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Perspective

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The Purdue Pharma Opioid Settlement — Accountability, or Just the Cost of Doing Business?

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The latest in a long series of legal challenges to actions taken by Purdue Pharma to increase prescriptions of its opioid medications has come to an end in the United States. Over the objections of numerous members of Congress, state attorneys general, and families of people killed by the company's opioid products, the company was permitted to resolve all federal criminal and civil charges and its owners, members of the Sackler family, were permitted to settle all federal civil claims against them.[1]

The November 2020 settlement was not Purdue's first. In 2007, the company pleaded guilty in federal court to illegally claiming that Oxycontin (oxycodone) was less addictive, less subject to misuse, and less likely to cause dependence and withdrawal symptoms than other pain medications. Purdue paid fines and penalties of approximately $600 million, and three corporate executives pleaded guilty to a single misdemeanor count and paid nearly $35 million in fines.[2]

Purdue has also settled numerous state legal challenges, all of which were resolved with only monetary penalties. Among other settlements, in 2007, the company agreed to pay $19.5 million to 26 states and the District of Columbia to resolve claims that it promoted Oxycontin for off-label use. In 2015, it reached a $24 million settlement with Kentucky over accusations that were nearly identical to the charges in the 2007 federal criminal case, and in 2019, it reached a $270 million agreement with Oklahoma to avoid trial on claims that it had deceptively marketed Oxycontin.

The activities to which Purdue pleaded guilty in 2020 occurred largely after Oxycontin was reformulated in 2010 to make it more difficult to misuse. This reformulation caused some people who had been misusing the drug to switch to other opioids, which substantially reduced Oxycontin prescribing. According to allegations in a separate civil settlement, members of the Sackler family, alarmed by the decrease in revenue associated with these changes, and undeterred by the 2007 settlement or the clear evidence that its products were implicated in a growing tide of preventable opioid-related deaths, pushed the company to increase sales.

According to the plea agreement, the company decided to concentrate its marketing efforts on practitioners who it knew were prescribing opioids that "were not

for a medically accepted indication, were unsafe, ineffective, and medically unnecessary, and/or were diverted for uses that lacked a legitimate medical purpose."[1] Those clinicians — who, despite accounting for less than 7% of all prescribers, together wrote more opioid prescriptions than the other 93% — were encouraged both to start more patients on opioids and to move patients currently taking opioids onto more expensive, higher-dose formulations. The company also paid kickbacks to some of the highest-prescribing practitioners, including approximately $475,000 to one physician who had been banned by Florida Medicaid but was the highest-volume Oxycontin prescriber in the entire Medicare program.

The company also repeatedly sent marketing representatives to the pharmacies used by its highest-volume prescribers, "including those that Purdue knew were writing medically unnecessary prescriptions, to ensure that Purdue opioids would be dispensed"[1] and paid kickbacks to three specialty pharmacies that dispensed prescriptions for Purdue's opioids that other pharmacies refused to fill. Finally, it conspired with an electronic health records company, Practice Fusion, to create alerts suggesting that Oxycontin and other opioids sold by Purdue be prescribed even when not medically necessary.

Purdue's punishment for these transgressions will be a criminal fine of approximately $3.5 billion, a civil fine of $2.8 billion, and $2 billion in forfeiture. In exchange, the federal government agreed not to pursue any other criminal charges against the company for its actions between May 2007 and October 2020. The Sacklers, who have reaped billions of dollars from Oxycontin sales,[3] agreed to pay $225 million in a civil settlement. No members of the Sackler family were charged or admitted to any criminal wrongdoing. Because the company is engaged in ongoing bankruptcy proceedings, it's unclear how much of the amount it owes under the agreement will ever be paid. The claims of hundreds of states, municipalities, and tribal entities against Purdue are ongoing, but it's also unclear whether funds will be available to cover financial liabilities that might arise from those lawsuits.

