in operating expenses, a renewed focus on R&D, and a plan for diversifying the company’s future product portfolio to include therapeutics for certain cancers and disorders of the central nervous system. I have also prioritized the advancement of three programs intended to address specific and critical elements of the current opioid crisis: (1) the approval and availability of buprenorphine/naloxone for the treatment of opioid use disorder; (2) the development through a third-party non-profit pharmaceutical company of an over-the-counter version of intranasal naloxone for the treatment of acute opioid overdose with the goal of making overdose reversal medicine more affordable and more accessible; and (3) the development of an opioid overdose reversal medicine (injectable nalmefene), specifically targeting overdoses occurring as a consequence of exposure to highly potent synthetic opioids such as fentanyl and its analogues.

Finally, since September of last year, I have helped shepherd the company through the bankruptcy process, working towards the goal of preserving value and ultimately putting Purdue’s assets to work for the benefit of the American public to help abate the opioid crisis and save lives. At the time Purdue filed for bankruptcy, the company faced nearly 2,800 lawsuits filed in all 50 states. We developed a plan to deliver much-needed resources to state, local, and tribal governments to abate the opioid crisis, while avoiding the delay, expense, and value destruction that would result from endless litigation or a years-long bankruptcy process. Under this plan, which has garnered significant support, Purdue as we know it will cease to exist, and one hundred percent of its assets will be transferred to a public benefit company or similar entity. This settlement framework would provide more than \$10 billion in value to claimants and communities, including supplying, for free or at cost, millions of doses of lifesaving opioid addiction treatment and overdose reversal medicines to communities across America.

I am grateful to the current staff of Purdue, as well as the current Purdue Board and those outside professionals who have supported all of these efforts. This progress would not have been possible without them.

I will set out more details on the bankruptcy and the company’s resolution with the U.S. Department of Justice (“DOJ”) in a moment, but first, I would like to provide background on Purdue and its products.

Background on Purdue

Purdue is a highly regulated pharmaceutical company that manufactures, among other products, opioid medicines that are approved and regulated by the FDA and the DEA, and are prescribed by licensed clinicians to hundreds of thousands of Americans for the treatment of pain. As the FDA continues to recognize, these medicines provide critical relief for cancer patients and extremely ill patients under end-of-life care, as well as those suffering from serious chronic pain. But these medicines, even when used as directed, carry risks of addiction, abuse, overdose, and death. Indeed, many of these medicines—including

OxyContin—are classified by the DEA as Schedule II substances, meaning that they have a high potential for abuse.

Purdue, like the other manufacturers, distributors, and dispensers of lawful prescription opioids, sits at the center of a difficult but critically important societal question: how do we get the balance right between keeping pain medicines available to those who need them while mitigating the known risks of addiction, abuse, overdose, and death?

For many, “OxyContin” has become synonymous with oxycodone (the active pharmaceutical ingredient in OxyContin) or even, more generally, all opioids. This is a misunderstanding. The prescription opioid market is divided between immediate-release (“IR”) and extended-release (“ER”) opioid products. Purdue’s OxyContin, Hysingla, and Butrans are all ER opioids. The market, however, has long been dominated by IR opioids. For example, over a recent twelve-month period, IR opioids (including IR oxycodone) accounted for more than ninety percent of the prescriptions of opioid pain medications dispensed by retail pharmacies in the U.S., while ER opioids made up less than ten percent of all opioid prescriptions. Branded ER opioids, such as OxyContin, Hysingla, and Butrans, make up a still smaller percentage.

In 1995, the FDA approved OxyContin, the first extended-release formulation of oxycodone that allowed dosing every 12 hours instead of every 4 to 6 hours. Because of its ER properties, each OxyContin tablet contained higher amounts of oxycodone intended to be released over time using a time-released technology. Unfortunately, the time-released technology could be easily and quickly defeated by crushing the tablets. This released all of the oxycodone at one time, which could then be snorted or injected.

To help mitigate these risks, Purdue spent nearly a decade and hundreds of millions of dollars to reformulate OxyContin to make it more difficult to abuse by crushing, snorting, and injecting.

The FDA approved the reformulated product in 2010. In 2013, reformulated OxyContin became the first opioid to receive FDA-approved labeling concerning its abuse-deterrent properties. Abuse deterrence, however, is not a silver bullet. It does not prevent all abuse or reduce the risk of addiction in patients taking the medication as prescribed. Reformulated OxyContin’s label therefore continues to state that abuse of OxyContin by the intranasal, intravenous, and oral routes is possible, and, as has been the case since 2001, the label for OxyContin includes a “black box warning” that calls attention to serious, life-threatening, and fatal risks associated with the medicine. The current black box warning states that “OxyContin exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death.”

Soon after the Centers for Disease Control and Prevention (“CDC”) issued the “Guideline for Prescribing Opioids for Chronic Pain” in March 2016, Purdue actively worked to increase awareness of this government publication. Purdue also supports the Centers for Medicare and Medicaid Services’ mandate to limit the duration of initial opioid prescriptions for acute pain to no more than seven days. Additionally, as noted above, the company and I have long supported mandatory education for all prescribers of opioids.

Purdue today is a very different company from the Purdue of the past. We have made significant changes to our management, governance, oversight, and operations. It has been almost two years since any member of the Sackler family has served on the Board of Directors. In 2018, Purdue added a new

independent Chairman of the Board, followed in 2019 by three other highly qualified and previously unaffiliated directors with restructuring and pharmaceutical industry experience.

