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Routes to success in the therapeutic cannabinoid market:

Insights from the e-cigarette experience

By David Lewis, BEng, CEng, MIMechE
CAMBRIDGE DESIGN PARTNERSHIP

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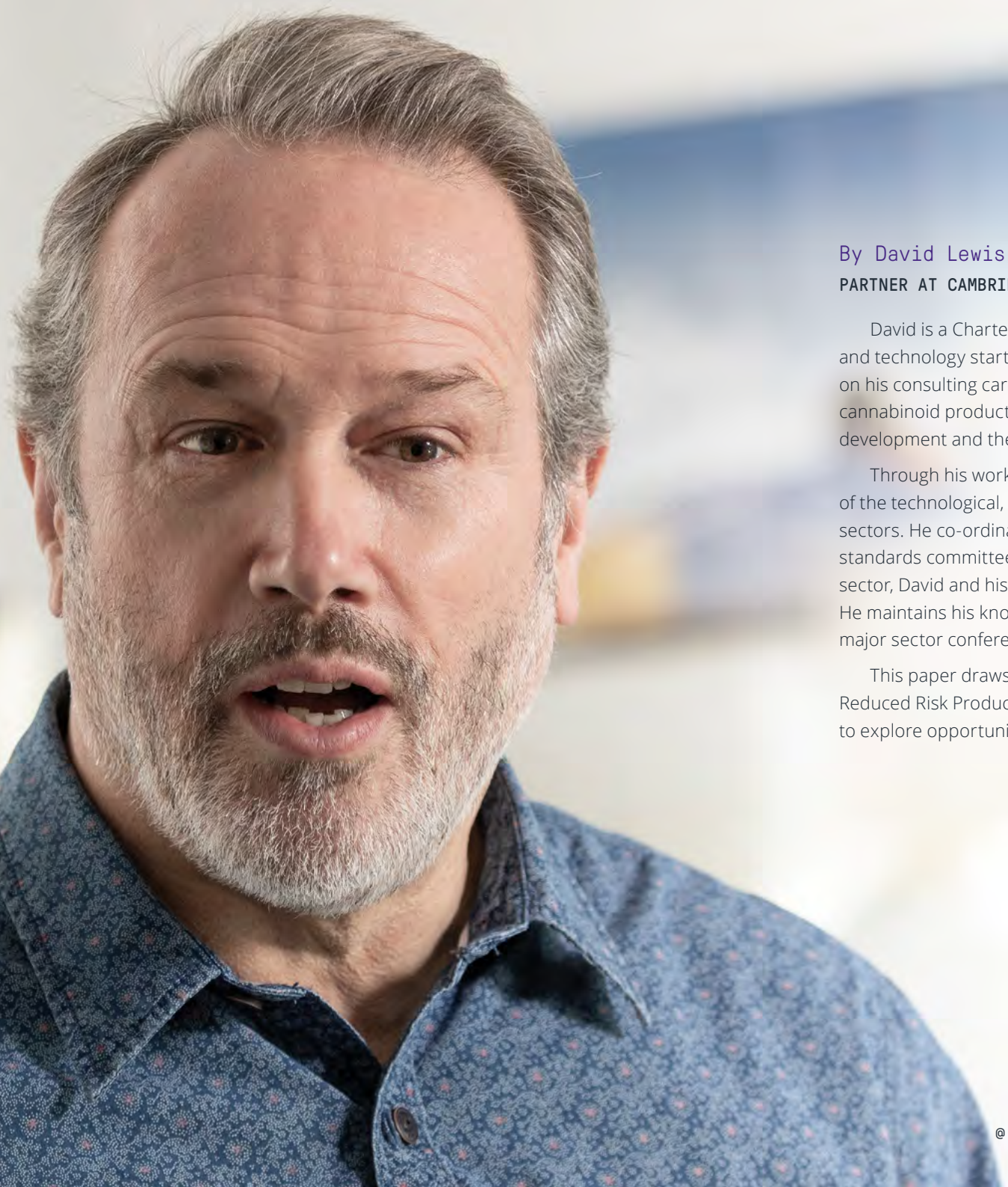

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David is a Chartered Engineer who has worked internationally in large corporations and technology start-ups commercialising innovative technology prior to embarking on his consulting career. His experience encompasses both reduced-risk nicotine and cannabinoid products, spanning the full development cycle of user research, prototype development and the transition to production.

Through his work supporting CDP's clients, he has developed a deep understanding of the technological, commercial and regulatory issues impacting these emerging sectors. He co-ordinates with regulatory bodies such as the MHRA, sits on the BSI standards committee and contributed to the TPD2 consultation. To help support the sector, David and his team regularly share their insights through white papers and blogs. He maintains his knowledge of the market through his participation and contribution to major sector conferences.

