Aegon Asset Management

OPIOID USE: THE CREDIT EFFECT

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While the opioid crisis traces its roots to the early 2000s, it has accelerated in recent years with a spike in overdose deaths due to potent black market opioid products. These products are being mixed with powerful synthetic additives such as fentanyl, which increase the potency, but also the risk. Investors are now trying to determine how the situation developed, and how the ultimate economic impact will affect credit quality across the supply chain.

Roots of the crisis

The opioid crisis started out as a routine drug launch in 1996 when Purdue Pharma introduced its ubiquitous painkiller, OxyContin. At the time, Purdue embarked on a strategy of expanding the opioid market by positioning OxyContin as a drug that could be safely prescribed for moderate pain. By opening the market beyond the traditional Schedule II narcotic patient population (patients suffering from cancer-induced severe pain), Purdue would have access to millions of additional customers.

To execute the plan, Purdue marketed the drug as having less likelihood of abuse due to its long-release nature. While the claim was allowed by the FDA (in the early years at least) it was not backed by scientific trials[1]. The aggressive marketing worked, and OxyContin sales grew from around $50 million in year one to $1.1 billion by 2000[2]. By 2001, Purdue was spending $200 million annually on marketing and promotion[3], targeting (1) doctors most likely to write prescriptions ("profiling") and (2) primary care doctors lacking expertise in pain management and treating those less severe patients. Purdue also trained its sales force to reiterate the risk of addiction was less than 1% (a figure taken from two flawed studies)[4], and targeted states that had lower reporting requirements for Schedule II narcotic prescriptions.

Behind the scenes, the industry was also grappling with the FDA, which was making note of the increased rate of opioid abuse. While the FDA required the statement, "delayed absorption… is believed to reduce the abuse liability of the drug," be removed from the OxyContin label in 2001, it permitted the, "only to be used in patients who require opiates for an extended period of time," signaling it was appropriate for long-term use.

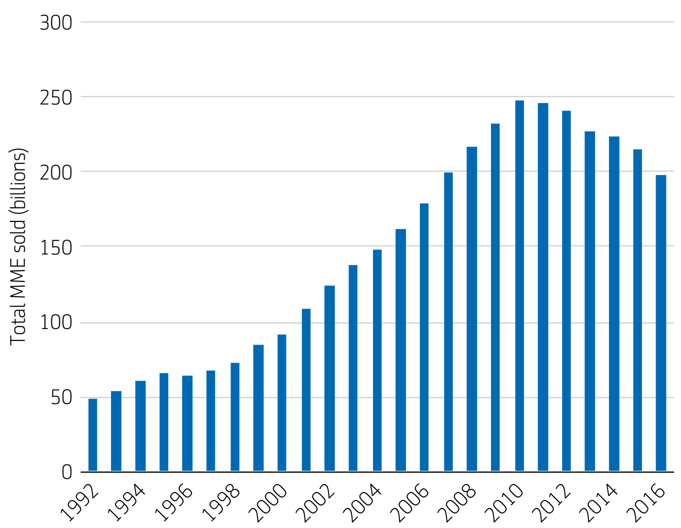
[1]https://www.marketplace.org/2017/12/13/health-care/uncertain-hour/opioid
[2]"OxyContin Marketing Plan, 2002." Purdue Pharma, Stamford, CN, 2002
[3]"OxyContin: balancing risks and benefits," in Hearing of the Committee on Health, Education, Labor, and Pensions, United States Senate, February 12, 2002, p 87 (testimony of Paul Goldenheim, Purdue Pharma)
[4]Meier B. Pain Killer Emmaus, PA: Rodale Press; 2003:99
[5]Carreyrou, John, "Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs," *Wall Street Journal*, Nov. 3, 2006, https://www.wsj.com/articles/SB116252463810112292
[6] Navann Ty, "Endo International PLC, Paid to wait, Overweight," *Citi Research*, July 30, 2018, pg 20
[7]"FDA Anaylsis of Long-Term Trends in Prescription Opioid Analegsics Products: Quantity, Sales, and Price Trends," March 1, 2018, https://www.fda.gov