Following my appointment as President and CEO in mid-2017, we also restructured and significantly reduced Purdue's commercial operations. We eliminated the entire opioid sales force and focused instead on diversifying beyond the company's historic focus on pain medicines, while continuing to make opioids for patients who have a legitimate medical need for them. And last year, as part of the bankruptcy proceedings, Purdue entered into a broad voluntary injunction in which it agreed to continue to refrain from promoting opioids with a sales force (a measure the company first implemented, under my leadership, in February 2018) and to refrain from lobbying for the enactment of laws that might be construed as encouraging the prescribing of opioid products for the treatment of pain—ongoing commitments that are subject to independent monitoring.

Moving forward, Purdue is developing through internal research, strategic collaborations, and partnerships a portfolio of medicines including non-opioid pain medications and therapies for select oncology and central nervous system disorders. Purdue has also received FDA fast-track designation for injectable nalmefene, a much-needed treatment that has the potential to reverse overdoses from powerful synthetic opioids such as illicitly manufactured fentanyl, which, along with heroin, has contributed to the majority of opioid-related overdose deaths in recent years.

Bankruptcy Proceedings

In September 2019, Purdue announced an agreement in principle for a framework for settling the U.S. opioid litigation facing the company and resolving the nearly 2,800 lawsuits pending across the country. That same day, Purdue filed for reorganization under Chapter 11 of the U.S. Bankruptcy Code with the hope of consummating a global resolution of the pending litigation while conserving the assets of the company so that billions of dollars in value and vital treatments for opioid addiction and overdose can be delivered to state, local, and tribal governments.

Twenty-four state attorneys general and analogous officials of all five U.S. territories and commonwealths support the framework for a comprehensive resolution. The framework also has the unanimous endorsement of the Plaintiffs' Executive Committee appointed in the multidistrict litigation ("MDL") in federal court in Ohio, which is composed of attorneys representing more than 1,000 counties and municipalities, including cities, towns, villages, Native American tribes, individuals, and third-party payors, and is charged with coordinating approximately 2,000 MDL plaintiffs and multiple litigation tracks.

The settlement framework proposes to dedicate all of the assets and resources of Purdue to abating the opioid crisis for the benefit of the American public. This structure is estimated to provide more than \$10 billion of value to help address the opioid crisis. Included in the framework is the requirement that the Sackler family give up one hundred percent of their holdings in Purdue, sell their international pharmaceutical businesses, and pay at least \$3 billion in cash for distribution to Purdue's creditors. This framework is, as we speak, the subject of an ongoing mediation led by two of the most respected mediators in the country.

Purdue's assets would be transferred to a newly created public benefit company or similar entity. The new company would be governed by a new board selected by stakeholders as part of the plan of reorganization that must be approved by the bankruptcy court and would be subject to continuing restrictions against the promotion of opioid products to healthcare professionals. The Sacklers will have absolutely no role in the design, governance, or decision-making of the new company.

Purdue currently has more than 600 employees, including a team of scientists and others with technical expertise and extensive experience in developing medicines. Under the proposed resolution, this expertise and experience would be dedicated to the benefit of the American public. The proposed agreement contemplates that the new company would use a substantial share of its profits from the sales of its opioid and other products to develop and provide for free or at cost millions of doses of lifesaving opioid addiction treatment and overdose reversal medicines, which could significantly increase access to life-saving opioid addiction and overdose reversal medicines, consistent with the research and policies of the FDA and the National Institutes of Health.

Agreement with the U.S. Department of Justice

More recently, as I have already outlined, Purdue entered into an agreement with the DOJ to resolve multi-year criminal and civil investigations into the company's past practices related to its opioid medicines. Last month, the bankruptcy court approved the company's request for permission to enter into the DOJ resolution, and Purdue formally entered its plea in federal district court on November 24, 2020. Purdue's resolution with the DOJ is an essential step in taking responsibility for the company's past wrongdoing, and in submitting a plan of reorganization to the bankruptcy court that would resolve the claims against the company and transfer all of the company's assets to a newly-established public benefit company or similar entity.

I am aware that some have criticized the DOJ resolution and, more broadly, the settlement framework. But it is Purdue's strongly held view—which is shared by many public officials and a critical mass of states and other creditors representing more than half of the U.S. population—that its top priority must be delivering maximum resources as quickly as possible to communities affected by the opioid crisis. The company's proposed global resolution does that, directing billions of dollars and critical resources to communities impacted by the opioid crisis across the country, while avoiding wasting years and hundreds of millions of dollars on protracted litigation. Purdue is committed to working with state attorneys general and other stakeholders to finalize and then implement this resolution as quickly as possible.

Conclusion

I am grateful for the opportunity to participate in this vital public policy discussion, and I reiterate my pledge to do my utmost to ensure that Purdue's resources are directed to communities that desperately need them as soon as possible.

However, one prescription opioid manufacturer alone cannot end this public health crisis. Any meaningful solution must involve input from the full array of stakeholders, including public health officials, other manufacturers, health insurers, distributors, academics, regulators, legislators, law enforcement, the addiction and recovery community, physicians, pain patients, and advocates for people with the disease of addiction.

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I appreciate the Committee's leadership on, and commitment to, this critical public health issue and hope to continue the dialogue about ways in which all relevant stakeholders can help address the crisis.

I look forward to your questions.