

Ed Rowland: US opioid epidemic and its impact on the CH world

The British writer Lawrence Durrell once said, "History is an endless repetition of the wrong way of living." The same can be applied to the present horrific US opioid epidemic. The ripple effect of this unfolding tragedy will be almost undoubtedly be felt as collateral damage on the consumer healthcare world.

Other national epidemics such as HIV / AIDs or health challenges such as tobacco offer lessons. The size of this tragedy and its lethal impact on the US is stark. No population segment has been untouched. And like many previous health challenges, cities and states have shouldered much of the financial burden for law enforcement, first responders, addiction treatment and education.

The legal precedent from the tobacco world is instructional and can be used as a guide. Who is at legal risk? The entire go-to-market chain is implicated: brand owners, wholesalers and retailers. Several "truths" and "burning questions" may and probably will play out on a state-by-state basis. Who knows what and when? The law of deep pockets and misleading health warnings and risks will all be part of the story.

While the legal epicentre of the opioid world is undoubtedly the OxyContin producer Purdue Pharma and its owner, the Sackler family, other producers and wholesalers face a mountain of lawsuits. Purdue filed for bankruptcy on 15 September 2019, but other household names are in jeopardy as well. This is how the consumer healthcare world will feel the impact.

On the wholesaler side, AmerisourceBergen, Cardinal Health and McKesson are potentially implicated, while on the manufacturing side, Endo Health Solutions, Teva subsidiary Cephalon, J&J subsidiary Janssen and Allergan are all on the hook. And the key parallel to the tobacco experience: it is states and not individuals who are leading the attack. J&J's recent experiences illustrate the point.

In late August 2019 in an Oklahoma case, J&J (fentanyl patch) was ordered to pay \$572mn in a landmark ruling. Cleveland County (Norman, OK) District Judge Thad Balkman ruled that J&J bears responsibility for helping to fuel the state's opioid epidemic by aggressively marketing painkillers. It is estimated that in the past 20 years, Oklahoma has lost over 4,000 residents to opioid abuse. J&J declined to comment and plans to appeal.

There were multiple Oklahoma defendants including Purdue Pharma and Teva, who negotiated an out-of-court combined settlement of \$355mn (Purdue reportedly settled for \$270mn of that figure), without admitting wrongdoing. However, J&J's court fight has now provided legal precedent that will almost undoubtedly be used elsewhere. The "public nuisance" legal argument ultimately felled the tobacco companies.

Ohio is next up and this concept will surely be a central argument. According to *All Things Considered*, Ohio estimates 200,000 opioid addicts at this point – roughly equal to Akron's entire population. Many observers feel that southern Ohio is the hardest hit area in the whole country. The Ohio filing was quite stark: "Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain required opioids." And West Virginia is filing shortly.

In a perverse reaction to the J&J verdict, the \$572mn judgment was good financial news for J&J. According to *Axios*, J&J (and other stocks) rebounded sharply upward. Some Wall Street analysts had expected J&J to pay \$2bn or more over a longer period to help the state defray ongoing costs. Oklahoma had asked for \$17bn, but the ruling pointed out that there was not enough evidence presented to warrant a longer-term payout. Will future rulings bring company-ending verdicts or can some companies weather it out? Certainly, Ohio and West Virginia now know

what needs to be presented. Ultimately, the Oklahoma judgment was less than 4% of J&J's 2018 net profit.

Overall, there is a financial question as to whether some companies implicated can survive a multi-billion dollar verdict. The distributor community, in particular, appears vulnerable. Endo Health and Allergan are also in a precarious position. The wholesale distributor community – McKesson, Cardinal Health, and AMB – all took financial hits in early August as their stock prices dipped as much as 7%. According to *Bloomberg*, a consolidated offer from the three for a \$10bn omnibus settlement offer was met with a \$45bn counter from the National Association of Attorneys General.

Purdue Pharma and the Sackler family announced a company ending settlement on 15 September 2019, when the company filed for bankruptcy protection. The settlement is reported to provide more than \$10bn to help address the crisis and to form a public-trust company to pay the governments bringing the lawsuits. The Sackler family would relinquish ownership. Purdue has sold more than \$35bn of OxyContin since its 1996 launch.

In the most recent legal battle in Oklahoma, both sides won and lost. Public Nuisance is now legal precedence, but more complete cases need to be crafted by the states. Email trails really do document extreme problems for all companies in the go-to-market chain. The NIH has focused a bright light on the legal jeopardy and the attempt to minimise opioid consumer risk. The NIH has documented several "smoking guns" (or perhaps opioid guns) including sales training messaging that the risk of addiction was "less than one percent" in one case.

The tragedy is immense. 2018 saw almost 70,000 overdose deaths with over half to opioids. This exceeds annual deaths linked to guns, cars, or even HIV / AIDS at their respective peaks, and the CDC has meticulously tracked the national opioid health tragedy. Overall, experts divide it into three distinct periods: Prescription Opioid Abuse 1999-2005, Heroin Abuse 2005-2012 and from 2013 onwards, Synthetic Opioid Abuse.

From 1999-2017 US drug overdoses resulted in 702,568 deaths with 399,230 (56.8%) involving opioids. More

recently, 2016 prescription opioids caused more than 20,000 deaths. In that year, drug overdoses (including heroin) became the leading cause of death in US adults under age 50. In 2017, it got a lot worse. Total overdoses were slightly more than 70,000 with about half from opioids centered mostly in the Northeast and Midwest. Black market synthetic opioids, especially fentanyl, drove the increase. From 2016 to 2017, synthetic opioid-involved overdose death rates jumped 45.2%. The highest synthetic opioid-involved overdose death rates in 2017 were in West Virginia (37.4 per 100,000), Ohio (32.4), and New Hampshire (30.4), states that either have or will shortly seek legal redress.

2018 figures (not yet finalised) seem to indicate a flattening of the epidemic. Curtailed painkiller prescriptions numbers are down. The opioid overdose antidote naloxone is much more available and has been deployed within the first responder community. Hopefully synthetic fentanyl won't offset the improvement. And in the coming months all eyes will be on Ohio and West Virginia to see who among the brand owners and wholesalers will survive the legal onslaught. ☒

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Nicholas Hall's *OTC INSIGHT* and the Nicholas Hall Group of Companies, while deeply sympathetic to the victims of the opioid crisis, has decided to take no point of view on the causes and outcomes of the crisis, or to apportion blame. This article is an op-ed piece submitted by our valued associate Ed Rowland, and we welcome and will print other points of view in *OTC INSIGHT North America* and its sister publications.