This paper draws on David and his team's long experience of operating in the Reduced Risk Products (smoking cessation, e-cigarette, vaping) market as a backdrop to explore opportunities for therapeutic cannabis.

Lessons learnt

It can be extremely challenging to identify an optimum business and product strategy in the current cannabinoid market.

Image: Biological microscope view x100 of glandular tricomes on a female marijuana flower

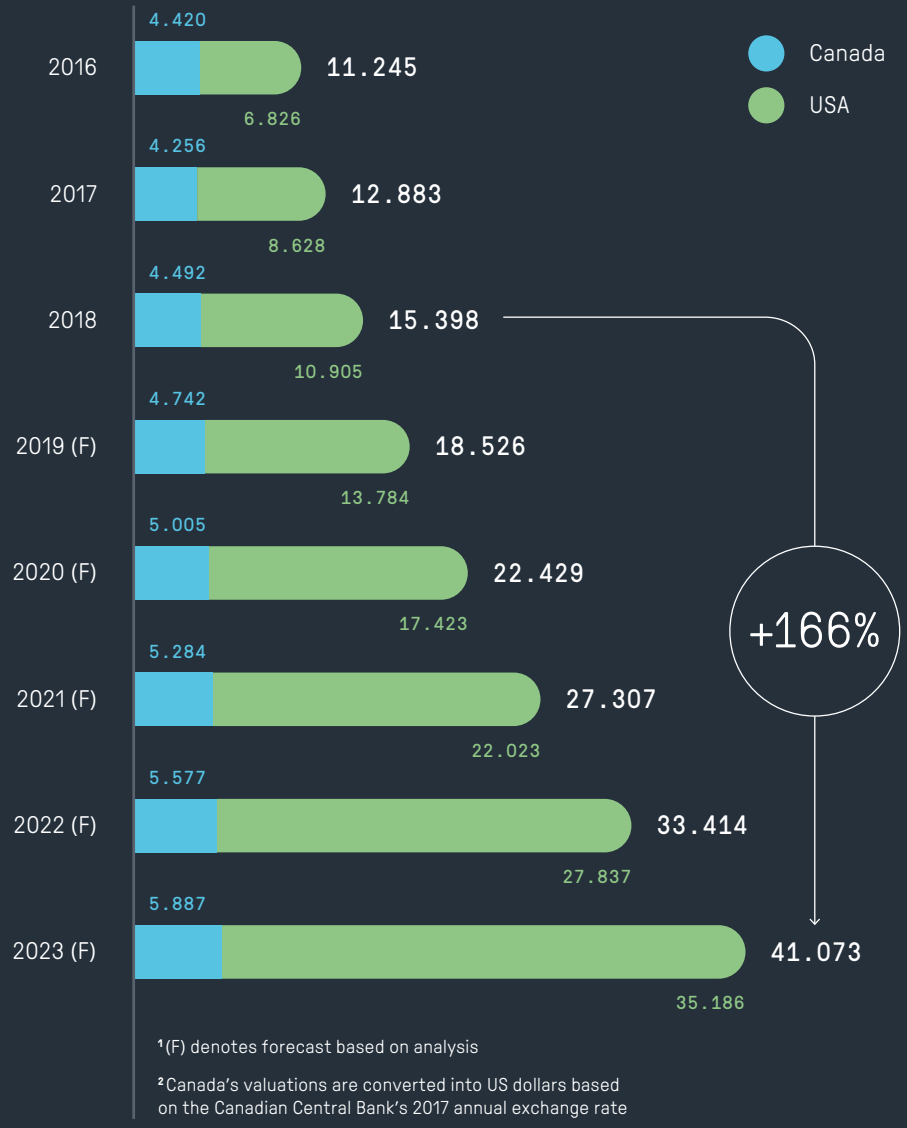
Our involvement in the cannabinoid market has prompted us to reflect on our experiences of working in the nicotine Reduced Risk Product (RRP) sector which since its inception has grown rapidly. Like RRP, the cannabinoid market also operates within an environment of volatile public perceptions, political instability and scrutiny from the regulators.

The expanding cannabinoid market is underpinned by increasing public acceptance and potentially more progressive legislation. However, this is balanced by a lack of evidence supporting the benefits of cannabinoid use and growing concerns over product stewardship. As the market matures there are significant opportunities for cannabis growers, processors, brand owners, technology developers and retailers who are committed to the safety and efficacy of their products.

This paper seeks to explore how insights from the RRP sector could help navigate the opportunities emerging in the therapeutic cannabinoid market. We teamed up with MBA students participating in the Cambridge Venture Project at the University of Cambridge Judge Business School to undertake complementary research which has added further depth to our inquiry and characterised the opportunities, especially in North America.

