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The opioid crisis in the US has turned our attention not just to those individuals who have struggled with addiction as a result of the over-prescription of opioids, but also towards the societal costs associated with those struggles. Costs that can be attributed to several stages in the supply chain—the unintended consequences of the questionable marketing, prescribing, distribution, and dispensing of opioids. In fact, it is possible that if all costs of the crisis were monetized and all damages paid, the total would be much more than the profits earned or possibly even the revenue generated throughout the supply chain. Some higher estimates have penned the financial effects at more than $1 trillion. Should those damages be paid, would we, as a society, lose pharmaceutical companies? Distributors? Pharmacies? Doctors? We have already seen Insys Therapeutics and Purdue Pharma declare bankruptcy and just in the past two weeks, Mallinckrodt has publicly considered taking that same step.

The litigation surrounding the opioid crisis began as more than 2,000 separate lawsuits comprising more than 2,500 cities and counties, Native American tribes, and individual claimants. These lawsuits targeted opioid manufacturers, pharmaceutical distributors, pharmacy benefits managers (PBMs), pharmacies, and medical care providers. The lawsuits were consolidated into a single multidistrict litigation overseen by a federal judge in the Northern District of Ohio. The Court scheduled bellwether trials for the Summit and Cuyahoga counties in Ohio, which settled on the eve of trial with all defendants except pharmacy defendants. All the remaining suits are pending. The opioid litigation has resulted in the bankruptcies of multiple opioid manufacturers, including Purdue Pharma and Insys Therapeutics, with the potential for additional bankruptcies in the future.

What if a different, wholistic strategy were available? One of the longest-lasting litigations in US history has been those related to asbestos. In 1969, the first personal injury lawsuit alleging asbestos-related disease was filed; by the late 1970s, claim filings had picked up speed and the first asbestos-related bankruptcy was filed in 1982 (The Johns Manville Corporation). Since then, more than 600,000 individuals have filed personal injury lawsuits due to asbestos exposure, more than 75 companies have declared bankruptcy, and dozens of insurance companies have become insolvent. Lawyers, economists, and conference organizers have seen their entire careers focus on asbestos litigation. While there were early attempts to remove asbestos from the

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4. A separate state public nuisance claim by the State of Oklahoma against Johnson and Johnson resulted in a nine-figure judgment against Johnson and Johnson. Separately, the Department of Justice has also pursued individual parties for civil and criminal penalties.
5. Additionally, Mallinckrodt’s generic business filed for Chapter 11 bankruptcy. It is generally stated that Manville was the first asbestos related bankruptcy https://www.asbestos.com/companies/johns-manville/#:~:text=Johns%20Manville%20was%20the%20first%2C%20use%20of%20the%20bankruptcy%20law. However, there is some ambiguity as to whether Unarco’s July 29, 1982 asbestos related bankruptcy filing pre-dates Manville’s 1982 filing.
traditional (individualized) tort system, it has mostly been left up to individuals, law firms, corporations, and insurance companies to litigate and settle claims as they arise.

Management of asbestos liability has become a significant source of activity for some defendant companies. In-house counsel specialists are often needed to manage the litigation (which can range from a few claims a year to thousands), outside counsel coordination, claims management, and insurance negotiations. Litigation can impact day-to-day operations and may be a significant expense, impact acquisitions and divestitures, distract management, and depress company value. While many defendants have used bankruptcy to mitigate the impact of asbestos liability, others have remained in the tort system intending to “manage” the liability. However, other asbestos defendant companies have sought solutions outside the courts.

A few asbestos defendants have attempted corporate restructuring as a method to “wall off” the ongoing operations of the company from the legacy of asbestos. In order to do so, a new corporate entity is created, and the liability is assigned to the new entity. The value of the asset depends on expected future liability (estimated by an economist or actuary), an estimate of any expected insurance asset that can offset the liability (estimated by an insurance coverage expert and taking into account the solvency of the insurance program), a possible infusion of cash (or other asset) by the original parent, and an ability to leverage timing and smart investments to maximize the asset value. This new “runoff” company can be a wholly owned subsidiary or (better yet) an independent entity so the parent is free from the asbestos overhang. Under ideal circumstances, the liability, asset, and investment estimates are reasonable and close to the actual experience and the new entity can run off the asbestos liabilities through their end (expected in the 2050s). If the estimates are too conservative, the runoff entity could complete the asbestos claim lifecycle and have assets remaining or if the estimates are too aggressive, the runoff entity could become insolvent.

