Ed Rowland: 2019 review part 2

In part 2 of his 2019 review, Ed Rowland discusses some of the major challenges affecting the healthcare market in the US, such as the question of CBD regulation, ingredient recalls, tougher retailer supply chain requirements and the vaping and opioid abuse crises.

Future of CBD uncertain

CBD was one of the leading 2019 US CH stories. The story does not have an ending yet; most industry leaders want it to be a romance and not a tragedy, but at the end of 2019, the FDA pulled in the regulatory reins. One industry leader put it well: "we have a lot of experience switching from Rx-to-OTC but no experience in switching from illegal to legal". A rising tide of public interest will almost certainly force the issue. There are several chapters still unwritten, FDA approval, clinical evidence and dosing among them.

There's a lot of hype and risk in a category that some project to $1bn in sales but so far CBD products are only available in a few states where it's legal and on-shelf in CVS and WBA in limited store counts. Walmart does not sell CBD yet.

The path to legality must address a wide array of products including CBD, cannabis and medical marijuana. The FDA confirmed Stephen Hahn as its new Commissioner in December 2019. Despite the fact that Hahn is known to be somewhat skeptical of CBD, the appointment of a permanent head should see some progress now being made. The crux of the regulatory challenge is the scientific nature of botanical categories like CBD. Like all botanicals, there is high (no pun intended) variability in growing conditions and consequently end product.

Ed Rowland is a valued Network Partner of the Nicholas Hall Group of Companies. As the principal of Rowland Global LLC (rowland-global.com) he believes in the promise of global business and supports companies in their strategy, tactics and execution of international growth initiatives.

The move from the Wild West (read Colorado) to meaningful CBD regulations will most likely be through a New Dietary Ingredient Notification. The key decision makers will be the FDA professional medical staff with a very singular mandate: Protection of Public Interest. This means that leading CBD states like Colorado probably won't sway future FDA rulings. Key Trade Associations like the CHPA, CRN and the NPA all support legalising CBD but are not consistent nor unanimous in their detailed statements. The FDA staff will make the call.

The CHPA's Citizen's Petition in November 2019 is typical of the industry efforts and was rather direct. The CHPA "urges the agency to exercise its statutory authority to issue regulations establishing a clear pathway for the inclusion of CBD in dietary supplements … utilising the authority it already has to establish a lawful regulatory pathway for manufacturers to bring dietary supplements containing CBD to market … in a manner that ensures product quality, safety, and a level-playing field for enforcement." This is a "now issue" and the CHPA also urged "the FDA to act, issuing either an interim or final rule".

The devil is always in the detail and CBD is no exception. There will be a challenge to reach consensus definitions including THC levels, cannabinoids, whole spectrum, etc. Next, policing the standards will almost certainly lead to expanded private enforcement. Clinicals and Process (handling metals mold, etc) issues lead to IP problems as there will be "me too just like him" from quasi under-the-radar followers who conducted no clinicals nor R&D work but want to piggyback on those who did. The CBD world, if legalised, will probably and eventually settle into a Master File / Licensing system.

In late November, the FDA finally responded to calls for immediate CBD clarity and, not surprisingly, put a hold on the category by stating that it "cannot conclude [that CBD] is generally recognized as safe". The FDA staff is looking for scientific support which to date is not definitive. Among issues still to be resolved: potential liver injury, interactions with other drugs, drowsiness, diarrhoea and mood changes. At the same time, the FDA issued 15 warning letters to companies for illegally selling CBD products. It remains to be seen how quickly the CBD industry and the FDA can resolve these issues. 2020 will undoubtedly see a continuation of the story. As one Trade group put it: "It's time for the FDA to announce a legal pathway to market for these CBD-containing supplements." In January 2020, Rep Colin Peterson (D-MN) introduced bipartisan legislation that would make hemp-derived CBD lawful for use in dietary supplements. The bill would amend the Federal Food, Drug & Cosmetic Act to explicitly include "hemp-derived cannabidiol and hemp-derived CBD-containing substances" within the definition of a dietary supplement.

Recall, QA trends

A major recall once again disrupted shelf space in 2019. Sanofi's Zantac recall was a hard-to-clearly-read situation as the FDA neither said yes or no to a mandatory US recall. The result was a limbo of sorts and empty shelf space. In late October Zantac marketer Sanofi announced that ranitidine-based Zantac 150, Zantac 150 Cool Mint, Zantac 75 may contain N-Nitrosodimethylamine (NDMA). As a precautionary measure Sanofi initiated a voluntary recall of all Zantac in the US and Canada on 18 October 2019. In mid-September the FDA had alerted Sanofi of the possible situation and requested further testing which was non-conclusive. NDMA is classified as a probable human carcinogen found in water and many foods.

In a more general trend, manufacturing and ingredient sourcing GMPs received far more scrutiny from major retailers as OTC QA requirements rose to the level of Rx molecules. Sourcing compliance according to one small player was "brutal" on third party audits leading to some

Regulatory changes: OTC Monograph system reform

The US's OTC Monograph system may finally be headed towards long awaited reform. The proposed package of streamlined processes, faster safety label changes, increased speed and oversight responsiveness and more resources in general has languished for many years. Monograph reform may very well be one of the few bi-partisan reforms that can move through the Federal process. Reform bills have passed in the Congress three times in the past 2 years only to be held up in the Senate.

However, the logjam might be over. In late October, the Bipartisan Senate OTC Monograph Bill S. 2740 was approved by the Senate HELP Committee. Co-sponsored by Senators Johnny Isakson (R-Ga.) and Bob Casey (D-Pa.), this would be the first significant reform in 40 years.

Vaping: Bans owing to reported lung injuries

Various states banned flavored e-cigarettes, while market leader Juul preemptively discontinued its mint flavor, encompassing 70% of sales. In mid-November, Apple removed all vaping-related apps from its mobile App Store. The CDC reported that as of 14 January 2020, there had been a total of 2,668 cases of death or hospitalisation owing to vaping-related lung injury.

shakeout, especially in the supplements arena. In the end, the larger brand owners won out as some smaller guys simply could not afford the incremental QA costs. Coupled with steep listing fees and trade promotion requirements, smaller brand owners in some cases opted to not list products at CVS or WBA. Within the marketing world, the media landscape remained challenging as well. Elusive micro-influencers continue to increase in importance, while traditional TVC, albeit with less reach, is still important and costly. The more immediate conundrum is how to break into the new order of a streaming world. Finally, most brand owners indicated that 5-7 key accounts, whether traditional or e-commerce, determined their business year success.

Opioid crisis continues

Tragically, the US opioid crisis continued in 2019. The size of this tragedy and its lethal impact on the US are stark. No population segment has been untouched (2018 saw almost 70,000 deaths overdose deaths across the US with over half to opioids, exceeding peak annual deaths rates of gun violence, auto accidents or even HIV/AIDS). While 2019 is trending somewhat lower the number is still tragically high. The epicenter of the opioid crisis is undoubtedly the now bankrupt OxyContin producer Purdue Pharma, but there are other producers and wholesalers caught in the storm. On the wholesaler side, AMB, 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.

The legal precedent from tobacco world is instructional and can be used as a guide. The entire go-to-market chain is implicated and who-knew-what-when will play out on a state-by-state basis. Similar to the tobacco experience, it is the states and not individuals who are leading the attack. J&J's (fentanyl patch) experience in late August in an Oklahoma case illustrates the point as the company J&J was ordered to pay $572mn in a landmark ruling. Oklahoma has lost over 4,000 residents from opioid abuse. J&J declined comment and plans to appeal.