Fig. 1 – North American Cannabinoid market [1]

US $ Millions[2]



[1] (F) denotes forecast based on analysis

[2] Canada's valuations are converted into US dollars based on the Canadian Central Bank's 2017 annual exchange rate

Fig.1 – Source: Cambridge Venture Project analysis of IBIS World (2018), Statistics Canada (2018), Bank of Canada (2018), Wee (2016), Aurora (2017).

Insights from evolution

Given the vibrancy and nascent nature of the current cannabinoid market, it can be extremely challenging to identify a robust business and product strategy. Companies seeking to capitalise on this opportunity need risk-mitigation plans that take account of the broad range of stakeholders operating within an ever changing political and regulatory landscape.

Since the first modern nicotine e-cigarette was developed in 2003, by Chinese pharmacist Hon Lik, the RRP market has seen dramatic growth, several iterations in device configuration and market profile, and increasing regulatory attention. There have been more losers than winners and given the market parallels the risks are just as high in the cannabinoid market. So what are the key lessons that can be learnt from the RRP journey?

The first e-cigarettes sought to faithfully replicate a combustible cigarette but didn't deliver on satisfaction and missed the opportunity to address non-obvious, unmet needs of consumers.

Managing market development

While Hon Lik was clearly an inspired inventor, his first e-cigarette was based on technology that did not progress to mass adoption, didn't create a valuable brand and was sold into unregulated markets. Despite being one of the first to identify a solution to a market need, Hon Lik was unable to fully capitalise on the opportunity that he essentially created. As with many 'replacement technologies', the first e-cigarettes sought to imitate a combustible cigarette using the same form factor, complete with a red LED to mimic the glowing cigarette tip. Replication missed the opportunity to reach the early majority market by failing to address how consumers would use these products to fulfil the associated 'jobs' they have in their lives.

'Jobs To Be Done' is an innovation methodology based on the understanding that we essentially hire products and services to complete the 'jobs' or challenges we face. Harnessing the 'jobs' approach focuses innovation on improving user outcomes rather than implementing today's product technologies. These 'jobs' may be functional, emotional or social in nature and further inquiry can identify the most important pains and gains experienced by users in order to focus innovation and create product value.

In the case of RRP, early designs were easily copied by opportunistic competitors who inundated the market with low quality products, corroding the developing public perception of the category and obscuring the potential health benefit. This short-termism failed to capitalise on the huge market potential and accelerated the sometimes-clumsy intervention of regulators who then sought to address safety issues and appease political pressure.

Lessons for the cannabinoid market

Having a clear vision of 'where to play and how to win' is a solid starting point for strategy development. Therapeutic cannabinoid users – some of whom may have limited experience of cannabinoids – will demand reliable, trustworthy products that are designed to get their 'jobs' done efficiently. This requires a deep understanding of user needs before embarking on product development and a commitment to product stewardship. This approach maximise return on investment (ROI), reduce business risk and will avoid denigration of the wider market for those committed to long term success.

A focus on majority sales

As demand for RRPs gained momentum, many larger corporations sought to capture market share through acquisition strategies focused on the most successful early RRP brands – success which depended on niche appeal to early adopters. This market segment is typically concerned with technology and performance, whereas volume sales come from the early and late majority who want ease of use, convenience, brand values and reliability. Without this robust mass market appeal, the early RRPs didn't achieve their anticipated market position, leading to a repeating cycle of product boom and bust.

Gaining consumer trust

The early proliferation of poor-quality RRP devices negatively impacted public perception and consequently impacted market growth, creating a legacy that still undermines the sector today. Consumers (and regulators) value the safety, quality and efficacy of products, but many early movers in the RRP market did not give these attributes sufficient focus.

Whilst significant research is now being undertaken into the relative safety of RRPs, the huge potential benefit to public health has been constrained by a lack of high-quality, compelling research evidence.

Frustrations are driving political and regulatory pressure to address these issues, which draws attention away from the voice of the producers who should be championing high levels of stewardship. The resulting tensions, lawsuits, regulatory muddles and confused public image of RRP have had a material impact on the potential public health benefit and market growth.

Lessons for the cannabinoid market

In the context of the therapeutic cannabinoids, there may also be the temptation to target early adopters first – those already familiar with cannabis, sympathetic to its use, and happy to use a product with a 'counter-culture' profile.

The emerging cannabinoid market is likely to show the same initial growth curve as for RRPs, making market entry through product acquisition, open innovation or start-up buy-out a tempting route to gain market share. But just as for RRP, developers of niche products or technologies are often focused on short-term gains rather than long term strategies and may lack the motivation or resources to fully explore mass market user needs and market drivers.