Crisis grows

Unsurprisingly, the rapid growth of OxyContin and liberalization of opioid use attracted other participants. In 1998, Cephalon launched Actiq, a lollipop formulation of fentanyl indicated for breakthrough cancer pain in opioid-tolerant patients. Actiq would grow to around $400 million in sales by 2005[5] before generic competition launched. Cephalon would later pay the second largest fine ($425 million in 2008)[6] in relation to opioids for marketing the powerful Actiq for off-label purposes (non-cancer pain). Generic manufacturers, which typically account for roughly 80-90% of prescription pill volumes[7], increased production to satisfy the steep growth in opioid prescriptions. Distributors continued to dispense the pills across the country, rarely reporting (if at all), and shipping large, suspicious amounts of Schedule II narcotics to small communities. Generic manufacturers, distributors and retailers (pharmacies) would eventually all pay fines of various amounts (the largest being $150 million)[6] for, amongst other things, failure to notify the DEA of suspicious orders, improper monitoring, and unlawful distribution.

Overall, the amount of opioid milligrams being prescribed grew five-fold from 1992-2010 (approximately 10% CAGR). Not until pressure began to mount in 2010 did prescription trends turn negative, though at a slower pace than the escalation (Exhibit 1).

Exhibit 1: Morphine milligram equivalents sold: Brands & Generic



Source: FDA. as of December 31, 2016.

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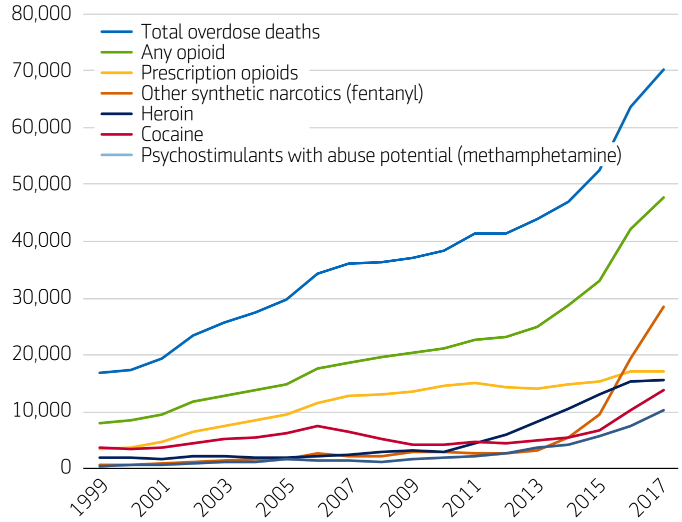
Aftermath

The result of the prescription opioid growth was a steady increase in prescription opioid overdose deaths from 1999 until 2010, when they leveled off at approximately 17,000 annually (Exhibit 2). However, as prescriptions declined, users moved to the black market, with heroin overdose deaths spiking in 2011, the first year of prescription contraction. A few years later, overdose deaths from black market synthetic opioid products spiked even more dramatically. In 2017, according to the CDC, there were nearly 60,000 opioid related overdose deaths, with about 70% of those from black market opioid products (primarily fentanyl). The roughly 60,000 deaths compares to approximately 90,000 annual deaths linked to alcohol, 40,000 from vehicular accidents and approximately 15,000 from gun homicides (all per CDC). In a matter of about 20 years, the industry has introduced a new health threat that now rivals alcohol and cars, and far exceeds gun-related homicides.

Exhibit 2: Overdose deaths in the United States



Source: CDC. as of December 31, 2017.

Responsibility & credit impact

Unlike prior product liability cases in the pharmaceutical industry where fault was straight-forward (manufacturer makes product, product harms patient, manufacturer compensates patient), the opioid situation is more complex, involving branded and generic manufacturers, distributors, retailers and doctors; all of which erred along the way.

Assuming the majority of stakeholders are motivated to resolve the situation with a global settlement rather than spend years fighting separate cases, we use historical precedent to triangulate a settlement amount and then assign proportions to various members of the supply chain. The best precedent is clearly the tobacco master settlement agreement reached in 1998. The settlement totaled $206 billion ($340 billion inflation adjusted) with an upfront payment of $12.7 billion (roughly 6%) paid over the first five years ($2.5 billion per annum), and the remaining annual payments made into perpetuity. Using comparable metrics between tobacco and opioids, we calculate an opioid settlement could total around $42 billion. Flexing that up to account for increased relative costs for opioid addiction (theft to support addiction, treatment) we estimate a settlement amount of $68 billion (Exhibit 3).