Although we can take some solace in knowing that Purdue's long course of illegal activity has most likely come to an end, we would be remiss if we failed to ask why it was permitted to go on for so long and why very few of the people involved have been held directly responsible for their actions. The company has admitted to conducting a sustained, illegal campaign to increase unsafe and medically unnecessary opioid prescribing. But companies don't make decisions — people do. Under the settlement agreement, none of the people who made decisions that contributed to the deaths of tens of thousands of people will face criminal penalties. Although the Sacklers will be responsible for paying a monetary settlement, the amount of that settlement is a small percentage of the profits they earned during the period in which Purdue was engaged in the illegal marketing of Oxycontin and other opioids.[3]

Most people involved in illegal drug activity don't get off so easy. More arrests are made in the United States for drug-law violations than for any other crime — including more than 1.5 million in 2019 alone[4] — and nearly half of all federal prisoners are serving time for a drug offense. As with most law-enforcement and criminal legal actions in the United States, these arrests and convictions fall disproportionately on poor people and people of color. State and local prosecutors have also convicted hundreds of people of "drug-induced homicide" for providing drugs that were implicated in overdose deaths. Why do these people face criminal penalties but pharmaceutical company executives and owners who knowingly unleashed millions of unnecessary and highly addictive pills into the market walk free?

The answer, of course, is money. Purdue and the Sacklers have a lot of it. The proceeds of the company's criminal activity were used to further increase profits at the expense of people in pain and people with substance use disorders.[5] It even hired Rudy Giuliani — at the time a well-respected and influential public figure — to help settle an investigation into illegal marketing of Oxycontin in Florida and to meet with the then-administrator of the Drug Enforcement Administration to prevent federal inquiries into the company's practices. Purdue has long been represented by some of the most storied law firms in the country (and those with the highest rates), and its efforts to increase opioid prescribing were partly informed by the major consulting firm McKinsey & Company.

Neither the 2020 settlement

nor Purdue's pending bankruptcy address the underlying problems of a health care system that all too often prioritizes profits over patients and a criminal legal system that grinds up the bit players while letting corporate kingpins off with fines that are viewed as simply the cost of doing business.

It's long past time to change the way that justice is carried out in the United States. People who commit drug crimes because of their substance use disorder should be given the treatment and resources they need. People who knowingly cause the suffering and deaths of others to line their already bulging pockets should be given the justice they deserve, including but not limited to personal responsibility for the repayment of all profits earned by means of illegal activities that occurred at their urging. These funds should go directly to the people and communities most affected by opioid-related harm and toward addressing its underlying social determinants.

An audio interview with Mr. Davis is available at NEJM.org

This approach would not solve the problems of preventable overdoses, the indifference of corporate executives and owners to the consequences of their illegal actions, or the inequities inherent in the criminal legal system. But it would be an important step in the right direction.

Disclosure forms provided by the author are available at NEJM.org.

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Drug-Coated Devices for Peripheral Arterial Disease

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Atherosclerotic peripheral arterial disease (PAD), which currently affects more than 8.5 million people in the United States, typically causes intermittent claudication or signs of chronic limb-threatening ischemia. For patients with claudication, the noninvasive mainstays of treatment are exercise, antiplatelet therapy, and treatment of risk factors for atherosclerotic disease.

Percutaneous revascularization procedures can improve claudication symptoms, and devices coated with antiproliferative drugs (drug-coated balloons and stents) reduce neointimal proliferation after revascularization procedures. Pivotal randomized, controlled trials (RCTs) of paclitaxel-coated devices (PCDs) in patients with femoropopliteal PAD reveal significantly reduced repeat-revascularization rates as compared with use of uncoated devices. Reasonable assurance of device safety and effectiveness at 1 year has led the Food and Drug Administration (FDA) to approve six PCDs to date, and their use has become common in symptomatic patients.

But questions about long-term PCD safety arose after a study-level meta-analysis of RCTs reported by Katsanos et al. in December 2018 revealed an increased risk of death among patients with femoropopliteal PAD who were treated with PCDs as compared with patients treated with uncoated devices.[1] In response, the FDA conducted its own meta-analysis of the pivotal RCTs of the approved PCDs and found an increase of approximately 7.1% in the crude risk of death at 5 years (hazard ratio, 1.57; 95% confidence interval [CI], 1.16 to 2.13) in patients treated with PCDs as compared with those treated with uncoated devices. An independent meta-analysis of patient-level data from four U.S. pivotal trials and four non-U.S. RCTs found a hazard ratio of 1.38 (95% CI, 1.06 to 1.80), which was reduced to 1.27 (95% CI, 1.03 to 1.58) after recovery of additional information on patients' vital status.[2] The increased mortality risk associated with PCDs appeared to be a late phenomenon, emerging 2 to 3 years