Significant growth opportunities will come from the majority of consumers looking for therapeutic solutions, but this group is likely to have different needs to those being addressed by many early entrants.

As with any administered therapeutic drug product, suppliers have a duty of care to their consumers. For medicinally licensed products these standards are mandated through regulations which have been developed over time to ensure safety and efficacy. However, products operating outside this arena can also benefit by selectively adopting these standards to enhance their product stewardship. This additional rigour will result in a more stable platform for product development and ultimately the safety of consumers, also building trust and longevity for the proposition.

Routes to success in the therapeutic cannabinoid market

Work with the regulators

In addition to considering 'where to play', we also need to look at the notion of the 'right to play'. When we first started working on e-cigarettes, the products and their promotion were not subject to any specific regulation, instead falling under general consumer product regulations despite delivering formulations to the human body. As a result of growing concerns over product stewardship and safety we have seen the introduction of TPD2 in the EU, PMTA in the US and fragmented policies in other territories ranging from outright bans to tolerance.

The emerging RRP industry initially took a confrontational stance with regulators, arguing that the public health opportunity and freedom of choice, would be adversely affected by regulation and that they would 'keep their house in order'. This has subsequently unravelled with a raft of regulations being introduced that have the unintended consequences of stifling innovation and negatively impacting the public health opportunity.

Regulatory compliance will certainly play a key role in creating a trusted market for cannabinoid products. But regulation will not only have to deliver healthcare standards but also satisfy a wide range of social and political concerns, given the contentious nature of cannabis use. Whereas the RRP industry, in its infancy, did not come together to positively engage with regulators, perhaps the players in the cannabinoid market can. Where regulations do apply, manufacturers have the opportunity to champion the high standards that demonstrate a commitment to product stewardship. This will pay dividends with consumer loyalty and will also put such companies ahead of the game when further regulation arrives – as it surely will. In addition, a demonstrable commitment to responsible product stewardship, and an acknowledgement of the importance of consumer safety, will enable participants to play a part in shaping regulations rather than being their unwilling recipient.

Protect and survive

In the race to market, many early RRP brands based their products on bought-in, low cost technologies without retaining full design authority or intellectual property (IP) ownership. This led to challenges to maintain a competitive advantage as design features quickly migrated to competitor products. The OEM manufacturers were also able to exert commercial leverage over their brand owning clients as they effectively held the keys to the design, making it difficult to transfer manufacture to an alternative supplier to control costs and quality.

We have monitored the growth in RRP patent filings over the last several years which has eclipsed that of the larger and more mature medicinal inhaler market. The remaining 'white space' has contracted, requiring ever more vigilance to avoid IP conflicts and uncover opportunities for protectable innovations.

The cannabinoid market is already awash with small companies with IP to sell, and this can make it challenging to identify real value, especially if the proposition is unfamiliar or the technology is tangential to your current core business. When reviewing IP, firstly determine its potential value – does it enable fulfilment of unmet user needs (as discussed earlier) and confer a valuable competitive advantage?

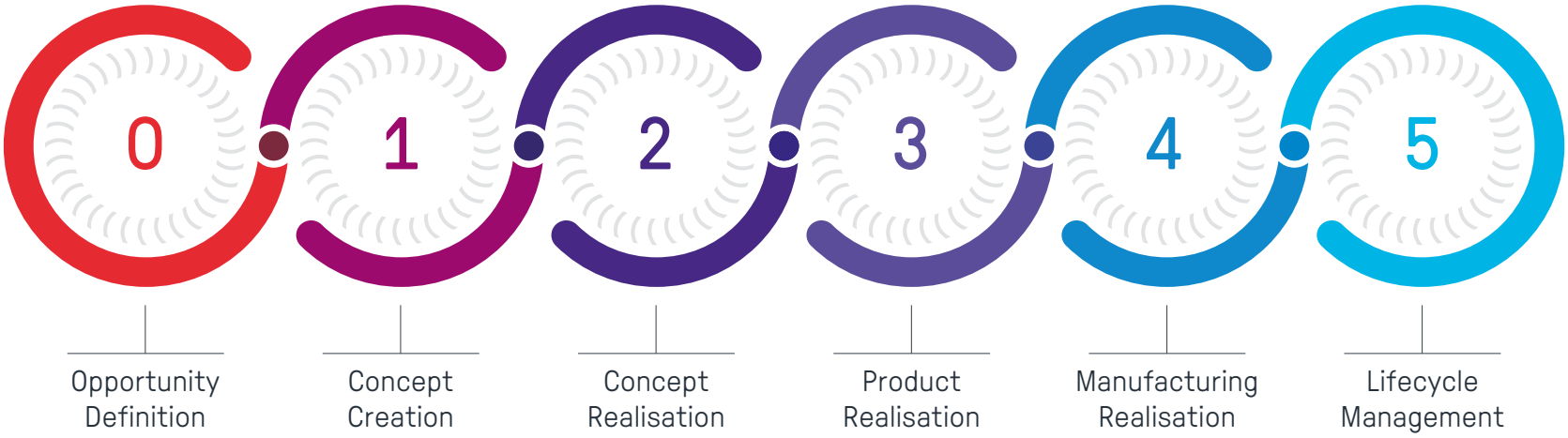
Assessing and acquiring external IP and 'know-how' also requires robust commercial and technical due diligence processes to avoid costly mistakes – a well-structured approach focusing on technical, market and commercial issues can be used to reduce the burden for initial screening. Alternatively, consider whether it would be preferential to develop designs independently or with an outsourced partner (unconstrained by ties to a manufacturer or third-party IP assignment), in order to assert ownership, build internal know-how and create a sustainable competitive advantage.