Exhibit 3: Global settlement cost: Tobacco v. Opioids

	Industry revenues	Marketing spending	Annual deaths	Settlement (Inflation adj.)	Settlement (Aegon adj.)
Tobacco	~$100B	~$5B	~480k	~$340B	~$340B
Opioids	~$7.5B	~$300m	~60k	$42B	$68B
Ratio	13.3x	16.6x	8.0x	8.0x	5.0x

Source: Aegon Asset Management.

Mirroring the structure of the tobacco settlement the $68 billion would be split into an upfront portion paid over the first five years ($4.2 billion, $800 million per annum) and annual payments (which increase over time) paid over 25 years and into perpetuity based on opioids sold/distributed by each stakeholder, which would necessitate an increase in opioid prices, similar to what we experienced with cigarette prices. The first ten years of the payments would resemble Exhibit 4.

Exhibit 4: Upfront and annual payments calculation ($millions)

Portion	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Upfront portion	$841	$841	$841	$841	$841					
Annual portion	$1,488	$1,654	$2,150	$2,150	$2,150	$2,150	$2,150	$2,150	$2,692	$2,692
Total	$2,329	$2,495	$2,991	$2,991	$2,991	$2,150	$2,150	$2,150	$2,692	$2,692

Source: Aegon Asset Management.

Utilizing historical opioid-related legal settlements made by the three main parts of the supply chain as precedent, we assume manufacturers would be responsible for 79%, distributors 15%, and retailers 7% of the settlement amount (Exhibit 5).

Exhibit 5: Supply chain liability waterfall ($millions)

Waterfall	Share	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Manufacturers	79%	$1,830	$1,960	$2,349	$2,349	$2,349	$1,689	$1,689	$1,689	$2,115	$2,115
Distributors	15%	$344	$369	$442	$442	$442	$318	$318	$318	$398	$398
Retailers	7%	$155	$166	$199	$199	$199	$143	$143	$143	$179	$179
Total	100%	$2,329	$2,495	$2,991	$2,991	$2,991	$2,150	$2,150	$2,150	$2,692	$2,692

Source: Aegon Asset Management.

As certain manufacturers are the weakest links in the supply chain, we need to determine if the manufacturers could afford the potential payments. Based on our near-term free cash flow estimates (through 2020), we believe some companies within the supply chain could afford the annual outlays, while smaller players could not. One of the larger manufacturer's ability to make payments is uncertain as they are private (Exhibit 6). The remaining manufacturers, as well as the distributors and retailers, are fairly strong and could likely shoulder their payments.

Exhibit 6: Manufacturers' potential payments over the next ten years ($millions)

Manufacturer	Share[1]	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Manufacturer 1	45%	$825	$883	$1,059	$1,059	$1,059	$761	$761	$761	$953	$953
Manufacturer 2	11%	$206	$221	$265	$265	$265	$190	$190	$190	$238	$238
Manufacturer 3	11%	$206	$221	$265	$265	$265	$190	$190	$190	$238	$238
Manufacturer 4	8%	$155	$166	$199	$199	$199	$143	$143	$143	$179	$179
Manufacturer 5	8%	$155	$166	$199	$199	$199	$143	$143	$143	$179	$179
Manufacturer 6	6%	$103	$110	$132	$132	$132	$95	$95	$95	$119	$119
Manufacturer 7	6%	$103	$110	$132	$132	$132	$95	$95	$95	$119	$119
Manufacturer 8	4%	$77	$83	$99	$99	$99	$71	$71	$71	$89	$89
Total	100%	$1,830	$1,960	$2,349	$2,349	$2,349	$1,689	$1,689	$1,689	$2,115	$2,115

Source: Aegon Asset Management. [1]Per IMS Health data (combined branded and generic opioid sales in Jan-19); adjusted to sum to 100% for top eight manufacturers

Conclusion

Based on the most relevant historical precedent, it appears a settlement could be structured such that the majority of companies in the supply chain would remain solvent (absent un-related credit issues) while also raising a considerable amount of money that could be used to address opioid addiction. The risk to this outcome is certain participants refuse to settle and the situation instead mirrors the decades long asbestos litigation, which was fought on a case-by-case basis and resulted in a number of bankruptcies. Other things to consider include where to invest in the capital structure, where secured bonds can partially shield investors from legal liabilities, or if environmental, social and governance (ESG) concerns may preclude investors from investing in parts of the opioid supply chain all together. As a fixed income investor, we support a global settlement which would maximize recoveries and include changes to the way opioids are marketed and prescribed.

Disclosure