**How could corporate restructure be a solution for the companies in the opioid supply chain?**

At first glance it seems that the supply chain for opioids is more complex than that of asbestos, but that is not necessarily the case. Even in the asbestos framework, there were manufacturers, distributors, designers, and installers (somewhat parallel to pharmaceutical manufacturers, distributors, retailers and prescribers). In the asbestos litigation, however, each entity in each step in the supply/exposure chain became a defendant without distinction as to their role (a distributor was sued for the same asbestos fibers as the company that specified or produced the final asbestos-containing product) but damages (other than punitive) were limited to the number of individuals diagnosed with asbestos-related disease.

Over time, as mesothelioma gained visibility with only one known cause, claims have grown to a level far higher than originally anticipated. Plaintiff law firms responded by establishing infrastructure to support ongoing asbestos litigation efforts, and defendant companies matched plaintiff firm efforts with comparable defense strategy and spend. A litigation that was expected to be relatively short lived has persisted and even flourished for decades. Depending upon the length of time over which opioid litigation persists, a similar pattern may emerge, i.e. diminishing claim numbers offset by increasing claim values.

Asbestos litigation has been further complicated by joint and several liability: a total award made to an individual would ideally be divided among all responsible parties, but if any entity in the chain were insolvent, the remaining parties would take on the share of those unable to pay. This same situation is applicable in the case of opioids: damages can arise from many sources, with any remaining (solvent) entity in the supply chain taking on the responsibility of those exiting the tort system, a domino effect that could be devastating to healthcare.

If our goal, as a society, is to continue to have functional and innovative pharmaceutical companies, we will need any resolution to the opioid crisis to preserve the solvency and functionality of the companies in the supply chain, lest we risk losing the firms most skilled at drug research, innovation, treatment development (and who could argue with that in the COVID-19 world?), and efficient and functioning systems for drug distribution and dispensation. The corporate restructure technique could be a means to maintain that goal in the face of a tsunami of litigation.

In order to restructure opioid-involved companies, a methodology for estimating their liabilities must be available. There are many potential sources of damages arising from opioids:

- **Municipality Claims**
- **State Attorneys General Claims**
- **Individual Claims**

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7. The Georgine case would have turned asbestos personal injury cases for a group of large defendants into a class action was decertified by the Supreme Court in 1997, and the FAIR Act would have prohibited asbestos personal injury claims from being brought against individual defendants and created a centralized (national) fund to compensate victims.

8. Absent an arms-length transaction with both parties’ legal and actuarial representatives offering defensible opinion letters, the risk of additional liability exposure does exist.

9. Idiopathic mesothelioma is observed, but rarely identified when even a tangential link to asbestos exposure can be made.
Insurance claimants (those who purchased insurance)
Hospital claims (arising from the undue allocation of hospital resources toward opioid patients)
Future claimants (babies born to addicted mothers)
Insurance claimants (those who purchased insurance at rates above what they would have been but for the cost of caring for addicts and covering unnecessary opioid prescriptions)
SEC investigations
Investigations of healthcare professionals
Congressional and other inquiries
Derivative lawsuits against directors of company

While this list seems daunting, there have been some estimates (or estimation methodologies) for many of these potential sources of damage in the opioid litigation that has proceeded to date. For example, market-wide estimates could then be parsed to each entity involved in the supply chain (possibly by market share). Others may be based on statutory provisions that nonetheless are readily estimable using company-specific data. Thus, there are reliable methods upon which to compute damages by a company.

If the claims could also be adequately quantified, it seems that opioid companies could take advantage of a restructuring that separated the opioid business from the non-opioid business. Through a properly structured transaction with a third party, an opioid company could achieve finality from contingent liabilities through a true sale. Just as in the context asbestos-related transactions, the seller and purchaser will both require legal and actuarial opinions from their respective advisors. While every transaction requires bespoke structuring, typically the selling entity can sell either a legacy subsidiary or ringfenced vehicle containing both funding and liabilities to a third party. After such a transaction, the selling company no longer retains any exposure to the described contingent liabilities on its balance sheet and maintains no control or ongoing involvement in any litigation, settlement, or other resolution of claims going forward. This approach is the only alternative to bankruptcy that achieves complete finality from exposure to contingent liabilities.

Market share in opioids is thoughtfully computed as morphine milligram equivalent (MME) rather than unit sales to control for the varying potency of different products.

By allowing companies a clean separation of past liabilities from ongoing operations, a fair and equitable resolution to opioid liabilities can be achieved while maintaining the innovation and dynamism of America’s pharmaceutical industry.

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