Next steps towards market entry

The public health and commercial opportunities for the cannabinoid market are significant, so too are the challenges facing both new entrants and companies with existing market presence. Drawing again on our experience within the RRP market, within the context of the Potential Realised™ innovation process, we have highlighted some key considerations for maximising chances of success.

- Initially focus on user needs rather than technologies or products – determine 'where to play' with a robust proposition that will be valued by majority markets.
- Use these requirements to drive your concept creation, or technology scouting, and verify that it resonates as expected with users at an early stage in the investment curve.
- Early IP landscaping research mitigates infringement risk and can uncover white spaces as the basis for a robust development roadmap and IP strategy to create and protect commercial value.
- Consider the needs of all stakeholders as your proposition develops – users are key, but success will come from also satisfying the needs of funders, manufacturers, supply chain participants, regulators and public health bodies.
- Understand that you are likely to need multiple technology platforms to manage the uncertainty as the market and regulations develop.
- Bear in mind there will also be a progression of product architectures that are appropriate as consumer needs and behaviours evolve.
- Ensure your supply chains are appropriate and scalable, and you have plans and expertise available to move between growth phases.
- Always maintain rigorous product stewardship as a commitment to your consumers, brand, regulators, public health bodies and ultimately the longevity of your business.
- Ensure your commercial and marketing plans build on the opportunities the technology and product can deliver.

Potential Realised™



Product innovation is one of the most critical investments a business can make to improve competitiveness and profitability – and to create growth. That's why many of the world's largest and most forward-thinking companies turn to us when they want to develop breakthrough products.

We start at the point a business decides upon the need for innovation and continue through the launch of a new product that is customer focused and commercially successful with a range of product lifecycle support services. We call this approach Potential Realised. We believe it delivers a high return on innovation investment by linking research, design, technology, engineering and manufacturing into a single integrated process.

This approach allows us to optimise product appeal and performance while streamlining development and manufacturing costs. We use it to manage innovation in sectors including consumer products and services, regulated medical devices, energy, and industrial and scientific systems.

Fig. 2 – Active components of cannabinoid and possible applications

Note: For many of the indications listed, cannabinoid is primarily used for the treatment of pain and nausea.

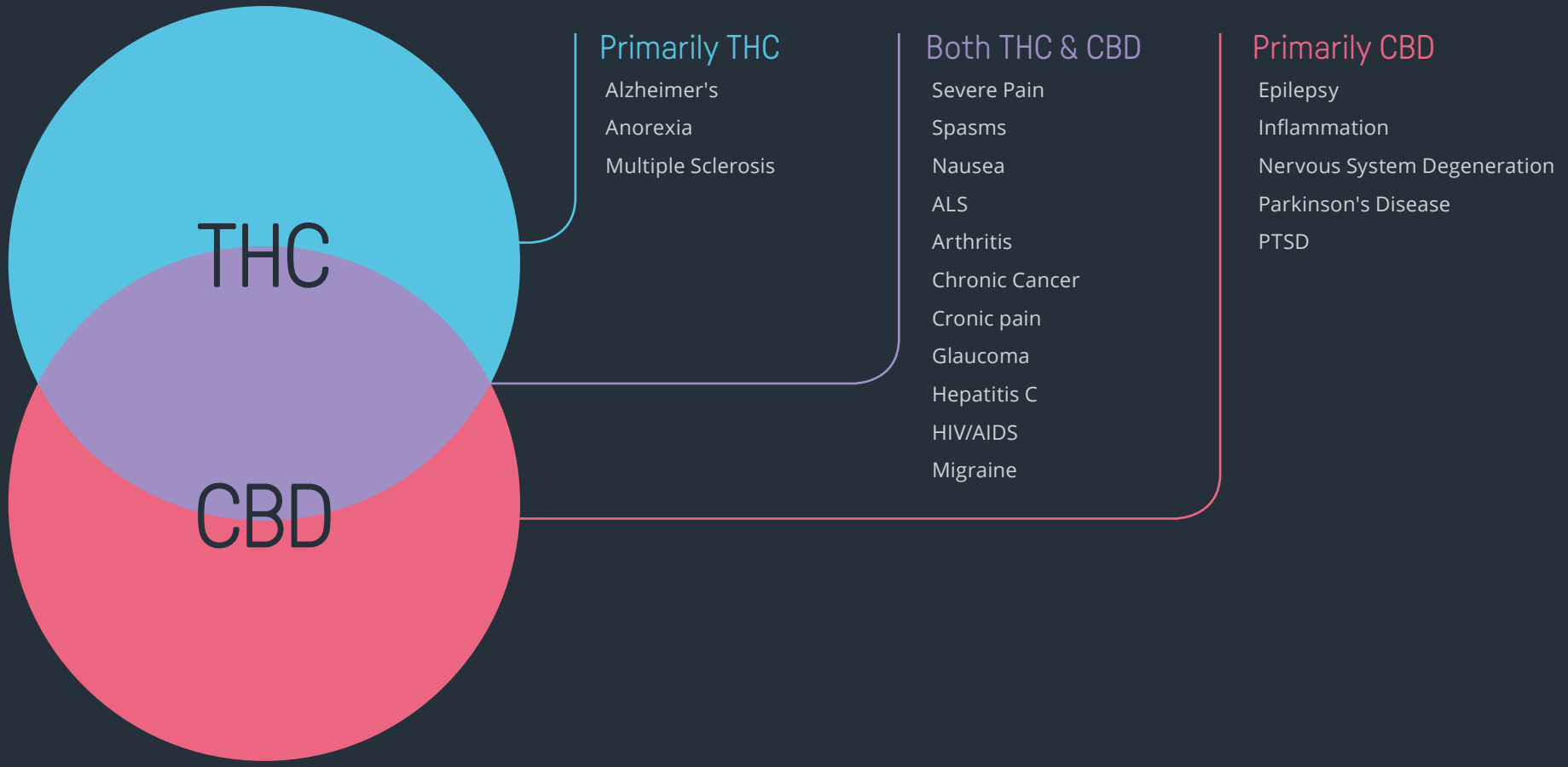
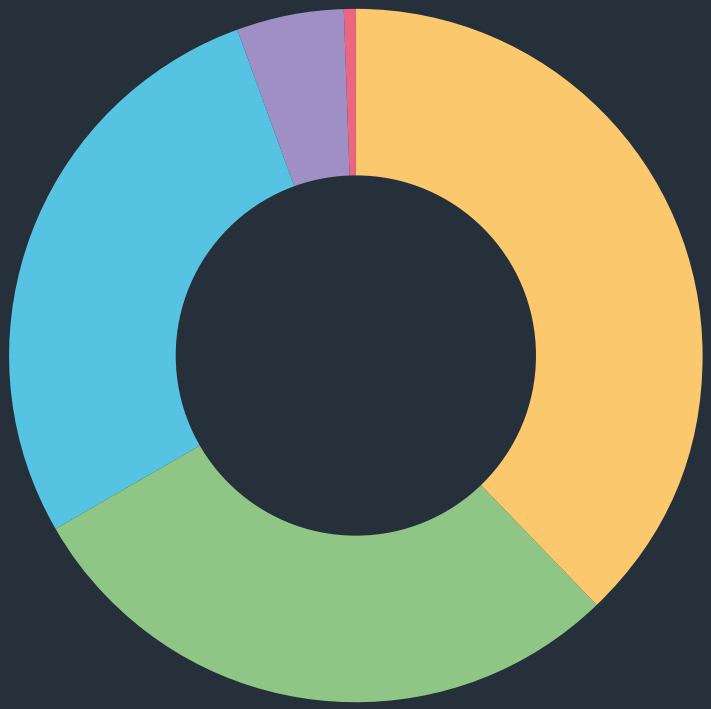


Fig. 2 – Source: 2018 Cannabis investment Report (2017), Walsh, Sharon (2018).

Fig. 3 – Cannabinoid delivery methods



37% Smoke

29% Other*

28% Vape

5% Consumables

<1% Spray

*Other includes users who do not have a preference, users who do not wish to declare a prefernce, or other methods not covered by the other categories

Therapuetic applications

Cannabinoids are increasingly being recognised as valuable therapies for a range of medical conditions. A limited number of prescription-only cannabinoid-based drugs are now available for conditions such as spasticity, Dravet syndrome and Lennox-Gastaut syndrome. There is also significant growth in non-medicinally regulated products motivated by therapeutic needs, such as nausea and pain relief which are available over the counter.

As consumers learn more about the potential benefits, they are seeking solutions in cannabinoids that were previously the domain of 'conventional' therapies. This has encouraged a surge in cannabinoid formulation and delivery technology innovation. Reflecting the wider move away from combustible cigarette smoking, around 30% of users prefer to use vaping devices for cannabinoid delivery with an expectation that this will grow further.

Topical and edible delivery are providing significant opportunity for innovation and product development, along with nasal inhalers, sublingual and infusion. The challenge for all these delivery methods is to control dosage with precision and provide a safe, reliable and engaging user experience.

Fig. 3 – Source: Cambridge Venture Project analysis of Shiplo et al. (2016).

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Fig. 4 – Source: Geiger and Hartig (2018), Halperin (2018).

Current and future market trends

We collaborated with MBA students participating in the Cambridge Venture Project at the University of Cambridge Judge Business School in the production of this report. Drawing on published information sources, government and financial databases, congressional bills and news reports, they generated insights into the current cannabinoid landscape, and identified future trends and product opportunities for therapeutic applications.

Fig. 4 – Public opinion on cannabis legalisation

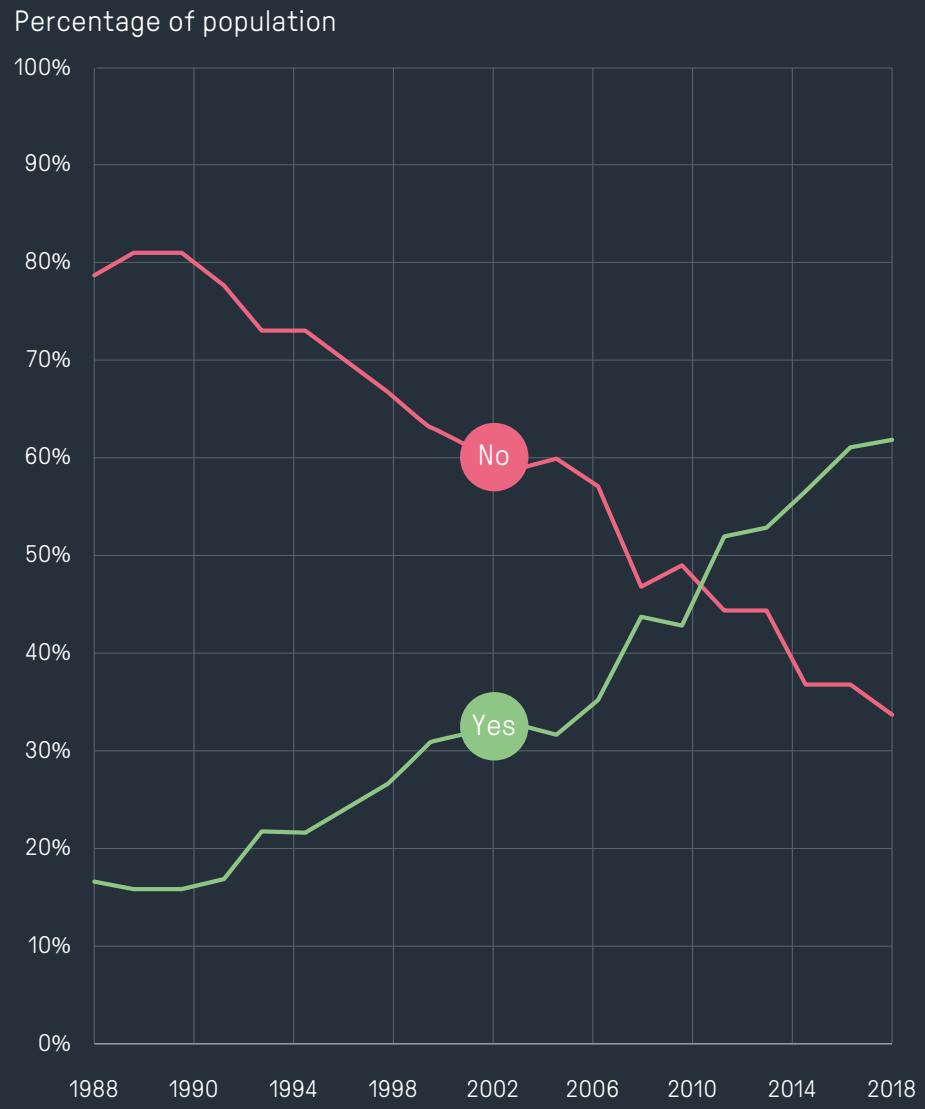

Fig. 5 – Cannabis legalisation in the USA

The research confirms that North America is an exciting market opportunity, which may also provide an indication of future global market trends:

- In the last 20 years, public support for the legalisation of recreational cannabis has increased from below 20% to over 60%.
- As of 25 June 2019, 14 states and territories have approved adult-use cannabis and 37 allow for the medical use of marijuana (although federally it remains a Schedule 1 drug). While in 2018 Canada legalised marijuana nationwide (although provinces can impose additional regulations).
- The North American cannabinoid market is estimated to be worth US$15 billion in 2019, and is predicted to increase to US$41 billion by 2023, with US revenue expected to grow by 284% during the same period.
- As we've seen in other markets the line between consumer and healthcare is now blurring.
- Further regulatory changes are expected in the US – such as state-legal cannabis retailers becoming exempt from federal prosecution, and the reclassification of cannabis as no longer a Schedule 1 drug – which will create further stimulus for growth.

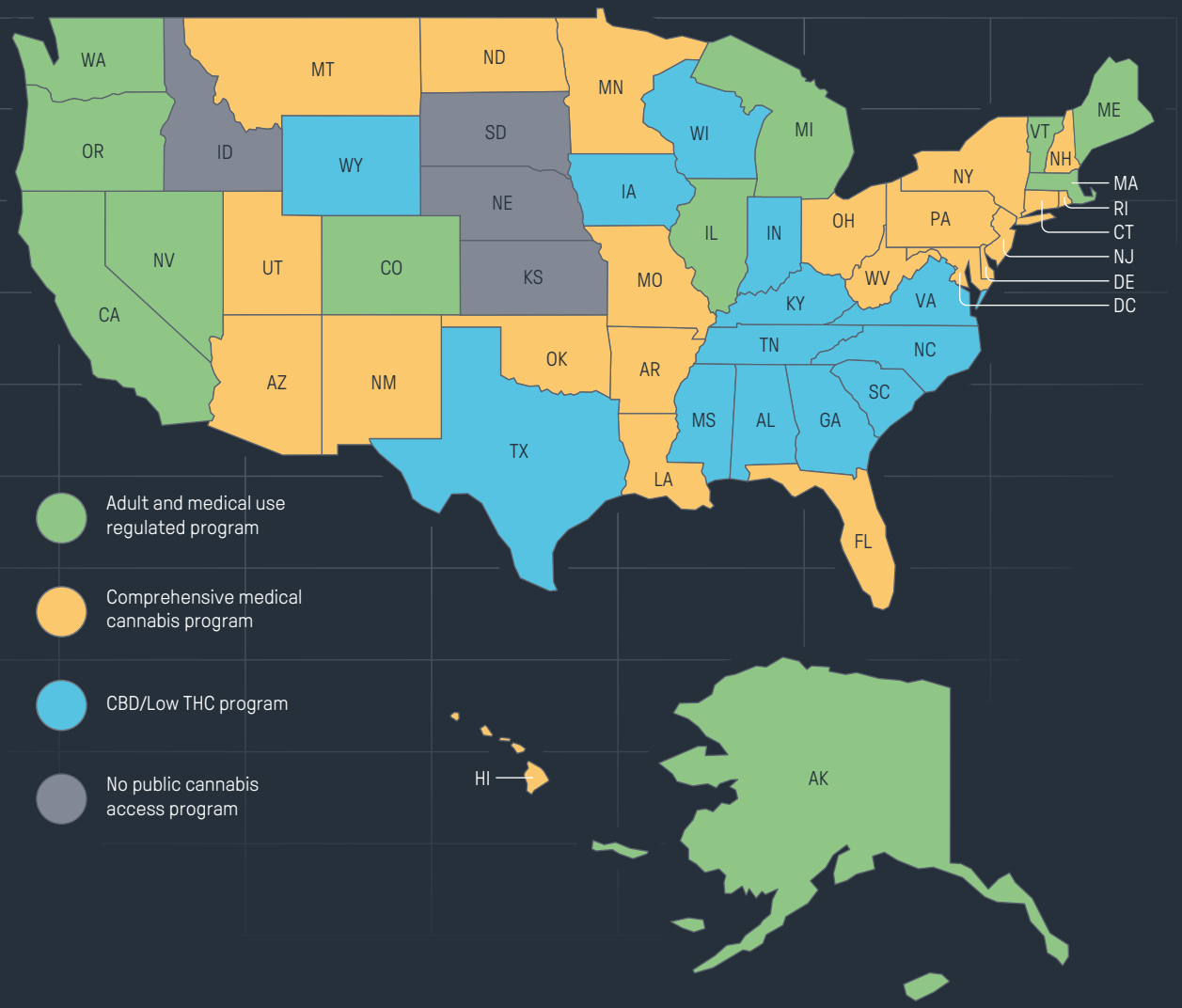

Fig.5 – Source: National Conference of State Legislatures. (1st August 2019).

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